LAVERDIA™-CA1
(verdinexor tablets)

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-526

Affordable

Priced to expand your options and treat more patients

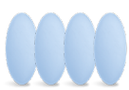
Three Dose Strengths

Hospital Price:	2.5 mg (50ct) bottle **$100**	10 mg (50ct) bottle **$160**	50 mg (16ct) bottle **$268**	50 mg (50ct) bottle **$800**

Cost to Treat

1.25 mg/kg twice weekly

MSRP to Client: calculated as 2X markup

Number of Pills per Dose				
	Small 24 lb.	Medium 56 lb.	Large 73 lb.	Extra Large 95 lb.
Hospital Price:	**$42 / mo**	**$77 / mo**	**$102 / mo**	**$150 / mo***
Client Price:	$84 / mo	$154 / mo	$204 / mo	$300 / mo*

*for extra large dog, cost to treat is calculated using the 50 mg 16ct pricing

For more information contact your Dechra Representative

1-866-683-0660 / laverdia.com

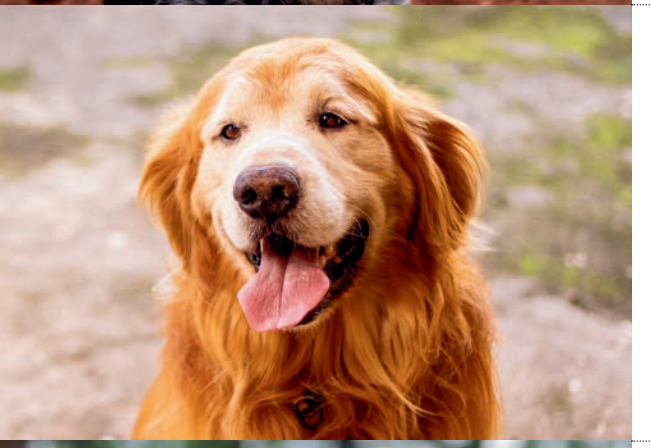
Dechra

A novel treatment option for canine lymphoma

Patient Status:
Declined Referral

Sadie	12 year old	Spayed Female	Aussie / Lab mix

- **Chief Complaint:** Rapid onset of symptoms including lethargy and loss of appetite.
- **Diagnosis:** Diffuse, large, B-cell lymphoma.
- **Client Perspective:** Concerned that aggressive treatment may further decrease quality of life, family opted not to pursue chemotherapy.
- **Treatment:** LAVERDIA-CA1 prescribed as a single agent treatment.



Patient Status:
Waiting for Specialist Appointment

Scout	10 year old	Neutered Male	Golden Retriever

- **Chief Complaint:** Owner noticed "swelling" in neck, otherwise happy and healthy.
- **Diagnosis:** Peripheral T-cell lymphoma.
- **Client Perspective:** Immediately confident about pursuing chemotherapy, client learns there's a 3-week wait to see a specialist.
- **Treatment:** Consulting with specialist, you prescribe LAVERDIA-CA1 to help slow lymphoma progression.

Patient Status:
Stopped Chemotherapy

Pepper	9 year old	Neutered Male	German Shepherd

- **Chief Complaint:** Patient completed CHOP 8 months ago, client recognized enlarged lymph node.
- **Diagnosis:** Relapse, diffuse, large, T-cell lymphoma.
- **Client Perspective:** Client can't manage another round of chemotherapy, concerned about quality of life and cost.
- **Treatment:** LAVERDIA-CA1 offers another treatment option, with the convenience of at-home administration.

What does Conditional Approval Mean?

For a veterinary drug to receive conditional approval, it must be shown to be safe when used according to the label. It must also demonstrate a "reasonable expectation of effectiveness," but has not yet proven that it meets the "substantial evidence" standard of effectiveness for full approval. While a drug is conditionally approved it is not to be used for any off-label species or indications.

First-in-class SINE technology

Targeted
Kills cancer cells at the nuclear core, generally sparing healthy ones[1]

Convenient
Twice weekly at-home oral administration

Affordable
Priced to expand your options and treat more patients

For technical questions contact **Dechra Veterinary Technical Support** at (866)-933-2472

IMPORTANT SAFETY INFORMATION
For use in dogs only. Laverdia™-CA1 (verdinexor tablets) is conditionally approved for the treatment of lymphoma in dogs. NOT FOR USE IN HUMANS. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. CHILDREN SHOULD NOT COME INTO CONTACT WITH LAVERDIA-CA1. Pregnant women, women who may become pregnant, nursing women and children should not handle or administer Laverdia-CA1 or come into contact with the feces, urine, saliva, or vomit of treated dogs for **3 days** following treatment. Laverdia-CA1 can affect male fertility based on animal studies and studies in humans. Wear protective disposable chemotherapy resistant gloves when handling Laverdia-CA1 to avoid direct exposure to moistened, broken or crushed tablets or biological waste from the treated dog (feces, urine, saliva, or vomit). Do not use in dogs that are pregnant, lactating or intended for breeding. Laverdia-CA1 is a possible teratogen and can affect female and male fertility. Dogs should be frequently monitored for hematologic and serum chemistry abnormalities. The most commonly reported adverse reactions in dogs include anorexia, weight loss, vomiting, diarrhea, lethargy, polyuria, polydipsia, elevated liver enzymes and thrombocytopenia. Please see package insert or visit dechra-us.com for full prescribing information.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. It is a violation of Federal law to use this product other than as directed in the labeling.

1. Etchin J, Sun Q, Kentsis A, Farmer A, Zhang ZC, et al. (2013) Antileukemic activity of nuclear export inhibitors that spare normal hematopoietic cells. Leukemia 27: 66–74.

*Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-526
14SD-LAV22011-0322

Dechra

LAVERDIA™-CA1
(verdinexor tablets)

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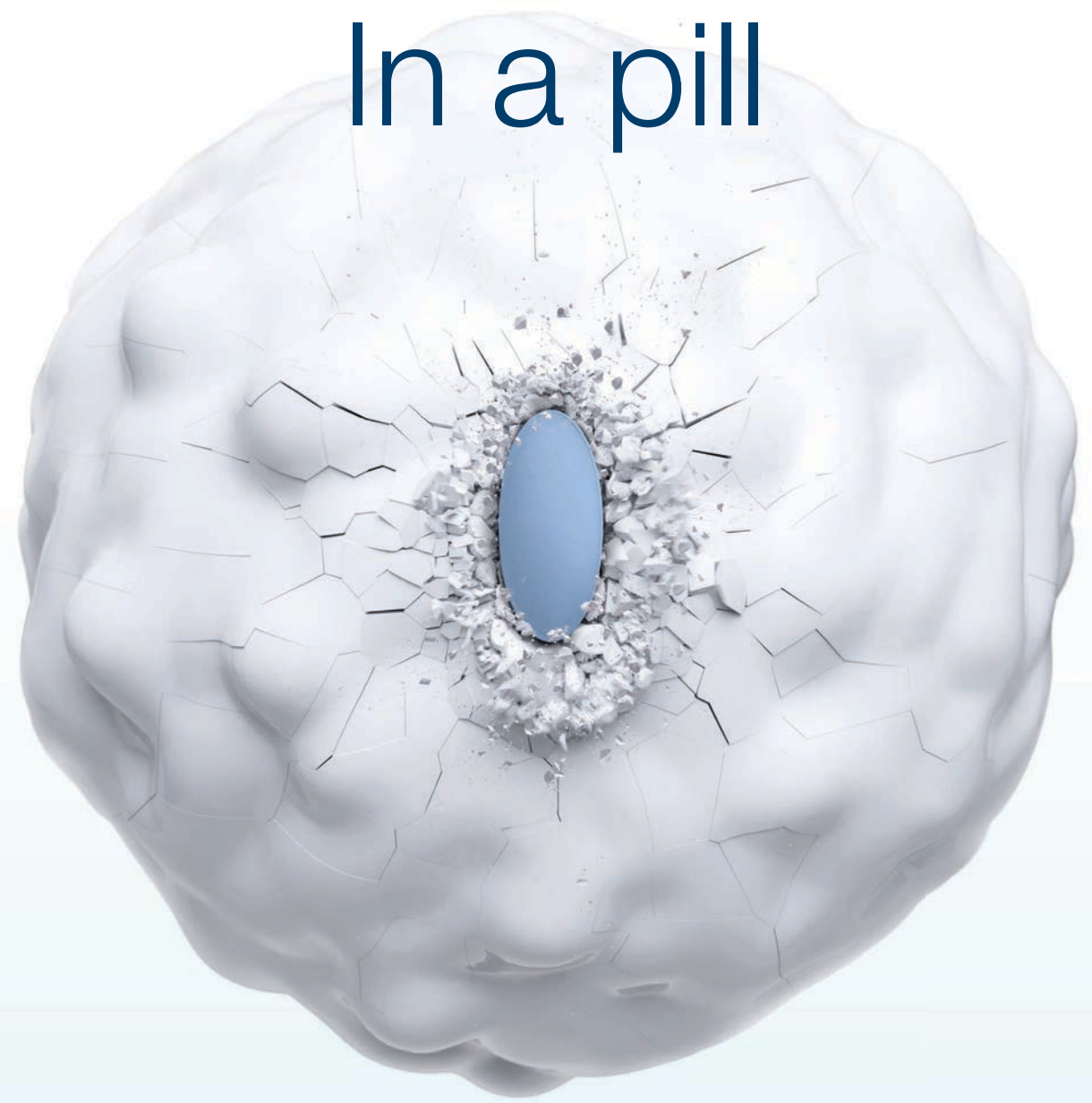
The Power To Treat Lymphoma, In a pill



Lymphoma Cells Overproduce XPO1

XPO1 enables cancer cells to grow uncontrolled by exporting TSPs out of the cell nucleus

LAVERDIA™-CA1 (verdinexor) Blocks XP01

XPO1 inhibition results in nuclear retention and reactivation of TSPs, leading to selective induction of apoptosis of lymphoma cells

Triggers Apoptosis in Lymphoma Cells

Healthy cells are generally spared in this process while TSPs accumulate in lymphoma cells and cause apoptosis

Figure 1. SINE Mechanism of Action

Exportin 1 (XPO1)

XPO1 is the sole nuclear exporter of several major tumor suppressor and growth regulatory proteins, including p53, Rb1, and p27 among others.

Verdinexor

Binds to XPO1 and selectively inhibits nuclear export of TSPs. This binding functionally inactivates XPO1 and targets the protein for proteasome degradation, resulting in restoration of TSP cellular localization and function. The binding is slowly reversible, contributing to relatively low toxicity for healthy cells.

Tumor Suppressor Protein (TSP)

TSPs act inside the cell nucleus to suppress tumor growth.

LAVERDIA™-CA1 (verdinexor tablets)

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-526

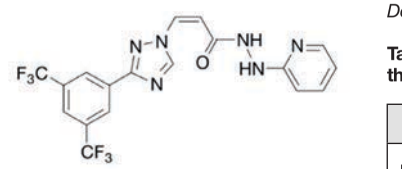
2.5 mg · 10 mg · 50 mg

Coated Tablets
Antineoplastic
For oral use in dogs only

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. **It is a violation of Federal law to use this product other than as directed in the labeling.**

DESCRIPTION: LAVERDIA-CA1 (verdinexor tablets) is a selective inhibitor of nuclear export (SINE) that blocks chromosome region maintenance 1 (CRM1).

LAVERDIA-CA1 has the following structural formula:



Chemical Formula: $C_{18}H_{12}F_6N_6O$
Molecular Weight: 442.33

INDICATION: LAVERDIA-CA1 is indicated for the treatment of lymphoma in dogs.

DOSAGE AND ADMINISTRATION: Always provide the Client Information Sheet to the dog owner with each prescription.

Dosing Instructions:

1. **Feed the dog immediately before giving LAVERDIA-CA1.**

2. Wear protective disposable chemotherapy resistant gloves when handling LAVERDIA-CA1 (see **USER SAFETY WARNINGS**).

3. Administer LAVERDIA-CA1 at an initial dose of 1.25 mg/kg administered orally twice per week (e.g., Monday and Thursday or Tuesday and Friday) with at least 72 hours between doses (see **Table 1**).

4. If tolerated after 2 weeks, increase the dose of LAVERDIA-CA1 to 1.5 mg/kg twice per week with at least 72 hours between doses (see **Table 2**).

5. Dose reductions of 0.25 mg/kg to a minimum dose of 1 mg/kg twice per week with at least 72 hours between doses (see **Table 3**) or dose interruptions may be considered as a result of adverse reactions (See **ANIMAL SAFETY WARNINGS**, **PRECAUTIONS**, and **ADVERSE REACTIONS**).

6. Do not split or crush tablets.

Dosing Restrictions:

Dogs weighing less than 9 kg may not be accurately dosed or undergo dose adjustments.

LAVERDIA-CA1 cannot be accurately increased in dose from 1.25 mg/kg to 1.5 mg/kg in dogs weighing 9 to 9.6 kg because the dose administered remains the same.

Dosing Tables:

Table 1. LAVERDIA-CA1 dose table for the 1.25 mg/kg dose*

Dog weight (kg)	Total mg to administer	Number of Tablets		
		2.5 mg tablets	10 mg tablets	50 mg tablets
9 — 11.5	12.5	1	1	-
11.6 — 13.5	15	2	1	-
13.6 — 15.5	17.5	3	1	-
15.6 — 17.5	20	-	2	-
17.6 — 19.5	22.5	1	2	-
19.6 — 21.5	25	2	2	-
21.6 — 23.5	27.5	3	2	-
23.6 — 25.5	30	-	3	-
25.6 — 27.5	32.5	1	3	-
27.6 — 29.5	35	2	3	-
29.6 — 31.5	37.5	3	3	-
31.6 — 33.5	40	-	4	-
33.6 — 35.5	42.5	1	4	-
35.6 — 37.5	45	2	4	-
37.6 — 39.5	47.5	3	4	-
39.6 — 41.5	50	-	-	1
41.6 — 43.5	52.5	1	-	1
43.6 — 45.5	55	2	-	1
45.6 — 47.5	57.5	3	-	1
47.6 — 49.5	60	-	1	1
49.6 — 51.5	62.5	1	1	1
51.6 — 53.5	65	2	1	1
53.6 — 55.5	67.5	3	1	1
55.6 — 57.5	70	-	2	1
57.6 — 59.5	72.5	1	2	1
59.6 — 61.5	75	2	2	1

** Use an appropriate combination of tablets to dose dogs over 61.5 kg.*

Table 2. LAVERDIA-CA1 dose table for the 1.5 mg/kg dose**

Dog weight (kg)	Total mg to administer	Number of Tablets		
		2.5 mg tablets	10 mg tablets	50 mg tablets
9.7 — 11.3	15	2	1	-
11.4 — 12.9	17.5	3	1	-
13 — 14.6	20	-	2	-
14.7 — 16.3	22.5	1	2	-
16.4 — 17.9	25	2	2	-
18 — 19.6	27.5	3	2	-
19.7 — 21.3	30	-	3	-
21.4 — 22.9	32.5	1	3	-
23 — 24.6	35	2	3	-
24.7 — 26.3	37.5	3	3	-
26.4 — 27.9	40	-	4	-
28 — 29.6	42.5	1	4	-
29.7 — 31.3	45	2	4	-
31.4 — 32.9	47.5	3	4	-
33 — 34.6	50	-	-	1
34.7 — 36.3	52.5	1	-	1
36.4 — 37.9	55	2	-	1
38 — 39.6	57.5	3	-	1
39.7 — 41.3	60	-	1	1
41.4 — 42.9	62.5	1	1	1
43 — 44.6	65	2	1	1
44.7 — 46.3	67.5	3	1	1
46.4 — 47.9	70	-	2	1
48 — 49.6	72.5	1	2	1
49.7 — 51.3	75	2	2	1
51.4 — 52.9	77.5	3	2	1
53 — 54.6	80	-	3	1
54.7 — 56.3	82.5	1	3	1
56.4 — 57.9	85	2	3	1
58 — 59.6	87.5	3	3	1
59.7 — 61.3	90	-	4	1

*** Use an appropriate combination of tablets to dose dogs over 61.3 kg.*

Table 3. LAVERDIA-CA1 dose table for the 1 mg/kg dose*

Dog weight (kg)	Total mg to administer	Number of Tablets		
		2.5 mg tablets	10 mg tablets	50 mg tablets
9 — 11.9	10	-	1	-
12 — 14.4	12.5	1	1	-
14.5 — 16.9	15	2	1	-
17 — 19.4	17.5	3	1	-
19.5 — 21.9	20	-	2	-
22 — 24.4	22.5	1	2	-
24.5 — 26.9	25	2	2	-
27 — 29.4	27.5	3	2	-
29.5 — 31.9	30	-	3	-
32 — 34.4	32.5	1	3	-
34.5 — 36.9	35	2	3	-
37 — 39.4	37.5	3	3	-
39.5 — 41.9	40	-	4	-
42 — 44.4	42.5	1	4	-
44.5 — 46.9	45	2	4	-
47 — 49.4	47.5	3	4	-
49.5 — 51.9	50	-	-	1
52 — 54.4	52.5	1	-	1
54.5 — 56.9	55	2	-	1
57 — 59.4	57.5	3	-	1
59.5 — 61.9	60	-	1	1

**** Use an appropriate combination of tablets to dose dogs over 61.9 kg.*

CONTRAINDICATIONS:
Do not use in dogs that are pregnant, lactating or intended for breeding. LAVERDIA-CA1 is a possible teratogen and can affect female and male fertility. Laboratory studies in the rat have shown reduced fertility, embryotoxicity, teratogenicity, and maternal toxicity. Administration of LAVERDIA-CA1 caused degeneration/atrophy and vacuolation in the seminiferous tubules and oligospermia in the epididymides in male dogs in the margin of safety study (see **TARGET ANIMAL SAFETY**).

WARNINGS:

USER SAFETY WARNINGS:
NOT FOR USE IN HUMANS. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. CHILDREN SHOULD NOT COME INTO CONTACT WITH LAVERDIA-CA1. Children should not come in contact with the feces, urine, vomit, or saliva of treated dogs.

Pregnant women, women who may become pregnant, and nursing women should not handle or administer LAVERDIA-CA1 or come in contact with the feces, urine, vomit, or saliva from LAVERDIA-CA1-treated dogs. LAVERDIA-CA1 may cause birth defects and can affect female fertility based on animal studies.

LAVERDIA-CA1 can affect male fertility based on animal studies and studies in humans.

Wear protective disposable chemotherapy resistant gloves when handling LAVERDIA-CA1 to avoid exposure to drug.

Wear protective disposable chemotherapy resistant gloves to prevent direct contact with moistened, broken, or crushed LAVERDIA-CA1 tablets.

Wear protective disposable chemotherapy resistant gloves to prevent contact with feces, urine, vomit, and saliva during treatment and for **3 days** after the dog has received the last treatment. Place all waste material in a plastic bag and seal before general disposal. Wash hands immediately and thoroughly with soap and water if contact occurs with the feces, urine, vomit, or saliva from LAVERDIA-CA1 treated dogs.

Any items that come in contact with feces, urine, vomit, or saliva should not be washed with other laundry during treatment and for **3 days** after the last treatment with LAVERDIA-CA1.

Wear protective disposable chemotherapy resistant gloves when handling the dog's toys, food bowl, and water bowl. Wash food and water bowls separately from other items during treatment and for **3 days** after the dog has received the last treatment.

If LAVERDIA-CA1 is accidentally ingested, or if there is significant contact with feces, urine, vomit, or saliva of dogs during treatment or within **3 days** after the last treatment without proper precautions, seek medical advice immediately. It is important to show the treating physician a copy of the package insert, label, or client information sheet.

Special instructions for handling and administering the product
- It is recommended that LAVERDIA-CA1 be administered under the supervision of, or in consultation with, a veterinarian experienced in the use of cancer therapeutic agents.
- Use standard measures for the safe handling of all chemotherapeutic drugs. Refer to Occupational Safety and Health Administration (OSHA) for appropriate guidelines, recommendations, and regulations for handling antineoplastic agents.
- Do not eat, drink, or smoke while handling the product.
- Do not store near food, in or near a food preparation area, or with medications intended for use in humans.

Skin contact
- In case of contact with the skin, wash the affected area immediately and thoroughly with soap and water.

Accidental eye exposure
- Rinse the eyes with large amounts of tap water (use eyewash station if present) for 10 minutes while holding back the eyelid.
- Remove contact lenses.
- Seek medical advice immediately and show the package insert or label to the physician.

Accidental oral exposure or ingestion
- Seek medical advice immediately and show the package insert or label to the physician.

ANIMAL SAFETY WARNINGS:
LAVERDIA-CA1 can cause severe anorexia. Patients should be carefully monitored for inappetence, vomiting, diarrhea and dehydration, and supportive care should be provided as clinically indicated (see **ADVERSE REACTIONS**). In the study used to support reasonable expectation of effectiveness, low doses of corticosteroids (prednisone) were found to reduce the incidence of anorexia and gastrointestinal adverse reactions associated with verdinexor.

Keep LAVERDIA-CA1 in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

PRECAUTIONS:
Safe use of LAVERDIA-CA1 has not been evaluated in dogs with concurrent serious infections; concurrent renal, cardiovascular, or hepatic disease; in dogs with diabetes mellitus; in dogs with clinically relevant hypercalcemia; or in dogs with concurrent malignancy.

LAVERDIA-CA1 can cause hematologic and serum chemistry abnormalities. Dogs should be frequently monitored for evidence of hematologic and serum chemistry abnormalities when initiating and maintaining treatment with LAVERDIA-CA1 (see **ADVERSE REACTIONS** and **TARGET ANIMAL SAFETY**).

The safety and effectiveness of LAVERDIA-CA1 has not been evaluated in conjunction with other chemotherapeutic agents or other treatment modalities for lymphoma.

The effect of concomitant medications on the metabolism of LAVERDIA-CA1 has not been evaluated.

The safe use of LAVERDIA-CA1 has not been evaluated in dogs younger than 7 months of age.

The primary metabolism of LAVERDIA-CA1 *in vitro* and *in vivo* is thought to be inactivation by glutathione (GSH) conjugation. Therefore, administration of LAVERDIA-CA1 with drugs which undergo substantial GSH conjugation (e.g., acetaminophen) should be minimized.

ADVERSE REACTIONS:
In the field study supporting reasonable expectation of effectiveness, 58 dogs were treated with verdinexor (not commercial formulation) at doses between 1.0 mg/kg and 1.75 mg/kg administered 2 to 3 times a week (see **REASONABLE EXPECTATION OF EFFECTIVENESS**).

All dogs experienced at least one adverse reaction. The most common adverse reactions across all dose groups included: anorexia, vomiting, diarrhea, weight loss and lethargy. Most adverse reactions were considered Veterinary Cooperative Oncology Group – common terminology criteria for adverse events (VCOG-CTCAE)[1] Grade 1 (mild) or 2 (moderate). Twenty-one dogs experienced a VCOG-CTCAE Grade 3 (severe), 4 (life-threatening), or 5 (death) adverse reaction.

Of the 58 dogs treated with verdinexor, adverse reactions occurring in ≥10% of dogs associated with verdinexor treatment included:
- *General:* lethargy, fever, weakness, generalized pain
- *Gastrointestinal:* anorexia, vomiting, diarrhea
- *Renal:* polyuria, polydipsia, hematuria, proteinuria, low urine specific gravity, urinary tract infection
- *Hepatic:* elevated liver enzymes, bilirubinuria
- *Cardiorespiratory:* cough/dyspnea
- *Metabolic:* weight loss
- *Hematologic:* thrombocytopenia, anemia, lymphopenia, neutrophilia, leukopenia, eosinopenia, neutropenia, monocytosis, leukocytosis, prolonged partial thromboplastin time, elevated blood urea nitrogen, hypercalcemia, hyperphosphatemia
- *Skin:* subcutaneous edema/swelling, pyoderma

Adverse reactions occurring in <10% of dogs associated with verdinexor treatment included:
- *Renal:* protein losing nephropathy, urinary incontinence
- *Hepatic:* hepatomegaly, elevated bilirubin, icterus
- *Cardiorespiratory:* heart murmur, arrhythmia, heart block
- *Hematologic:* hypoglubulinemia, hypoproteinemia, hypoalbuminemia, prolonged prothrombin time
- *Neurologic:* seizure, tremor, disorientation
- *Ocular:* corneal opacity
- *Skin:* bruising, erythema, alopecia
- *Other:* nasal discharge, epistaxis, lymphadenitis

Thrombocytopenia
Thrombocytopenia (VCOG-CTCAE Grade 1 and 2) was observed in verdinexor treated dogs in the study supporting reasonable expectation of effectiveness. Two dogs with thrombocytopenia during the study were reported with bruising and one dog with thrombocytopenia was reported with epistaxis. In human studies of a closely related compound, idiosyncratic reductions in platelets (severe or medically significant but not immediately life-threatening in 10-20% of patients) were reported.

Protein losing nephropathy
One dog was reported with a protein losing nephropathy (PLN). Two additional dogs, though not reported, may have had a PLN. One dog was reported with hypoalbuminemia and proteinuria on study day 21 which progressed until study end (study day 194). Another dog was reported with proteinuria at study day 7 which persisted (and worsened) to the end of the study (study day 105). At the start of the study the dog had hyperalbuminemia; by study day 105 the dog had hypoalbuminemia.

CONTACT INFORMATION:
To report suspected adverse events, for technical assistance, or to obtain a copy of the Safety Data Sheet (SDS) contact Dechra Veterinary Products at (866) 933-2472.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or at www.fda.gov/reportanimalae.

INFORMATION FOR DOG OWNERS:
Always provide the Client Information Sheet with each prescription and review it with the dog owner or person responsible for care of the dog. Advise dog owners about possible adverse reactions, when to contact a veterinarian, how to handle and administer the product, and how to clean up any feces, urine, vomit, or saliva from dogs treated with LAVERDIA-CA1 (verdinexor tablets). The Client Information Sheet also contains warnings for humans and what to do in case of accidental human exposure to LAVERDIA-CA1.

CLINICAL PHARMACOLOGY:
Mechanism of action
Verdinexor is a reversible, selective inhibitor of CRM1-mediated nuclear export (SINE) that specifically blocks Chromosome Region Maintenance 1 (CRM1, also known as XPO1). Verdinexor inhibits the export of Tumor Suppressor Proteins (TSP) and Growth Regulatory Proteins (GRP) from the nucleus where they carry out their normal functions; it is selectively cytotoxic for cells with genomic damage (i.e. for tumor cells).
Pharmacokinetics
Verdinexor administered orally is well absorbed in dogs and achieves therapeutic levels (>0.5 to 1.0 µM) with doses of 1 to 3 mg/kg. Following oral administration of a preliminary formulation of verdinexor three times per week for 13 weeks to fed healthy young adult Beagle dogs, overall mean exposure in terms of area under the plasma concentration time curve from time zero to the last quantifiable plasma concentration (AUClast) and maximum plasma concentration (Cmax) showed an increase from 1.25 mg/kg to 1.5 mg/kg; however, exposure at 1.75 mg/kg was either similar or lower than exposure for the 1.5 mg/kg dose group on both evaluation days. The increase in exposure as assessed by dose normalized AUClast and dose normalized Cmax was approximately dose proportional from 1.25 mg/kg to 1.5 mg/kg and less than dose proportional from 1.5 mg/kg to 1.75 mg/kg in males on both evaluation days. In females, the increase in AUClast and Cmax was greater than dose proportional from 1.25 mg/kg to 1.5 mg/kg and there was minimal increase in exposure from 1.5 mg/kg to 1.75 mg/kg on both evaluation days.

Time to maximum plasma concentration (Tmax) was typically reached between 1.1 and 2.5 hours post-dose under fed conditions and there were no differences in Tmax related to sex, dosage, or evaluation day. In general, the terminal elimination half-life for all dose groups was similar, regardless of sex, dosage, or evaluation day and ranged from approximately 2.0 to 4.0 hours.

Inter-animal variability was relatively high in all dose groups (%CV ranging from 16% to 81% for AUClast), so care should be taken in assessing actual pharmacokinetic differences or trends observed.

Following oral administration of a preliminary formulation of verdinexor to fed and fasted dogs, there was a significant food effect on the pharmacokinetics of verdinexor with a 3-fold and 5-fold increase in AUC and Cmax, respectively, when verdinexor was administered orally in the presence of food. Time to reach Cmax (Tmax) was markedly more variable (1-18 hours) when dogs were dosed under fasted conditions as compared to when verdinexor was administered under fed conditions (1.1-2.5 hours).

REASONABLE EXPECTATION OF EFFECTIVENESS:
LAVERDIA-CA1 is conditionally approved pending a full demonstration of effectiveness.

Additional information for Conditional Approvals can be found by searching https://www.fda.gov for "animal conditional approval".

A field study was used to demonstrate a reasonable expectation of effectiveness for LAVERDIA-CA1 for the treatment of lymphoma in dogs.

An open-label, single arm, multicenter field study was conducted to evaluate the effectiveness and safety of verdinexor tablets (not commercial formulation). The study enrolled 58 client-owned dogs with lymphoma either newly diagnosed (n=35), or in first relapse following completion of one chemotherapy regimen (n=23). Treatment groups were designated by the following verdinexor dose regimens: 1.5 mg/kg 3 times weekly; 1.25 mg/kg 3 times weekly; or 1.25 mg/kg 2 times weekly then increased to 1.5 mg/kg twice weekly if well-tolerated. Dose increases and decreases, including changes in dosing amount (mg/kg) and dosing frequency (2 versus 3 times per week) were allowed based on drug tolerability and response to treatment. Response to treatment was evaluated using Veterinary Cooperative Oncology Group (VCOG) response criteria for peripheral lymphoma in dogs (v1.0).[2]

For all dogs enrolled, median time to progression (TTP) was 29.5 days (range 7-244 days). The median TTP for the naïve and first relapse cases was 36.5 days (range 7-244 days) and 22 days (range 7-194 days), respectively. The objective response rate (best response of partial or complete response) for all dogs was 34.5% (20/58), distributed proportionately between the naïve (12/35, 34.3%) and first relapse (8/23, 34.8%) subgroups. Among dogs with objective response, the median duration of response was 18 days (range 7-187 days). No clinically significant differences in treatment benefit were noted when comparing dose groups. A subset (n=17, 29%) of the overall enrolled population had a TTP of at least 56 days. Of these 17 dogs, 11 were naïve to treatment and 6 had relapsed lymphoma; 5 had T-cell lymphoma and 12 had B-cell lymphoma. Three dogs, 2 dogs with T-cell lymphoma (1 naïve and 1 relapsed) and 1 dog with B-cell lymphoma naïve to treatment had TTP of 182 days or longer.

During the study, verdinexor was administered concomitantly with other medications such as corticosteroids (prednisone, 39 dogs), proton pump inhibitors, antibiotics, H2 blockers, anti-emetics, gastrointestinal motility modifiers, and opioids.

TARGET ANIMAL SAFETY:
In a 13-week margin of safety study, 32 healthy Beagle dogs (4/sex/group), approximately 7 months old at study initiation, were administered LAVERDIA-CA1 at either 0, 1.0, 1.5, or 1.75 mg/kg of body weight 3 times a week (Monday, Wednesday, and Friday). Dogs in the control group were sham-dosed. Dogs were fed prior to dosing. All dogs survived to study termination.

Dose-dependent LAVERDIA-CA1-related clinical findings included vomiting, inappetence, decreased body condition, decreased body weight, loss of skin elasticity, lacrimation, slight depression, and slight decrease of forelimb strength. Non-dose-dependent LAVERDIA-CA1-related findings included abnormal feces (soft, watery, or mucoid feces), excessive shedding, and sparse hair.

Dogs in the 1.0 mg/kg group and dogs in the 1.5 and 1.75 mg/kg groups had lower body weight values, starting on study days 28 and 21 respectively, that continued to the end of the study compared to control dogs.

Dose-dependent LAVERDIA-CA1-related clinical pathology findings included decreases in chloride and increases in fibrinogen. Non-dose-dependent LAVERDIA-CA1-related clinical pathology findings included decreases in lymphocytes, eosinophils, and monocytes, and increases in albumin and blood urea nitrogen.

Dose-dependent organ weight findings in the LAVERDIA-CA1 treated dogs included lower testes, thymus, and thyroid/parathyroid gland weights. Dose-dependent histopathological findings in the LAVERDIA-CA1 treated dogs included lesions in the testes and epididymides (moderate to marked seminiferous tubules degeneration/atrophy, minimal to moderate vacuolation, and minimal Leydig cell hypertrophy in the testes; and severe oligospermia/germ cell debris in the epididymides) and in the thymus (minimal to mild cortical lymphoid depletion).

HOW SUPPLIED:
LAVERDIA-CA1 is presented as immediate release coated tablets in three dosage strengths, 2.5 mg, 10 mg and 50 mg. The 2.5 mg tablets are supplied in 10-count and 50-count, the 10 mg tablets are supplied in 10-count and 50-count, and the 50 mg tablets are supplied in 16-count and 50-count in an HDPE bottle with a heat sealed, child-resistant cap and a desiccant included in each bottle. The bottles are individually packaged into cartons.

DISPOSAL:
Dispose of any unused product or waste materials in accordance with proper procedures for cytotoxic drugs.

STORAGE INFORMATION:
Store the bottles at controlled room temperature 20° to 25°C (68° – 77°F).

REFERENCES:
1. Veterinary co-operative oncology group – common terminology criteria for adverse events (VCOG-CTCAE) following chemotherapy or biological antineoplastic therapy in dogs and cats v1.1. *Vet Compar Onco.* 2016, Vol.14(4), p.417-446.
2. Response evaluation criteria for peripheral nodal lymphoma in dogs (v1.0)–a veterinary cooperative oncology group (VCOG) consensus document. *Vet Compar Onco.* 2010, Vol.8(1), p.28-37.

Manufactured by:
Halo Pharmaceutical, Inc.
(d/b/a Cambrex Whippany)
Whippany, NJ USA

Distributed by:
Dechra Veterinary Products
7015 College Boulevard, Suite 525
Overland Park, KS 66211
(866) 933-2472

Product inquiries should be directed to Dechra Veterinary Products, (866) 933-2472.

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-526

Issued: February 2022

1894-02
PIN-7001-05

Dechra
Veterinary Products

Recheck for relief done right.

Canine otitis externa (OE) treatment is only successful when you're confident your treatment is working.

That's why the follow-up appointment is so important. Resolve the infection with 2-dose Osurnia® (florfenicol-terbinafine-betamethasone acetate), use the follow-up to monitor the response to treatment and trust the Dechra dermatology portfolio to help you treat the underlying problem.

Because when it comes to treating canine OE, a "one-and-done" treatment leaves many questions unanswered.

- *Was the underlying issue identified?*
- *Is the ear infection actually improving?*
- *Is the ear infection likely to return?*
- *Are more diagnostics warranted?*

The follow-up appointment isn't a "nice-to-have." It's necessary to get to the root of the problem.

With two doses delivered by you, Osurnia delivers results.

We're here for ears.

The Dechra portfolio can help you solve even the most stubborn OE cases.

Chronic or recurrent canine OE is a common problem for patients. Osurnia® (florfenicol, terbinafine, betamethasone acetate) will resolve the infection. But if an underlying condition is to blame, OE will present itself again in the future. This creates a painful cycle for patients and frustration for clients.

The Dechra dermatology portfolio specializes in solutions for skin and ear health—including the most common underlying conditions responsible for recurrent canine OE.

Partner with Dechra for your dermatology needs.

To order or schedule a lunch and learn,
call your Dechra representative or call **(866) 683-0660**.
For more information, please visit ***www.dechra-us.com***.

Important Safety Information

As with all drugs, side effects may occur. In field studies and post-approval experience the most common side effects reported were vomiting, increased liver enzymes and loss of hearing. Other signs reported were ear discharge, ear irritation and pain, vomiting, head shaking, head tilt, ataxia, vocalization, corneal ulcer, keratoconjunctivitis sicca, nystagmus, tympanic rupture, and facial paralysis.

Osurnia® should be administered by a veterinary professional. Do not use in dogs with known tympanic perforation or a hypersensitivity to florfenicol, terbinafine or corticosteroids. **Osurnia may cause eye injury and irritation. Wear eye protection when administering Osurnia and restrain the dog** to minimize post-application head shaking. **Do not use in cats.** Refer to the prescribing information for complete details or visit www.dechra-us.com.

Dechra
Veterinary Products

For Veterinary Technical Support Contact Dechra Veterinary Products at:
866-933-2472, www.dechra-us.com, support@dechra.com.

06SD-OSU21012-0421

Dechra
Veterinary Products

Two reasons to recheck.

1

2

Osurnia®
(florfenicol, terbinafine, betamethasone acetate)

Confidently treat canine otitis externa with two-dose Osurnia, part of the Dechra dermatology portfolio.

All the more reason(s) to reach for Osurnia®

(florfenicol, terbinafine, betamethasone acetate).

Osurnia offers unique advantages for veterinarians and patients.

Applied by You

Each dose is administered by your team with no need to clean the affected ears throughout the course of treatment (45 days)—offering improved compliance and no homework for clients.

Alcohol-Free Patented Gel

Adaptable gel penetrates deep, coating and adhering to the entire ear canal. Lipophilic formulation works well in a waxy environment.

Flexible Tip

Soft applicator tip is ideal for thorough administration deep into the ear canal and more comfortable for patients in pain.

45-Day Continual Treatment

Patented formulation is uniquely designed to increase contact time at the infection site for long-lasting efficacy and better patient outcomes.

Easy Administration

Dosing is always accurate. Premeasured, single-dose tube is ready to treat patients of any size without the need to count drops during application.

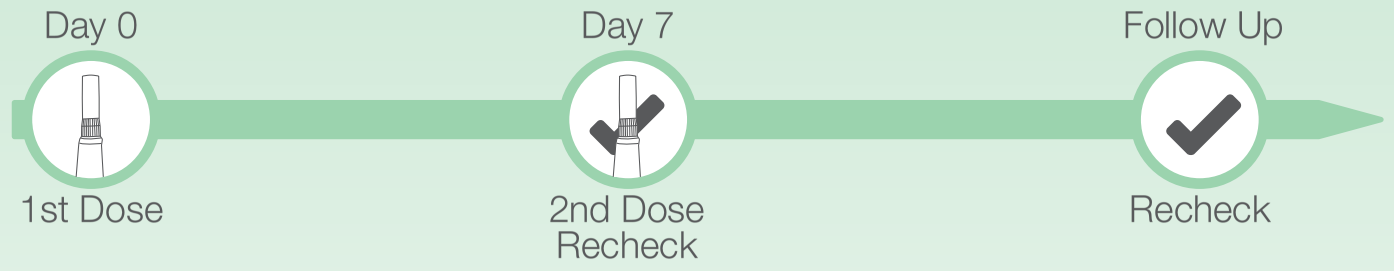
Complements the Dechra Portfolio

If cytology findings and clinical signs direct you to an underlying problem causing recurrent OE, the Dechra dermatology portfolio can provide solutions.

Osurnia® (florfenicol, terbinafine, betamethasone acetate) brings the owner back to your clinic.

Successful management of otitis externa (OE) can often involve long-term, or even lifelong, treatment depending on the underlying cause. This care requires a high level of owner commitment and a good relationship between you and your patient's owner.

The benefits of the second dose are twofold. It provides you with an opportunity to recheck the dog mid-treatment to ensure it's responding as planned. It also brings the owner back to the clinic to help build trust and strengthen the relationship while uncovering any necessary next steps to address OE and its underlying cause.



Dechra has a range of products to support you in the treatment and long-term management of OE. The Dechra dermatology portfolio is able to offer you effective, convenient treatment with considerations for your clinical preference and the owner's lifestyle.

Confidently manage even the most challenging canine OE cases with Osurnia and the Dechra dermatology portfolio.

Osurnia®

(florfenicol, terbinafine, betamethasone acetate)

Otic Gel
Antibacterial, antifungal, anti-inflammatory

For Otic Use in Dogs Only
Do not use in cats

CAUTION:
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:
OSURNIA contains 10 mg florfenicol, 10 mg terbinafine and 1 mg betamethasone acetate per mL and the inactive ingredients propylene carbonate, glyceryl formal, hypromellose, phospholipid, oleic acid and BHT in an off-white to slightly yellow translucent gel.

INDICATION:
OSURNIA is indicated for the treatment of otitis externa in dogs associated with susceptible strains of bacteria *(Staphylococcus pseudintermedius)* and yeast *(Malassezia pachydermatis)*.

DOSAGE AND ADMINISTRATION:
OSURNIA should be administered by a veterinary professional. Wear eye protection when administering Osurnia (see **Human Safety Warnings, Precautions, Post-Approval Experience** and **Animal Safety).**

Splatter may occur if the dog shakes its head following administration. Persons near the dog during administration should also take steps to avoid ocular exposure.

1. Clean and dry the external ear canal before administering the initial dose of the product.
2. **Verify the tympanic membrane is intact prior to each administration** (see **Precautions, Contraindications, Animal Safety** and **Post-Approval Experience).**
3. Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.
4. Open tube by twisting the soft tip. Insert the flexible tip in the affected external ear canal(s) and squeeze entire tube contents into the external ear canal(s). After application, gently massage the base of the ear to allow the gel to penetrate the lower part of the ear canal.
5. **Restrain dog to minimize post-application head shaking** to reduce potential for splatter of product, and accidental eye exposure in people and dogs (see **Post-Approval Experience and Animal Safety**).
6. Do not clean the ear canal for 45 days after the initial administration to allow contact of the gel with the ear canal. Cleaning the ear may affect product effectiveness (see **Effectiveness**). If alternative otic therapies are required, it is recommended to clean the ear(s) before application.

CONTRAINDICATIONS:
Do not use in dogs with known tympanic perforation (see **Precautions**).

Do not use in dogs with a hypersensitivity to florfenicol, terbinafine or corticosteroids.

WARNINGS:
Human Safety Warnings:

OSURNIA may cause eye injury and irritation (see **Precautions, Post-Approval Experience** and **Animal Safety).**
In case of accidental eye contact, flush thoroughly with water for at least 15 minutes. If symptoms develop, seek medical advice.

Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. In case of accidental skin contact, wash area thoroughly with water.

PRECAUTIONS:
Wear eye protection when administering OSURNIA and restrain the dog to minimize post-application head shaking. Reducing the potential for splatter of product will help prevent accidental eye exposure in people and dogs and help to prevent ocular injury (see **Human Safety Warnings, Post-Approval Experience** and **Animal Safety**).

The use of OSURNIA in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membrane should be confirmed before administering this product. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.

Proper patient selection is important when considering the benefits and risks of using OSURNIA. The integrity of the tympanic membrane should be confirmed before administering each dose of product.

Changes to the middle ear, such as ulceration of the mucosal lining, have been associated with OSURNIA administration. (see **Animal Safety**).

Signs of tympanic membrane rupture, internal ear disease such as head tilt, ataxia, nystagmus, facial paralysis, and keratoconjunctivitis sicca have also been reported (see **Post-Approval Experience**).

Do not administer orally.

Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **Animal Safety**).

Use with caution in dogs with impaired hepatic function (see **Animal Safety** and **Adverse Reactions**).

The safe use of OSURNIA in dogs used for breeding purposes, during pregnancy, or in lactating bitches, has not been evaluated.

ADVERSE REACTIONS:
The following adverse reactions were reported during the course of a US field study for treatment of otitis externa in dogs treated with OSURNIA with 1 tube per affected ear(s) and repeated after 7 days:

Frequency of Adverse Reaction by Treatment

Adverse Reaction	OSURNIA (n=190)	Placebo (n=94)
Elevated Alkaline Phosphatase	15 (7.9%)	3 (3.2%)
Vomiting	7 (3.7%)	1 (1.1%)
Elevated AST, ALT, ALP*	2 (1.1%)	0 (0.0%)
Weight loss (>10% body weight)	1 (0.53%)	0 (0.0%)
Hearing Decrease/Loss	1 (0.53%)	1 (1.1%)

*Aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP). Two dogs with pre-existing elevations in ALP were reported to have an increase in liver enzymes (ALP, ALT and/or AST) at study exit. Subsequent clinical chemistries returned to pre-treatment levels in one dog, while no follow-up was performed for the second dog.

Post-Approval Experience (2020)
The following adverse events are based on post-approval adverse drug experience reporting for OSURNIA. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data.

In humans, accidental exposure leading to corneal ulcers and other ocular injuries such as eye irritation, burning, stinging, and itchiness have been reported to occur when the dog shook its head after application of OSURNIA.

In dogs, the adverse events reported for OSURNIA are presented below in decreasing order of reporting frequency: Deafness, ear discharge, pinnal irritation and ear pain, emesis, head shaking, internal ear disorder (head tilt and vestibular), ataxia, vocalization, corneal ulcer, keratoconjunctivitis sicca, nystagmus, tympanic rupture, and cranial nerve disorder (facial paralysis).

OSURNIA is not approved for use in **cats**. The adverse events reported following extra-label use in **cats** are presented below in decreasing order of reporting frequency:

Ataxia, anorexia, Horner's syndrome (third eyelid prolapse and miosis), internal ear disorder (head tilt and vestibular), anisocoria, lethargy, head shake, emesis, nystagmus, deafness, and tympanic rupture.

CONTACT INFORMATION:
To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Dechra at 1-866-933-2472

For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

INFORMATION FOR DOG OWNERS:
Owners should be aware that adverse reactions may occur following administration of OSURNIA and should observe dog for signs such as deafness, ear pain and irritation, vomiting, head shaking, head tilt, incoordination, eye pain and ocular discharge (see **Animal Safety** and **Post-Approval Experience**). Owners should be advised to contact their veterinarian if any of the above signs are observed.

Owners should also be informed that splatter may occur if the dog shakes its head following administration of OSURNIA which may lead to ocular exposure. As a result, eye injuries in humans and dogs have been reported including corneal ulcers. Owners should be careful to avoid ocular exposure (see **Precautions** and **Post-Approval Experience**).

CLINICAL PHARMACOLOGY:
OSURNIA is a fixed combination of three active substances: florfenicol (antibacterial), terbinafine (antifungal) and betamethasone acetate (steroidal anti-inflammatory). Florfenicol is a bacteriostatic antibiotic which acts by inhibiting protein synthesis. Its spectrum of activity includes Gram-positive and Gram-negative bacteria. Terbinafine is an antifungal which selectively inhibits the early synthesis of ergosterol. Betamethasone acetate is a glucocorticosteroid with anti-inflammatory activity.

OSURNIA dissolves in ear wax and is slowly eliminated from the ear mechanically. Ear inflammation can increase the percutaneous absorption of active substances in OSURNIA.

In a laboratory study conducted in healthy dogs (see **Animal Safety**), low plasma concentrations of florfenicol, terbinafine, and betamethasone acetate were measurable during the first 2-4 days after administration of 1X dose, and during the first 2-7 days after administration of 5X dose. No quantifiable plasma concentrations of any of the three active ingredients were observed in the pre-dose samples of most dogs prior to second and third administrations. Although total and peak exposure in the blood tended to be highly variable between dogs, systemic drug concentrations tended to increase in a less than dose-proportional manner as the administered dose increased from 1X to 5X.

MICROBIOLOGY:
The compatibility and additive effect of each of the components in OSURNIA was demonstrated in a component effectiveness and non-interference study. An *in vitro* study of organisms collected from clinical cases of otitis externa in dogs determined that florfenicol and terbinafine inhibit the growth of bacteria and yeast commonly associated with otitis externa in dogs. No consistent synergistic or antagonistic effect of the two antimicrobials was demonstrated. The addition of betamethasone acetate to the combination did not impair antimicrobial activity to any clinically significant extent.

In a field study (see **Effectiveness**), the minimum of 10 isolates from successfully treated cases with OSURNIA was met for *Staphylococcus pseudintermedius, Malassezia pachydermatis,* and *Pseudomonas aeruginosa.* However, there were only three dogs where *P. aeruginosa* was the only pathogen cultured and they were all treatment failures. Therefore, OSURNIA may not be effective in treating otitis externa in which *P. aeruginosa* is the only pathogen present.

EFFECTIVENESS:
Effectiveness was evaluated in 235 dogs with otitis externa. The study was a double-masked field study with a placebo control (vehicle without the active ingredients). One hundred and fifty-nine dogs were treated with OSURNIA and seventy-six dogs were treated with the placebo control. All dogs were evaluated for safety. Treatment (1 mL) was administered to the affected ear(s) and repeated 7 days later. Prior to the first administration, the ear(s) were cleaned with saline but not prior to the Day 7 administration. Six clinical signs associated with otitis externa were evaluated: pain, erythema, exudate, swelling, odor and ulceration. Total clinical scores were assigned for a dog based on the severity of each clinical sign on Days 0, 7, 14, 30 and 45. Success was determined by clinical improvement at Day 45. The success rates of the two groups were significantly different ($p=0.0094$); 64.78% of dogs administered OSURNIA were successfully treated, compared to 43.42% of the dogs in the placebo control group.

ANIMAL SAFETY:
In a target animal safety study, 24 mixed breed dogs (4 dogs/sex/group) were aurally administered 0X, 1X (1 mL/ear or 2 mL/dog with repeated administration in 7 days) or 5X (5 mL/ear or 10 mL/dog with repeated administration in 7 days) doses of OSURNIA for a total of 6 administrations in 5 weeks. All dogs remained in good health with normal hearing throughout the study. Decreased weight gain was noted in the 1X and 5X groups compared to the control group. Clinical findings included post-administration ear wetness in 1X and 5X groups and unilateral, transient brown/red discharge from one ear each in two 5X dogs, with erythema in one dog after the 4th application. Local microscopic changes in ears (without clinical effects) included: slight or moderate unilateral vesicle formation within the epithelium of the tympanic membrane in two 1X and four 5X dogs, and unilateral mucosal ulceration in the lining of the middle ear cavity in three 5X dogs. Three 5X dogs had slightly elevated ALT activity, accompanied by minimal or mild microscopic hepatocellular vacuolation (in two dogs). Cortisol response to ACTH stimulation was decreased, but within the normal reference range, in 1X dogs. The 5X dogs had a decrease in serum cortisol levels after ACTH stimulation (below normal reference range) accompanied by decreased adrenal gland and thymic weights with minimal adrenal cortical atrophy and slight (in three dogs) or moderate (in one dog also noted with slightly lower lymphocyte counts) lymphoid depletion of the thymus. The ACTH stimulation test results are consistent with systemic absorption of betamethasone resulting in a likely reversible suppression of the hypothalamic-pituitary-adrenal axis as seen with administration of exogenous corticosteroids.

STORAGE CONDITIONS:
OSURNIA should be stored under refrigerated conditions between 36° - 46° F (2° - 8° C). To facilitate comfort during administration, OSURNIA may be brought to room temperature and stored for up to three months.

HOW SUPPLIED:
OSURNIA is a gel in a single-use tube with a flexible soft tip, supplied in cartons containing 2 or 20 tubes.

Osurnia 2 tube carton NDC 17033-283-02
Osurnia 20 tube carton NDC 17033-283-20

Approved by FDA under NADA # 141-437

MANUFACTURED FOR:
Dechra Veterinary Products
7015 College Boulevard, Suite 525
Overland Park, KS 66211 USA
Product of Great Britain

Rev. December 2020 PIL-44029-002

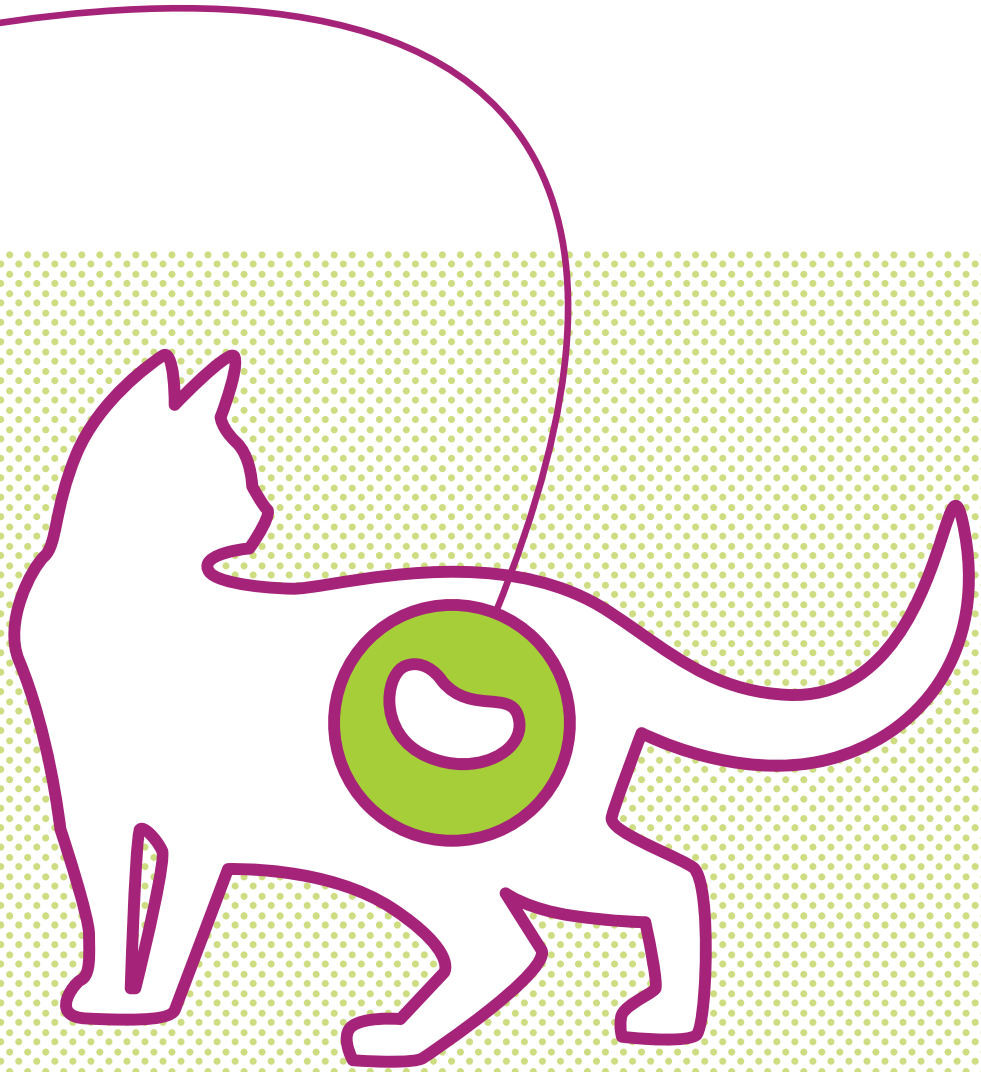
Dechra

PORUS® ONE

Dechra
Veterinary Products

Porus® One

For the support of feline kidney health



Porus® One is a selective carbon-based adsorber of protein byproducts with a large adsorption capacity.*

5 reasons for **Porus One**

Selectivity

Innovative adsorber; selectively binds small molecules that are excreted in the feces.

Adsorption capacity

The innovative active ingredient has a large adsorption surface area per dose.

Palatability

Porus One has no taste or smell and is readily accepted by cats.

Ease of administration

Each packet contains one daily dose, which is 500 mg.

General tolerance

No metabolism or absorption. Excreted in the feces and no accumulation in the body.*

What are uremic toxins?

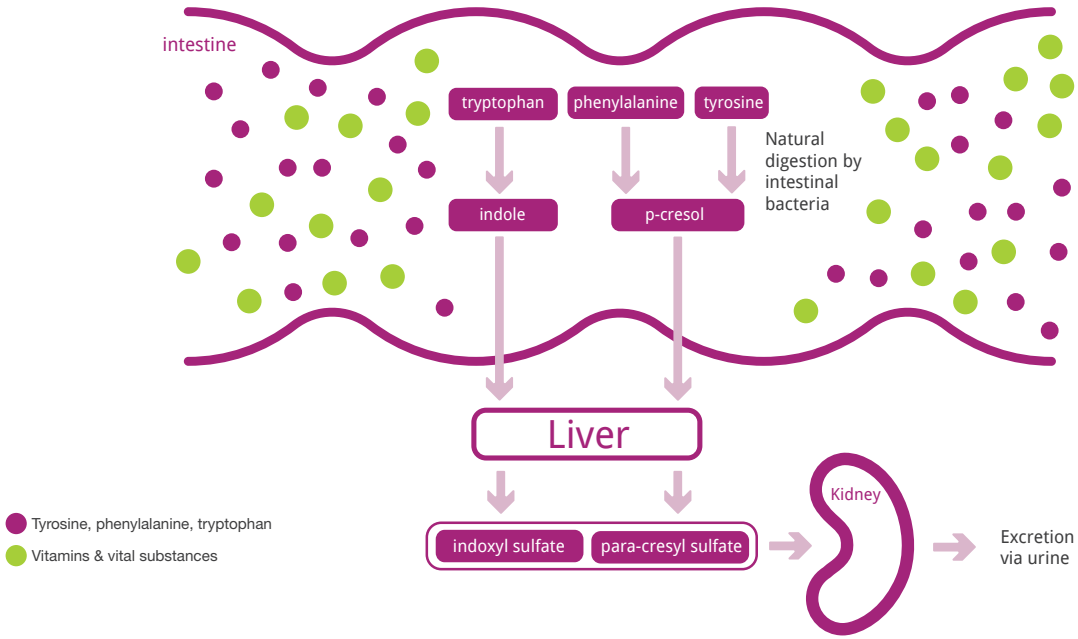
Cats, unlike dogs, are obligate carnivores because they derive their energy solely from meat. Their bodies depend on protein-rich food. Protein metabolism leads to a large amount of waste products, which are typically excreted by the kidneys.

Uremic toxin precursors are produced when intestinal bacteria digest the amino acids tryptophan, phenylalanine, and tyrosine. The uremic precursors indole and p-cresol are then absorbed and transported to the liver and metabolized into the uremic toxins indoxyl sulfate and para-cresyl sulfate. These toxins are transported to the kidneys for excretion.

Introducing Porus® One

Porus One binds protein byproducts in the intestines where they are excreted in the feces.* This binding process helps to prevent the byproducts from being converted into uremic toxins, which supports kidney health.

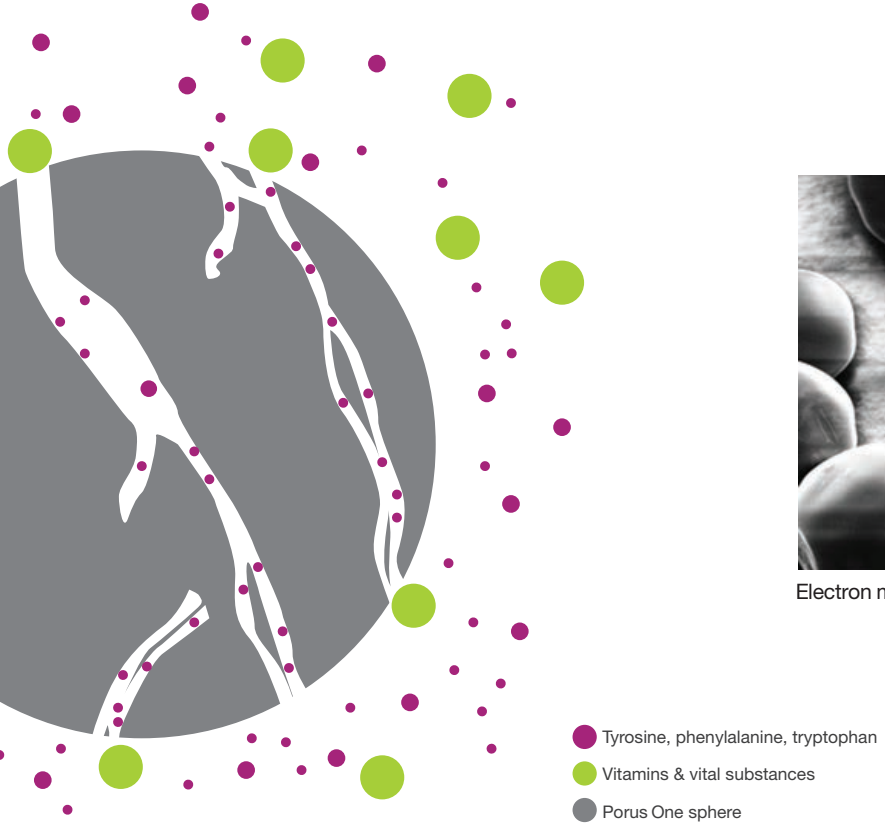
Uremic toxins are formed from essential amino acids

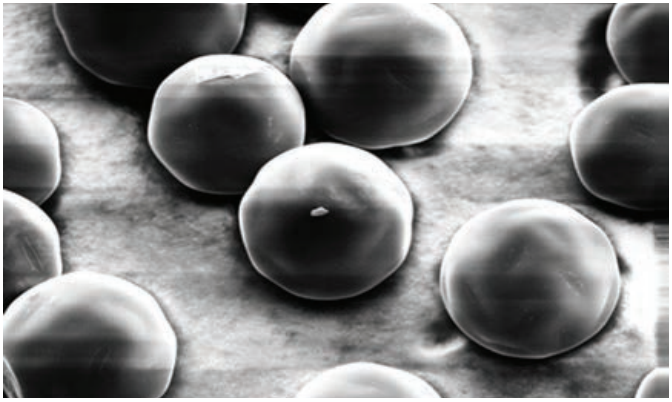


What is Porus® One?

Each packet of Porus One contains Renaltec™, a selective carbon-based adsorber of protein byproducts in the gut.

Renaltec is composed of tiny, black homogenous spheres with diameters of 0.1 to 0.3 mm. Each sphere has a smooth surface and is perforated by numerous pores leading to a branched channel system similar to the bronchi. This smooth surface assures an unimpeded passage through the GI tract, neither adhering to the mucosa nor accumulating in the intestine.*





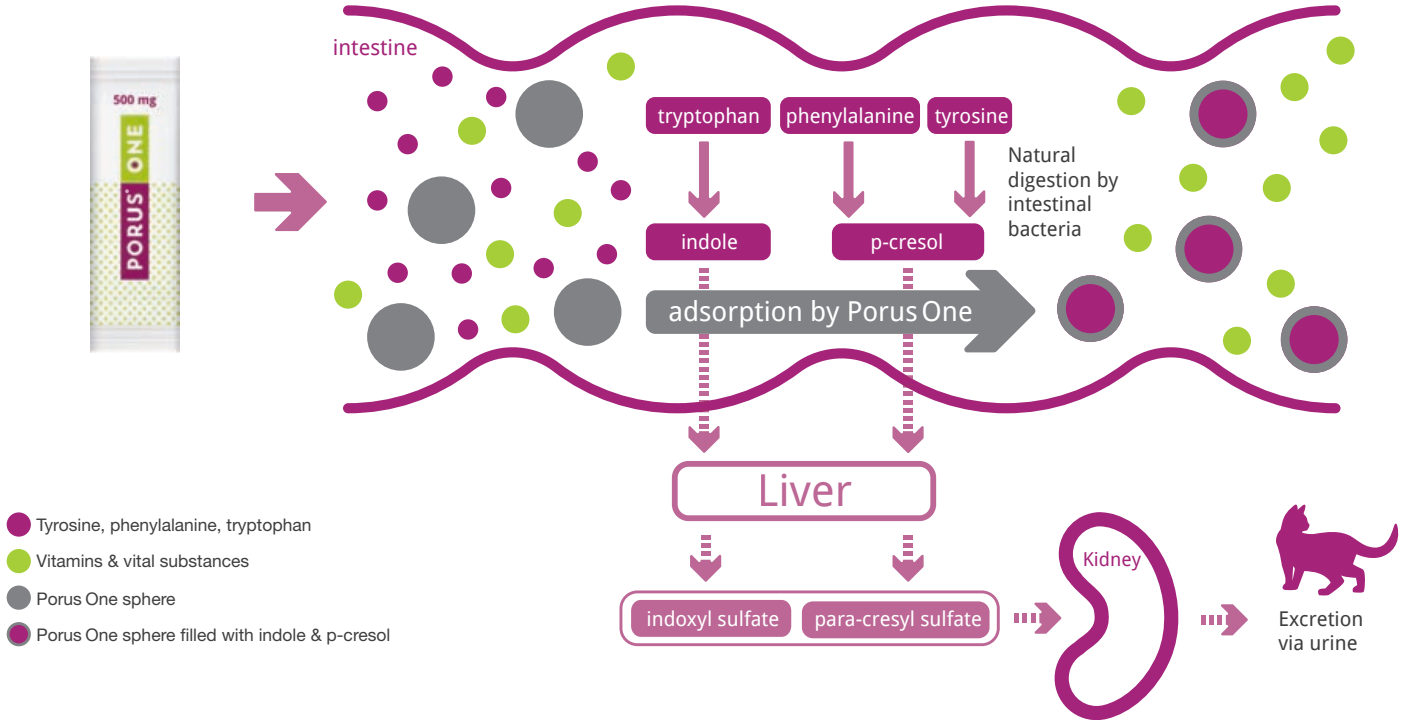
Electron microscope image of Renaltec


500 mg
PORUS® ONE

How does Porus® One work?

Porus One binds protein byproducts in the intestines where they are then excreted in the feces. As a result, the byproducts cannot be converted into uremic toxins.

Reducing uremic toxin production supports kidney health



Selectivity is key

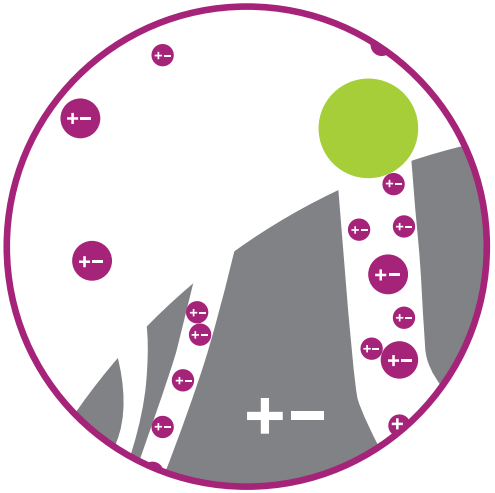
Molecular Size

The pores are manufactured to be so tiny that only very small molecules, such as uremic toxins, can enter the sphere's interior. Particles with a larger diameter (such as vitamins and enzymes) are less able to enter.

Molecular Charge

Uremic toxins are bound inside the spheres because of an opposite electrical charge.

The electrical charge of the Renaltec spheres facilitates this binding.



Large adsorption capacity

Due to its spherical shape and the inner branched channel system, Porus One has a large adsorption capacity.

General tolerance

Porus One is excreted in the feces. It is neither metabolized nor absorbed and does not accumulate in the body.

Has Porus® One been studied in cats?

In an 8-week study of 18 healthy geriatric cats (11 to 16 years of age), Porus One was shown to be beneficial for kidney health. Twelve cats received 500 mg of Porus One daily and six cats served as a negative control, receiving the same type of food as the Porus One group. The mean serum indoxyl sulfate concentration was reduced by more than 60% in the Porus One group while no significant change was observed in the control group. Porus One was also readily accepted and well tolerated by the cats.**

How is Porus® One used?

Porus One is tasteless and odorless, and can be easily administered to cats once daily at mealtime. If your feline patient takes other oral medications, those should be given at least two hours prior.

NOTE: it is normal for a thin layer of Porus One to remain inside the packet.

One carton contains
30 daily doses

For more information contact your Dechra Representative or call (866) 683-0660.

24-hour Veterinary Technical Support available at (866) 933-2472.
Nonurgent Technical Support available by emailing support@dechra.com.

QUALITY SEAL nasc NATIONAL ANIMAL SUPPLEMENT COUNCIL

*Data on file.
**Mottet J, Kowollik N: BSAVA Congress Proceedings. 2019. 424-425.

PORUS® ONE

Dechra
Veterinary Products

24-Hour Veterinary Technical Support
(866) 933-2472

Customer Support
(866) 683-0660

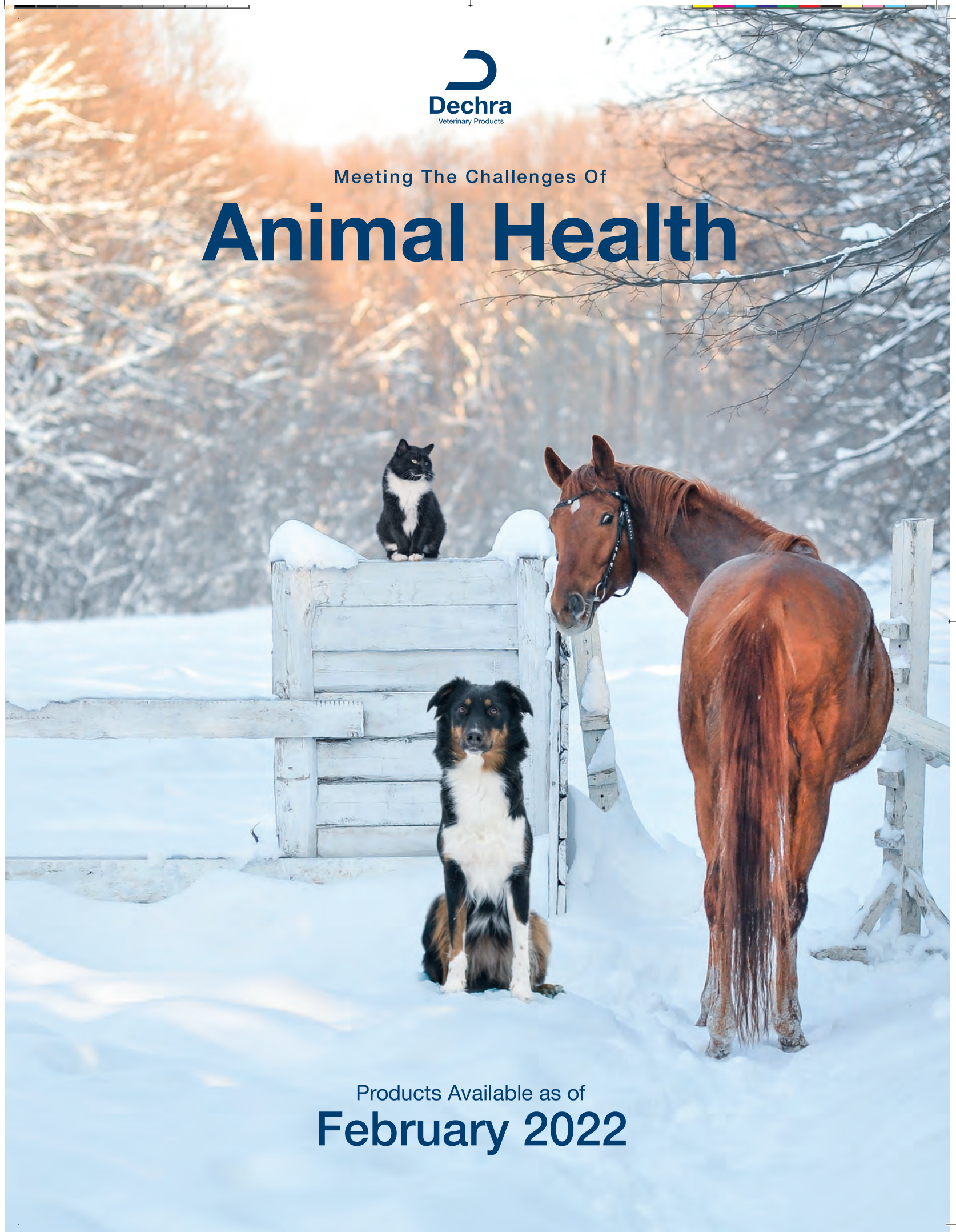
Dechra Website
www.dechra-us.com

00FR-DEC22020-0222

Dechra
Veterinary Products

Meeting The Challenges Of

Animal Health



Products Available as of

February 2022

Table of Contents

Companion Animal New & Coming Soon Products

Laverdia™-CA1
(verdinexor tablets)

Isoflurane, USP

Sevoflurane

Vetivex®
Hypertonic Saline Solution 7.2%, USP

OPHTHAVET®

Rederox®
(deracoxib)

Amoxicillin and Clavulanate Potassium for Oral Suspension

Tzed™
(tiletamine and zolazepam for injection)

Enrofloxacin
Antibacterial Injectable Solution 2.27%

Equine New & Featured Products

ProVet® APC
Autologous Platelet Concentrate System

Butorphanol Tartrate Injection

Rompun®
(xylazine injection)

SucroMate® Equine
(deslorelin acetate)

ONCOLOGY

PRODUCT	SIZE	
Laverdia™-CA1 (verdinexor tablets)	2.5 mg tablets, 50 ct 10 mg tablets, 50 ct 50 mg tablets, 50 ct 50 mg tablets, 16 ct **COMING SOON**	 New!

ENDOCRINOLOGY

PRODUCT	SIZE	
FELIMAZOLE® Coated Tablets (methimazole)	2.5 mg tablets, 100 ct 5.0 mg tablets, 100 ct	
VETORYL® CAPSULES (trilostane)	5 mg capsules, 30 ct 10 mg capsules, 30 ct 30 mg capsules, 30 ct 60 mg capsules, 30 ct 120 mg capsules, 30 ct	
Zycortal® Suspension (desoxycorticosterone pivalate injectable suspension)	25 mg/mL, 4 mL vial	

WEIGHT MANAGEMENT

PRODUCT	SIZE	
Mirataz® (mirtazapine transdermal ointment)	5g tube	

KIDNEY HEALTH

PRODUCT	SIZE	
Porus® One	500 mg packets, 30 ct	

SYSTEMIC ANTI-INFECTIVES

PRODUCT	SIZE	
Cefpoderm® (cefpodoxime proxetil) Tablets	100 mg tablets, 100 ct 200 mg tablets, 100 ct	
Clavacillin® (amoxicillin trihydrate/ clavulanate potassium) Veterinary Tablets Each carton can hold 5 strips with 14 tablets (70 tablets per carton) or 15 strips with 14 tablets (210 tablets per carton).	62.5 mg tablets, 70 ct, 210 ct 125 mg tablets, 70 ct, 210 ct 250 mg tablets, 70 ct, 210 ct 375 mg tablets, 70 ct, 210 ct	
Amoxicillin and Clavulanate Potassium Oral Suspension Drops	15 mL Suspension	 New!
Enroquin® (enrofloxacin) Flavored Tablets	22.7 mg tablets, 100 and 500 ct 68 mg tablets, 50 and 250 ct 136 mg tablets, 50 and 200 ct	
Enrofloxacin Antibacterial Injectable Solution 2.27%	20 mL vial	 New!
Marboquin® (marbofloxacin) Tablets	25 mg tablets, 100 and 250 ct 50 mg tablets, 100 and 250 ct 100 mg tablets, 50 ct 200 mg tablets, 50 ct (coming soon)	

TOPICAL ANTI-INFECTIVES

PRODUCT	SIZE	
ANIMAX® Ointment (nystatin, neomycin sulfate, thiostrepton, triamcinolone acetonide ointment)	7.5 mL tube 15 mL tube 30 mL tube	
GENTACALM® Topical Spray (gentamicin sulfate with betamethasone valerate)	60 mL bottle 120 mL bottle	
MURICIN® (mupirocin ointment 2%) 2% mupirocin	15 g tube	

OTIC TREATMENT

PRODUCT	SIZE	
Osurnia® (florfenicol, terbinafine, betamethasone acetate)	1 mL tube, 2 ct 1 mL tube, 20 ct	

OTIC CLEANSERS

PRODUCT	SIZE	
EpiKlean® Ear Cleanser propylene glycol, glycerin, salicylic acid	8 oz bottle 12 oz bottle 32 oz bottle	
KlearOtic Ear Cleanser 22% squalane	4 oz bottle	
MalAcetic® Otic Cleanser 2% acetic acid, 2% boric acid	4 oz bottle 8 oz bottle 16 oz bottle	
MalAcetic ULTRA® Otic Cleanser 1% acetic acid; 1% hydrocortisone, USP; 0.15% ketoconazole, USP; ceramide complex	2 oz bottle 8 oz bottle	

EAR AND SKIN FLUSHES

PRODUCT	SIZE	
Mal-A-Ket® Plus TrizEDTA® Flush 0.15% ketoconazole, USP; 0.15% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	4 oz bottle 12 oz bottle	
TrizCHLOR® Flush 0.15% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	4 oz bottle	
TrizEDTA® Aqueous Flush TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	4 oz bottle 16 oz bottle	
TrizEDTA® Crystals Flush TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	4 oz bottle 16 oz bottle	

EAR AND SKIN FLUSHES (Continued)

PRODUCT	SIZE	
TrizUltra+Keto® Flush 0.15% ketoconazole, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	4 oz bottle 12 oz bottle	

SHAMPOO, SPRAY CONDITIONERS, AND MOUSSE

PRODUCT	SIZE	
DermAllay Oatmeal Shampoo hydrolyzed oats, safflower seed oil, glycerin, ceramide complex	12 oz bottle Gallon bottle	
DermAllay Oatmeal Spray Conditioner hydrolyzed oats, safflower seed oil, glycerin, ceramide complex	8 oz bottle 12 oz bottle Gallon bottle	
DermaBenSs® Shampoo 2.5% benzoyl peroxide, USP; 1% salicylic acid, USP; sulfur, ceramide complex	12 oz bottle Gallon bottle	
DermaLyte® Shampoo glycerin, safflower seed oil, sodium lactate, ceramide complex	12 oz bottle Gallon bottle	
Hypoallergenic Cream Rinse glycerin, safflower oil (linoleic acid), ceramide complex	8 oz bottle	
MalAcetic® Spray Conditioner 2% acetic acid, 2% boric acid	16 oz bottle	
MalAcetic ULTRA® Shampoo 1% acetic acid; 2% boric acid; 1% hydrocortisone, USP; 0.15% ketoconazole, USP; ceramide complex	8 oz bottle	
MalAcetic ULTRA® Spray Conditioner 1% acetic acid; 2% boric acid; 1% hydrocortisone, USP; 0.15% ketoconazole, USP; ceramide complex	8 oz bottle	
Mal-A-Ket® Shampoo 1% ketoconazole, USP; 2% chlorhexidine gluconate, USP; 2% acetic acid	8 oz bottle Gallon bottle	

SHAMPOO, SPRAY CONDITIONERS, AND MOUSSE (Continued)

PRODUCT	SIZE	
Mal-A-Ket® Plus TrizEDTA® Spray Conditioner 1% ketoconazole, USP; 2% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	8 oz bottle	
MiconaHex+Triz® Shampoo 2% miconazole nitrate, USP; 2% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP); ceramide complex	8 oz bottle 16 oz bottle Gallon bottle	
MiconaHex+Triz® Spray Conditioner 2% miconazole nitrate, USP; 2% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP); ceramide complex	8 oz bottle 16 oz bottle	
MiconaHex+Triz® Mousse 2% miconazole nitrate, USP; 2% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP); ceramide complex	7.1 oz	
TrizCHLOR® 4 Mousse 4% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	7.1 oz	
TrizCHLOR® 4 Shampoo 4% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	8 oz bottle 16 oz bottle Gallon bottle	
TrizCHLOR® 4 Spray Conditioner 4% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	8 oz bottle	
TrizCHLOR® 4 HC Shampoo 4% chlorhexidine gluconate, USP; 1% hydrocortisone, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	8 oz bottle	
TrizCHLOR® 4 HC Spray Conditioner 4% chlorhexidine gluconate, USP; 1% hydrocortisone, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	8 oz bottle	

WIPES

PRODUCT	SIZE	
MalAcetic® Wet Wipes 2% acetic acid; 2% boric acid	6" x 8", 25 ct pack 5" x 7", 100 ct jar	
MalAcetic® HC Wipes 1% hydrocortisone, USP; 1% acetic acid; 1% boric acid; ceramide III	25 ct jar	
Mal-A-Ket® Wipes 1% ketoconazole, USP; 2% chlorhexidine gluconate, USP; 2% acetic acid	50 ct jar	
TrizCHLOR® 4 Wipes 4% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	50 ct jar	
MiconaHex+Triz® Wipes 2% miconazole nitrate, USP; 2% chlorhexidine gluconate, USP; TrizEDTA® (tromethamine, USP; disodium EDTA, USP)	50 ct jar	

VETERINARY OPHTHALMICS

PRODUCT	SIZE	
Puralube® Vet Ointment petrolatum sterile ocular lubricant	3.5 g tube (1/8 oz)	
OphtHAvet® Complete Ophthalmic Gel Sterile Veterinary Ophthalmic Lubricant, Preservative-Free 0.2% Viscoadaptive Sodium Hyaluronate + Hydrating Lipid	10 mL bottle	 New!
OphtHAvet® Ophthalmic Solution Sterile Veterinary Ophthalmic Lubricant, Preservative-Free 0.18% Viscoadaptive Sodium Hyaluronate	10 mL bottle	 New!
OphtHAvet® Ophthalmic Ointment Isotonic, Sterile Veterinary Ophthalmic Lubricant 0.4% Sodium Hyaluronate	5 g tube (0.18 oz)	 New!

FATTY ACIDS

PRODUCT	SIZE	
Eicosa3FF® SnipCaps fish oil as a concentrated source of beneficial Omega-3 Fatty Acids in a free fatty acid form	<60 lbs; 60 ct, 120 ct >30 lbs; 60 ct, 120 ct	
EicosaCaps® Omega 3 & 6 Capsules purified marine oil extract, borage oil, vitamin C & E, zinc sulfate, safflower oil	<40 lbs, 60 ct 41-70 lbs, 60 ct	
EicosaDerm® Omega 3 Liquid purified marine oil extract, vitamin E	8 oz pump bottle 32 oz pump bottle	

SUPPLEMENTS AND TREATS

PRODUCT	SIZE	
Redonyl® Ultra Feline Powder PEA-um (Ultra-micronized Palmitoylethanolamide)	3.5 oz	
Redonyl® Ultra Soft Chews PEA-um (Ultra-micronized Palmitoylethanolamide)	100 mg soft chews, 120 ct 200 mg soft chews, 120 ct	
EpiTreats® Healthy Canine Treats semi-moist hypoallergenic treat containing a single carbohydrate source (dried potato product) and a hydrolyzed protein source (chicken liver)	8 oz bag 1 bag = approx. 40 treats	
CAT LAX® cod liver oil-caramel-lecithin-malt syrup-white petrolatum	56.7 g tube (2 oz)	
ProbioWrap™ Mircroencapsulated, peanut butter flavored pill wrap containing a proprietary strain of probiotics	100 million CFUs per 2 gm serving 4.2 oz, (120gm) tub	

ANESTHETICS/SEDATIVES

PRODUCT	SIZE	
Ketamine Hydrochloride Injection	100 mg/mL, 10 mL vial, 12 vials per tray	

ANESTHETICS/SEDATIVES (Continued)

PRODUCT	SIZE	
Dexmedesed® (dexmedetomidine hydrochloride) Sterile Injectable Solution	0.5 mg/mL, 10 mL vial	
Tzed™ (tiletamine and zolazepam for injection) Previously known as Tilzolan® (tiletamine HCl and zolazepam HCl)	5 mL vial 100mg/mL total (equivalent to 50mg/mL tiletamine and 50mg/mL zolazepam)	 New Name
Isoflurane, USP Inhalation Anesthetic	250 mL bottle Each mL contains 99.9% isoflurane	Coming Soon! 
Sevoflurane Inhalation Anesthetic	250 mL bottle Contains 250 mL sevoflurane	Coming Soon! 

VETERINARY IV FLUIDS

PRODUCT	SIZE	
Vetivex® Lactated Ringer's Solution Injection, USP Each 100 mL of solution contains: 600 mg sodium chloride, 310 mg sodium lactate, 30 mg potassium chloride, 20 mg calcium chloride	250 mL, 500 mL, 1000 mL, and 5000 mL bags	
Vetivex® 0.9% Sodium Chloride Injection, USP Each 100 mL of solution contains: 900 mg sodium chloride	250 mL, 500 mL, 1000 mL, and 3000 mL bags	
Vetivex® Lactated Ringer's and 5% Dextrose Injection, USP Each 100 mL of solution contains: 5000 mg dextrose hydrous, 600 mg sodium chloride, 310 mg sodium lactate, 30 mg potassium chloride, 20 mg calcium chloride	1000 mL bag	
Vetivex® Veterinary pHyLyte® Injection pH 7.4 *(Multiple Electrolytes Injection, Type 1, USP)* Each 100 mL of solution contains: 526 mg sodium chloride, 502 mg sodium gluconate, 368 mg sodium acetate trihydrate, 37 mg potassium chloride, 30 mg magnesium chloride	1000 mL, 3000 mL and 5000 mL bags	
Vetivex® Hartmann's Solution for Injection Each 100 mL of solution contains: 600 mg sodium chloride, 317 mg sodium lactate, 40 mg potassium chloride, 27 mg calcium chloride dihydrate	3000 mL and 5000 mL bags	
Vetivex® Hypertonic Saline Solution 7.2%, USP 1000 mL bag Each 100 mL of solution contains: 7.2 g sodium chloride	1000 mL bag	 New!

DENTAL RANGE

PRODUCT	SIZE	
VETRADENT® Water Additive sodium citrate, citric acid, zinc chloride	17 oz bottle	
VETRADENT® Dental Spray sodium citrate, citric acid, zinc chloride	2 oz bottle	
VETRADENT® Dental Wipes sodium citrate, citric acid, zinc chloride	60 count jar	
VETRADENT® Beef Rawhide Dental Chews For Dogs sodium citrate, citric acid, zinc chloride	Approximately 30 chews per bag Medium — For Dogs 11-25 lbs Large — For Dogs 26-65 lbs	
VETRADENT® Toothpaste sodium citrate, citric acid, zinc chloride	2.3 oz tube (toothbrush included!)	
VETRADENT® Powder Water Additive sodium citrate, citric acid, zinc citrate	10.6 oz tub	
DentAcetic® Dental Gel 1% acetic acid, sodium hexametaphosphate	2 oz bottle	
DentAcetic® Dental Wipes 1% acetic acid, sodium hexametaphosphate	25 ct jar	
DenTees® Chews acetic acid, sodium hexametaphosphate	12 oz bag	
DenTees® Stars acetic acid, sodium hexametaphosphate	4 oz bag	

PAIN MANAGEMENT

PRODUCT	SIZE	
Carprovet® (carprofen) Caplets	25 mg caplet, 60 and 180 ct 75 mg caplet, 60 and 180 ct 100 mg caplet, 60 and 180 ct	
Carprovet® (carprofen) Chewable Tablets	25 mg tablet, 30, 60 and 180 ct 75 mg tablet, 30, 60 and 180 ct 100 mg tablet, 30, 60 and 180 ct	
Carprovet® (carprofen) Flavored Tablets	25 mg tablet, 60 and 180 ct 75 mg tablet, 60 and 180 ct 100 mg tablet, 60 and 180 ct	
CARPROFEN Sterile Injectable Solution	50 mg/mL, 20 mL vial	
MELOXICAM Solution for Injection	5 mg/mL, 10 mL vial	
Rederox® (deracoxib) Chewable Tablets	12mg tablet, 30 and 90 ct 25mg tablet, 30 and 90 ct 75mg tablet, 30 and 90 ct 100mg tablet, 30 and 90 ct	New! 

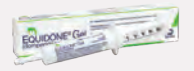
JOINT SUPPORT

PRODUCT	SIZE	
Phycox® HA MAX Joint Supplement Soft Chews Phycox® HA MAX Joint Supplement chews contain the same hydrolyzed vegetable protein as Phycox® HA Joint Supplement and in addition, 3x more phycocyanin and six additional antioxidants for maximum joint support.	90 ct	
Phycox® MAX Joint Supplement Soft Chews Phycox® Max Joint Supplement chews contain 3x more phycocyanin than the original formula and six additional antioxidants. It is recommended for sporting and working dogs and dogs of all ages who require maximum joint support.	90 ct	
Phycox® MAX Joint Supplement Small Bites Developed for dogs under 30 pounds who require advanced joint support. It contains 3x more phycocyanin than the original formula and six additional antioxidants.	120 ct	
Phycox® HA Joint Supplement Soft Chews Developed for dogs with food sensitivities or intolerances. Phycox® HA Joint Supplement chews use hydrolyzed vegetable protein derived from soybeans and do not contain beef, chicken, or wheat.	120 ct	
Phycox® HA Joint Supplement Small Bites Developed for dogs with food sensitivities or intolerances under 30 pounds or for dogs who prefer a smaller chew.	120 ct	
Phycox® Joint Supplement Soft Chews The original formula is recommended for active dogs and dogs of all ages who require a moderate level of joint support.	60 ct 120 ct	
Phycox® Joint Supplement Small Bites Developed for dogs under 30 pounds who require moderate joint support or for dogs who prefer a smaller chew.	120 ct	
Phycox® Joint Supplement Granules Developed for dogs requiring moderate joint support who may not be able to chew Phycox® Joint Supplement Soft Chews.	480 gm 960 gm	

EQUINE JOINT SUPPORT

PRODUCT	SIZE	
Phycox® MAX EQ Joint Supplement Granules A complete joint supplement containing 3x more phycocyanin than the original formula and six additional antioxidants. It provides maximum joint support for highly active performance or mature horses.	2.7 kg	
Phycox® EQ Joint Supplement Granules A complete joint supplement for moderately active or aging horses who require daily joint support.	2.88 kg	

EQUINE PRODUCTS

PRODUCT	SIZE		
OSPHOS® (clodronate injection)	60 mg/mL 15 mL vial		
Zimeta® (dipyrone injection)	500 mg/mL 100 mL vial		
EQUIDONE® Gel (domperidone)	25 mL single syringe		
Osteokine® Easy PRP Preparation Device autologous platelet-rich plasma (PRP)	1 PRP kit = 6 mL of Citrate Sodium (anticoagulant) and syringes/ needles for processing		
Orthokine® vet irap 10 Autologous Conditioned Serum (ACS) Device	1 kit = three 10 mL syringes + supplies		
Orthokine® vet irap 60 Autologous Conditioned Serum (ACS) Device	1 kit = one 60 mL syringe		
ProVet® APC Autologous Platelet Concentrate (APC) Kit	1 60 mL kit		New!
ProVet® Autologous Platelet Concentrate (APC) Centrifuge	1 device		New!
Butorphanol Tartrate Injection	10 mg/mL 50 mL vial		New!
Rompun® (xylazine injection)	100 mg/mL 50 mL vial		New!
SucroMate® Equine (deslorelin acetate)	1.8 mg/mL 10 mL vial		New!