Dechra

Veterinary Products

COMPANION CATALOGUE

YOUR COMPLETE VETERINARY SUPPLY AND SUPPORT SOLUTION

EUROVETS

VETERINARY SUPPLIERS

ABOUT EUROVETS

EUROVETS IS YOUR COMPLETE VETERINARY SUPPLY & SUPPORT SOLUTION

Eurovets, established in 2001 has become the Middle East's foremost supplier of some of the world's best known veterinary products to veterinary clinics throughout the UAE.

We represent leading multi-national brands in nutrition, veterinary equipment, medicines and consumables for companion, -equine and production animals. In addition to the traditional wholesaling, Eurovets provides warehousing, distribution, marketing and sales resources in order to support the product in the region.

We also offer a host of value-added services such as maintenance and support for all equipment supplied; service-based offerings such as Spectrum allergy testing; even end-to-end IT solutions for clinics.

Eurovets supports Continued Professional Development, imparting knowledge of the latest developments in the field to veterinary professionals through high-powered seminars.

We pride ourselves on our professional approach and offer vet specialized product advice where required.

In conclusion our mission is to not only deliver excellent products but to be committed to deliver exceptional customer service to all veterinary clinics and pet retailers in the region.

Eurovets YOUR headquarters for veterinary supply and support and a proud distributor of the Dechra brand.

ABOUT DECHRA VETERINARY PRODUCTS

A business unit of Dechra Pharmaceuticals PLC, Dechra Veterinary Products specialises in the sales, marketing and technical support of Dechra's branded veterinary products to the veterinary profession in Europe.

Dechra's key areas of expertise span endocrinology, dermatology, cardiology, water soluble powder products and injectable antibiotics, anaesthetics and analgesics, equine medicine and diet and nutrition. Major products cover the treatment of canine hyperadrenocorticism (Cushing's syndrome), feline hyperthyroidism, canine congestive heart disease and hypothyroidism, an anti-inflammatory and analgesic for equine musculoskeletal disorders and a premium diet range that provides precise nutritional solutions throughout the lives of cats and dogs.

Dechra is committed to licensing new products and developing services that support the work of veterinary professionals and enhance the lives of their patients.

INDEX

VETORYL

For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.
Active(s): Trilostane

- Species: Dogs
- Client: Vet / Clinic

Eurovets Code	Description	Unit size
E005360	Vetoryl Capsules 10mg	30 Caps
E005356	Vetoryl Capsules 30mg	30 Caps
E005357	Vetoryl Capsules 60mg	30 Caps

FELIMAZOLE

For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.
For the long-term treatment of feline hyperthyroidism.
Active(s): Thiamazole (methimazole)

- Species: Cats
- Client: Vet / Clinic

Eurovets Code	Description	Unit size
E005358	Felimazole 2.5mg	100 Tabs
E005359	Felimazole 5mg	100 Tabs

CARDISURE

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid regurgitation) or dilated cardiomyopathy.

Active(s): Pimobendan

- Species: Dogs
- Client: Vet / Clinic

Eurovets Code	Description	Unit size
E005439	Cardisure 1.25mg	100 Tabs
E005353	Cardisure 5mg	100 Tabs

URILIN

For the treatment of urinary incontinence associated with acquired urethral sphincter incompetence in the bitch only.

- Species: Dogs
- Client: Vet / Clinic

Eurovets Code	Description	Unit size
E005444	Urilin Syrup	100ml

CANAURAL

For the treatment of otitis externa including the ear mite, Otodectes cynotis, in the dog and cat.

Active(s): Fusidic acid, framycetin sulphate, nystatin, prednisolone

- Species: Dogs / Cats
- Client: Vet / Clinic

Eurovets Code	Canaural Description	Unit size
E005361	Compositum Ear Drops	15ml
E005362	Compositum Ear Drops	25ml

DERMABENSS SHAMPOO

It is a soap-free formulation to treat full range of Seborrheic skin conditions. DermaBenss™ shampoo effectively flushes out the infectious microbes in hair follicles and contains Ceramides to moisturize, repair and restore skin. Added benefits of Antimicrobial, Keratolytic and Keratoplastic properties.

Active Ingredients: 2.5 % Benzoyl peroxide, 1 % Sulphur, 1 % Salicylic acid, Antioxidants, Vitamine E, Ceramides.

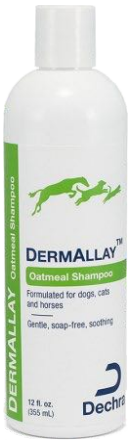
- Species: Cats, Dogs, Horses
- Client: Vet / Clinic

Eurovets Code	Size
E000302	12oz

DERMALLAY OATMEAL SHAMPOO

For itchy, dry and/or sensitive skin. Reduces pruritus & inflammation. Contains Solubilized oatmeal, Safflower oil (essential fatty acids). Also contains Ceramides to repair and restore skin and with gentle conditioning and moisturizing properties.

Active Ingredients: Contains Solubilized oatmeal, Safflower oil and Ceramides.



- Species: Cats, Dogs, Horses
- Client: All

Eurovets Code	Size
E000301	12oz

DERMALYTE SHAMPOO

Hypo-allergenic, no soaps, no dyes and pH balanced. Recommended for allergic animals. Cleans, moisturizes, and nourishes normal, sensitive or dry skin. Contains Ceramides and Essential fatty acids to repair and restore skin.

Active Ingredients: Natural Coconut oil, Safflower oil (Linoleic acid, Sodium Lactate, Glycerin, purified water, Ceramides).

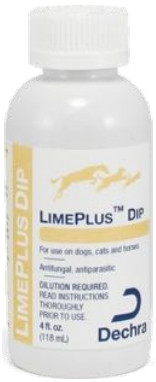
- Species: Cats, Dogs, Horses
- Client: All

Eurovets Code	Size
E000303	12oz

LIMEPLUS DIP

An effective generalized topical treatment for dermatophytosis (fungal infections), and especially surface demodicosis *(Demodex gatoi)* in cats. May be used as an adjunctive treatment of *Malassezia* dermatitis, cheyletiellosis, chiggers, notoedric mange, fur mites, lice, canine demodicosis, and sarcoptic mange. It must be diluted prior to application.

Active Ingredient: 97.8 % Sulfurated lime solution.



- Species: Cats, Dogs, Horses
- Client: All

Eurovets Code	Size
E000299	4oz
E000304	16oz

MALACETIC SHAMPOO

Antimicrobial, degreasing, conditioning and deodorizing. First ever vinegar shampoo. All the functions of the ear/skin cleanser in a shampoo base.

Active Ingredients: 2 % Acetic Acid, 2 % Boric Acid.

- Species: Cats, Dogs, Horses
- Client: All

Eurovets Code	Size
E000293	12oz
E000294	16oz

TRIZCHLOR FLUSH

Effective for wound irrigation and cleansing to inhibit bacterial infection. Useful in the treatment of mixed and resistant bacterial infections. Otic skin cleanser. Provides enhanced antimicrobial effects when used on the skin, respiratory and urogenital systems.

Active Ingredients: 0.15 % Chlorhexidine Gluconate in USP tris-EDTA.

- Species: Cats, Dogs
- Client: All

Eurovets Code	Size
E000297	4oz

MALACETIC OTIC CLEANSER

For routine ear and wound cleansing. Cleans moist, waxy, odoriferous ears. Multi-cleanse, hypo-allergenic, pH balanced, antimicrobial, acidifying, drying solution with surfactants. Apple fragrance.

Active Ingredients: 2 % Acetic Acid, 2 % Boric Acid with surfactants.

- Species: Cats, Dogs, Horses
- Client: All

Eurovets Code	Size
E000296	4oz
E000292	8oz
E000295	16oz

TRIZEDTA AQUEAOUS FLUSH

An antimicrobial, multi-cleanse patented solution for use in dogs and cats. Used for cleansing, alkalinizing (pH 8) and as a treatment/pre-treatment solution. It has antibiotic potentiating activity and disrupts the bacterial cell wall by chelating metal ions making the cell wall more porous. Aids in breakdown of inflammatory discharge in ears. TrizEDTA buffer solutions are valuable as a long-term therapy for preventing the recurrence of Pseudomonas infection. Such solutions are typically applied two to three times per week as needed.

Active Ingredients: Tromethamine (tris) USP, edetate disodium dihydrate (EDTA) USP.

- Species: Cats, Dogs
- Client: All

Eurovets Code	Size
E000298	4oz

NOTES

NOTES

ALL THE BEST BRANDS

Eurovets is dedicated to providing your clinic with all your veterinary needs. We offer a comprehensive product range at highly competitive prices for small and large animal practices, stables and wholesale outlets. This include biological, diagnostics, nutritionals, medicines, equipment, consumables and more.

Contact us today

Eurovets Veterinary Suppliers

Tel: +971 4 434 2436 **OR** Technical Support Team contact: +971 56 880 9212

E-mail: orders@eurovetsworld.com

Address: Warehouse A6, Dubai Science Park, Dubailand, Al Barsha South, Dubai, United Arab Emirates

EUROVETS VETERINARY SUPPLIERS

F10 PRODUCTS · iM3 The Veterinary Dental Company · Henry Schein Animal Health · IDEXX Laboratories · Dechra Veterinary Products · Harrison's Bird Foods · Mazuri Zoo Foods · Qalian

Destron Fearing™ · Kyron · Saracen Horse Feeds · Cipla Vet Animal Health · Spectrum · Rita Leibinger Medical · AAS Advanced Animal Specialties Darvall · Vi Do more. Treat better.

VSSI Inc. · Midmark · Foschi · LW Scientific

www.eurovetsworld.com

Dechra

Veterinary Products

EQUINE CATALOGUE

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VETERINARY SUPPLIERS

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INDEX

THE FIRST CHOICE PHENYLBUTAZONE FOR OVER 30 YEARS

EQUIPALAZONE® POWDER, PASTE AND INJECTION

No other phenylbutazone is available in powder, paste and injection. Another reason why Equipalazone® has sold over 100 million sachets. Only EQUIPALAZONE offers three choices. EQUIPALAZONE Injection for rapid pain relief and EQUIPALAZONE Powder and Paste – two convenient oral presentations for longer-term administration. And because of this choice, EQUIPALAZONE provides a comprehensive equine pain management programme. No.1 in equine pain management

- Species: Horses
- Client: Vet / Clinic
- Category: Pharmaceutical > Anti-inflammatory

Eurovets Code	Description	Size
E005364	Oral Paste	36g
E005365	Oral Powder Sachets	1g - 100 p/box
E006603	Injection 200mg/ml	50ml

Effective pain management

EQUIPALAZONE®

Immediate and long-term anti-inflammatory and analgesic relief for musculo-skeletal disorders including:

Laminitis
- acute and chronic

Carpitis

Bursitis

Osteoarthritis

Post-surgical soft tissue inflammation

Comprehensive management of inflammation, pain and lameness

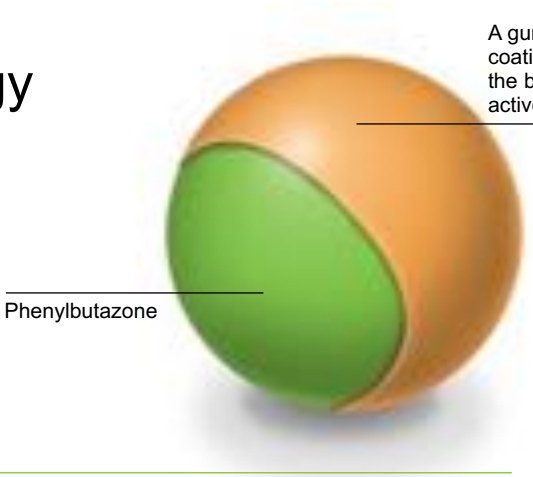
INJECTION	POWDER	PASTE
Phenylbutazone PhEur 200 mg / ml for parenteral administration.	1 g phenylbutazone PhEur per sachet for oral administration. 100 sachet packs 32 sachet packs	1 g phenylbutazone PhEur per unit dose for oral administration.
Equipalazone Injection should be administered by slow intravenous injection as a single dose, which may be followed, if necessary, by oral phenylbutazone therapy commencing 24 hours after the injection. In acute cases and in hospitalised patients, Equipalazone Injection may be administered once daily for not more than five consecutive days.	For ease of administration Equipalazone Powder may be mixed with a small quantity of hand feed.	Equipalazone Paste for situations that require direct administration.
VETERINARY TREATMENT	OWNER MANAGEMENT	

Treatment and care partnership

EQUIPALAZONE POWDER®

Unique patented MICROCAPS® technology

Providing excellent palatability and maximum intake



		Equipalazone Powder	Phenylbutazone PhEur (no microencapsulation)	Suxibuzone PhEur
	NSAIDs appear to inhibit both COX 1 and COX 2[1]			
	Palatability	Good due to microencapsulation	Blended with a palatable base	Good due to microencapsulation
	Other presentations		?	?
	Contra-indication in possible GI ulceration			
Weight per sachet	Weight of product base / Weight of active ingredient	0.5 g / 1 g	4 g / 1 g	8.5 g / 1.5 g*
	Total weight of sachet	1.5 g	5 g	10 g
Size of carton		75mm, 180mm, 85mm	155mm, 175mm, 105mm	85mm, 360mm, 105mm
Dispensing	Sachets available	25 strips of 4	100 single sachets	60 single sachets
	Plastic dispensing bags available		?	

*Metabolises to 1 g phenylbutazone

[1]Veterinary Pharmacology and Therapeutics (2001). Ed. H. Richard Adams, 436.

EQUIPALAZONE®

Proven and trusted
Phenylbutazone used in horses and ponies for over 50 years
Licensed for veterinary use since 1972
Very few reported adverse effects

Palatability
Over 10 million sachets consumed per year

Highly effective
Used for over 30 years

Owner compliance
Over 10 million sachets consumed per year

Complete range
Injection, powder and paste

This is why EQUIPALAZONE® continues to be the first choice for ‘Bute’.

Equipalazone contains phenylbutazone PhEur.
More information and datasheet available on request.
Legal category POM.

OSPHOS®

A stride forward

Easily administered

Well tolerated[1]

Proven efficacy[1]

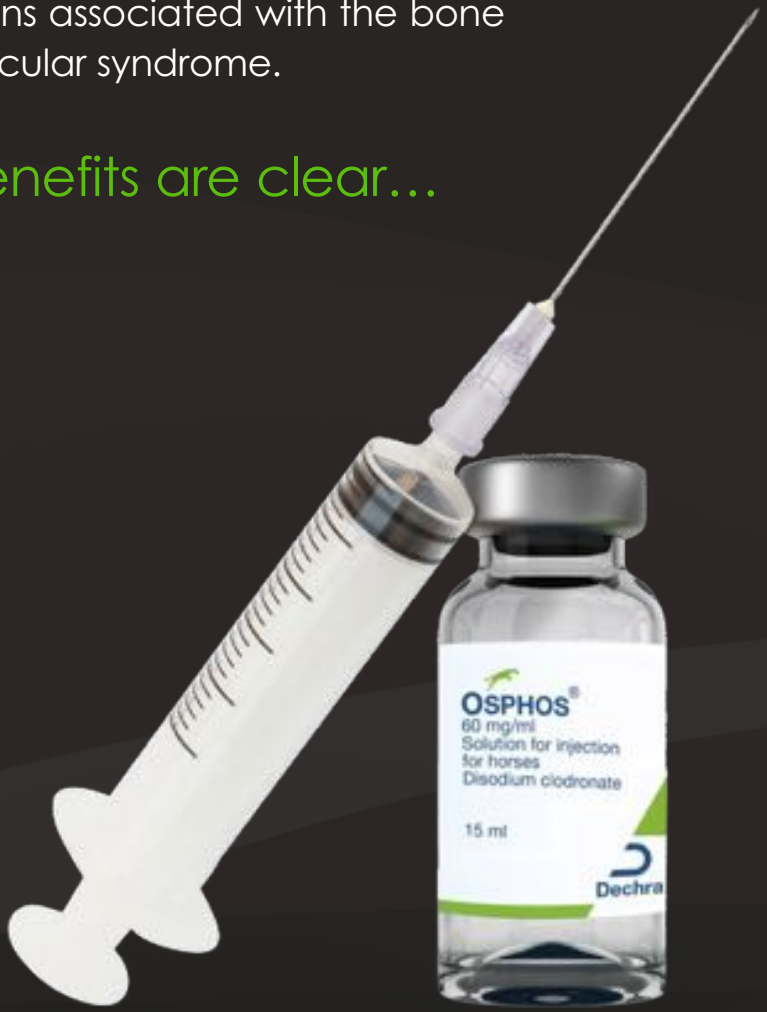
- Species: Horses
- Client: Vet / Clinic
- Category: Pharmaceutical > Bisphosphonate

Eurovets Code	Description	Size
E005900	Osphos	15ml

Introducing Osphos, the **new intramuscular injection** from the innovators in equine health

Osphos 60 mg/ml Disodium clodronate as 51 mg/ml clodronic acid solution is administered by simple intramuscular injection. It is the only UK licensed product for the control of clinical signs associated with the bone resorptive processes of navicular syndrome.

With Osphos the benefits are clear...

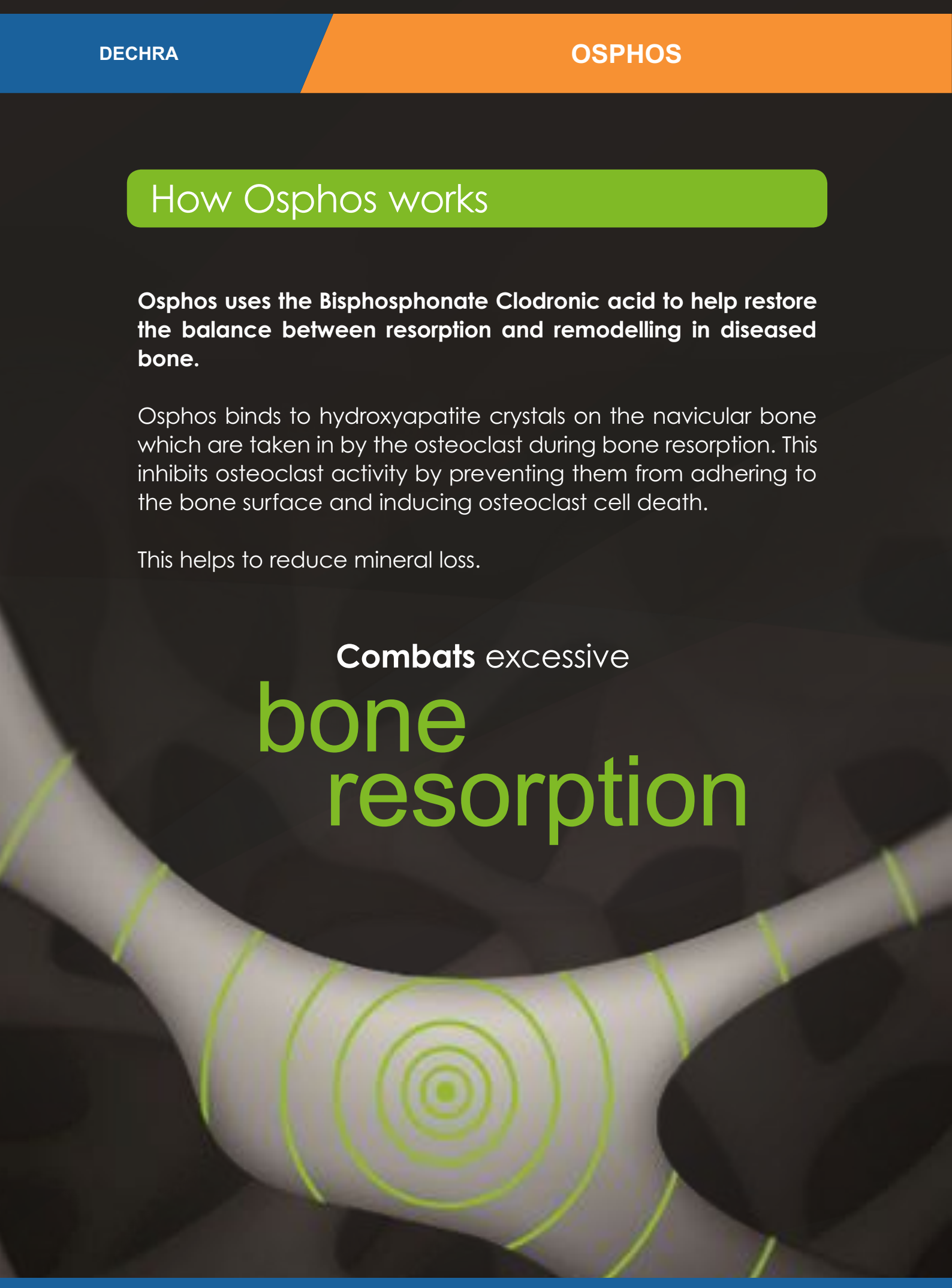


How Osphos works

Osphos uses the Bisphosphonate Clodronic acid to help restore the balance between resorption and remodelling in diseased bone.

Osphos binds to hydroxyapatite crystals on the navicular bone which are taken in by the osteoclast during bone resorption. This inhibits osteoclast activity by preventing them from adhering to the bone surface and inducing osteoclast cell death.

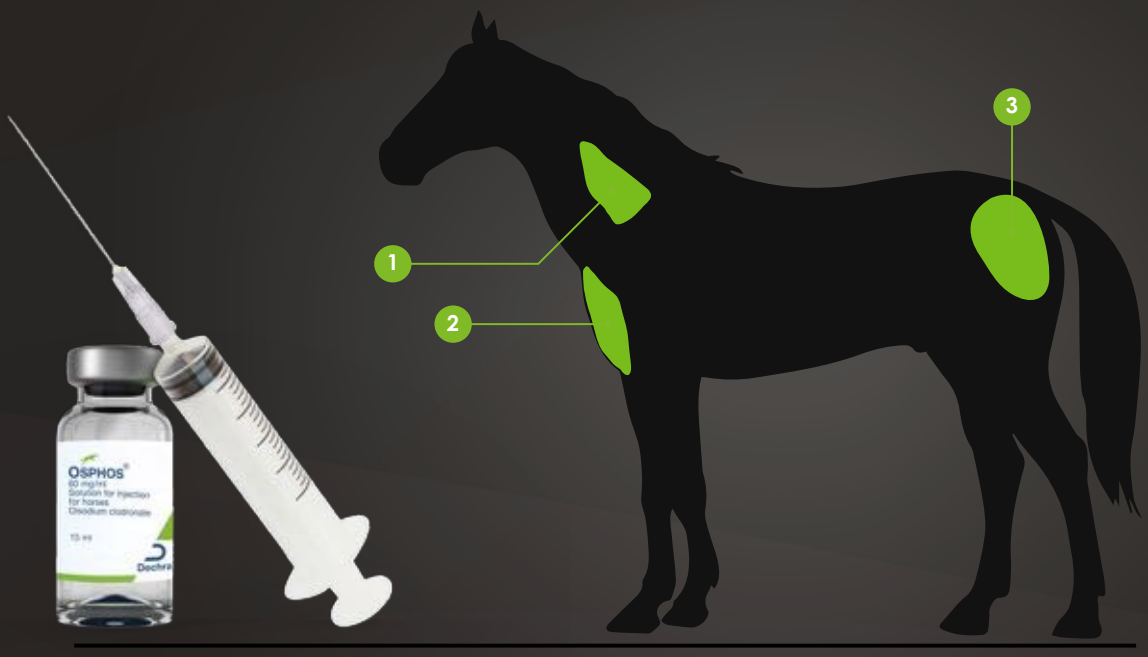
This helps to reduce mineral loss.



Simple administration

Osphos solution for injection is presented in a 15 ml vial sufficient to treat one horse.

It is administered via **intramuscular injection** and should be evenly spread over 2 to 3 injection sites.



Suitable sites for injection:

1. CENTRE OF THE LOWER NECK
2. PECTORAL MUSCLES
3. GLUTEAL MUSCLES

Recommended dosage

3 ml per 100 kg of bodyweight

Solution for injection

Disodium Clodronate 60 mg/ml as Clodronic acid 51 mg/ml

Intramuscular injection provides a quick and easy route of administration, and a full dose can be administered in minutes.

Clinical improvement
visible at

day28[1]

Lameness
improved in

74.7%

of horses by at least
one grade

Only

1.6%

of treatments resulted in
signs of mild, transient colic

Efficacy

- Clinical improvement in lameness visible at 28 days after treatment with Osphos[1].

- Lameness in **74.7%** of horses improved by at least one grade at 56 days after treatment.

- Horses with navicular syndrome positively respond to treatment with Osphos.

Well tolerated

Side effects recorded in horses treated with Osphos have all been **mild and transient.**

Only 1.6% of treatments resulted in signs of colic.

Only 0.8% of injection sites showed any reaction which resolved without medical intervention within 2-3 days.

[1] Internal report Osphos 01 (2014)

Repeat treatments

Osphos has proven efficacy at 6 months post-treatment in 65.8% of cases.

Treatment with Osphos may be repeated from 3 months onwards depending on results and level of work that the horse is in.

Complementary care

A holistic approach is beneficial when treating lameness; husbandry, management, shoeing and exercise should all be considered for the best results.

Remedial farriery

Trimming and shoeing can greatly aid in correcting and maintaining foot balance; this is particularly important when dealing with navicular syndrome.

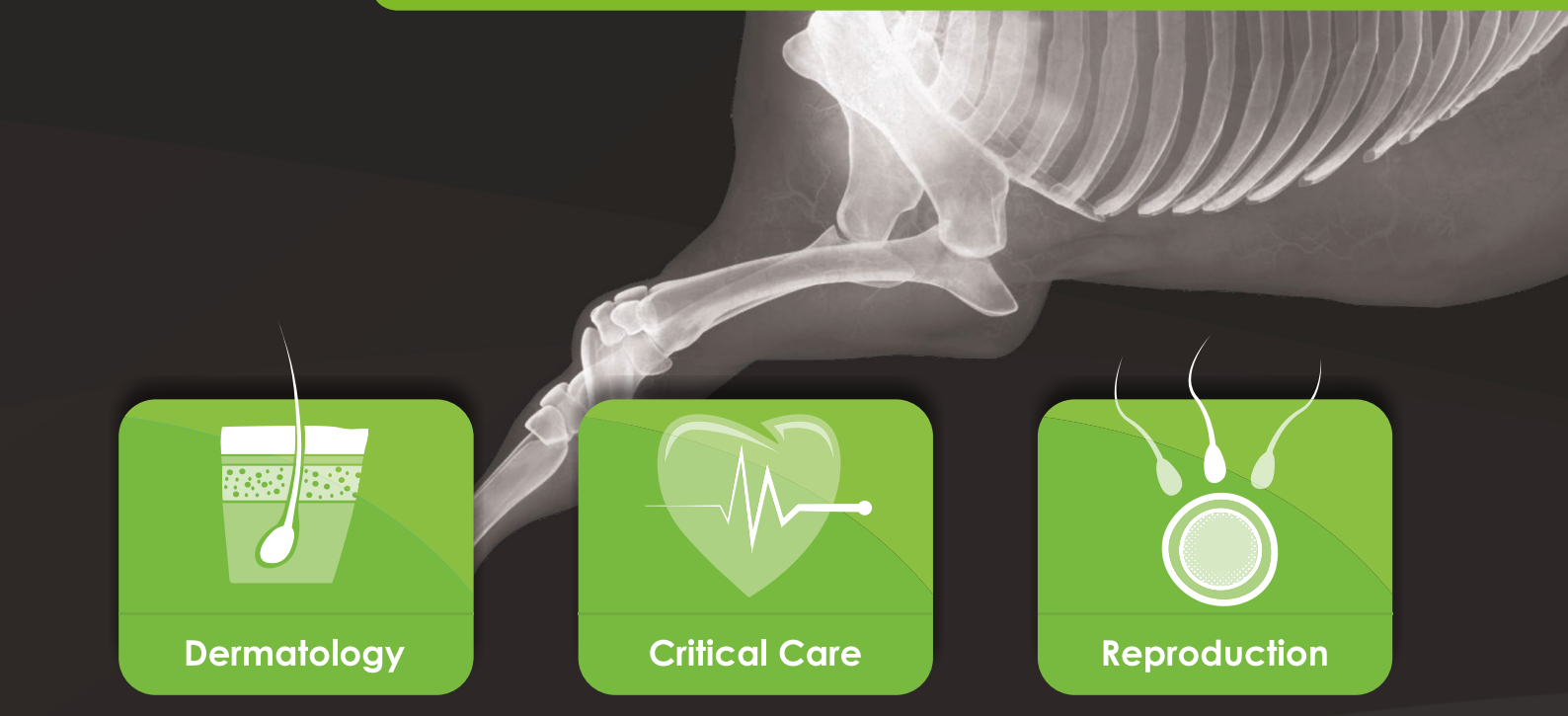
Exercise

Controlled exercise has been proven to be beneficial.

Interim analgesia

It may be advisable to prescribe non-steroidal anti-inflammatory drugs in order to relieve pain associated with the condition. Concurrent administration of Phenylbutazone has been shown to be well tolerated.

Understanding equine health **inside out**



- Dermatology
- Critical Care
- Reproduction
- Locomotion
- Pain Management
- Anaesthesia

HY-50® Vet

No more lame excuses
HY-50 Vet is the sound choice

High dose Sodium Hyaluronate in a small volume

- Species: Horses
- Client: Vet / Clinic
- Category: Pharmaceutical > Sodium Hyaluronate

Eurovets Code	Description	Size
E005363	HY-50 Injection	3ml

HY-50® Vet 17 mg/ml solution for injection

Name of the Veterinary Medicinal product

HY-50 Vet
17 mg/ml solution for injection Sodium Hyaluronate

Statement of the active substance and other ingredients

HY-50 Vet is a sterile, colourless, clear solution containing

Active substance

Sodium Hyaluronate.....17 mg/ml

Excipients

Sodium Chloride.....7.57 mg/ml

Disodium Phosphate Heptahydrate.....3.78 mg/ml

Sodium Dihydrogen Phosphate Monohydrate
..... 0.45 mg/ml

Water for injection.....qs to 1 ml

Indication

For intra-articular and intravenous treatment of lameness caused by joint dysfunction associated with non-infectious synovitis.

Contraindications

Do not use in cases of joint infection.

Adverse reactions

Transient mild swelling and/or heat has been exported in treated joints (2.7%). These self-limiting local signs resolve spontaneously within,48 hours, and do not negate a successful therapeutic outcome.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species

Horse

Dosage for each species, route and method of administration

Intravenous use: 3 ml intravenously repeated at weekly intervals for a total of three treatments.

For single intra-articular injection: 3 ml (51 mg) intra-articularly into medium sized and large joints. Smaller joints such as intertarsal, tarsometatarsal and interphalangeal joints can be treated with a 1.5 ml (25.5 mg) dose.

More than one joint may be treated at the same time.

Advice on correct administration

Excess synovial fluid should be removed whenever possible prior to injection.

Remove product from refrigerator approximately 10 minutes before performing injection. The injection should be administered under strict aseptic conditions. Ensure removal of dirt, hair, topical medicaments and soap/antiseptic residues. Intra-articular injections should not be made though overlying skin that is infected, blistered, scurfed or otherwise compromised. A sterile dressing and clean bandage should be applied after injection, as appropriate for the particular joint treated.

Withdrawal period

Meat and offal - zero days

Special Storage Precautions

Keep out of reach and sight of children.
Store in a refrigerator (2°C-8°C).
Do not freeze
Do not use after the expiry date stated on the label and carton.
Single dose syringes made ready for injection shall be used immediately. Any unused portion of a syringe is to be discarded.

Special Warnings

Radiographic evaluation should be carried out in cases of acute, severe lameness to ensure that the joints are free from serious fractures.

Interaction with other medicinal products and other forms of interaction.

No data available.
Do not mix with any other product.

Use during pregnancy and lactation

Safety in pregnant and lactating mares has not been documented. Use only according to the benefit/risk assessment by the responsible veterinarian.

Special precautions for the disposal of unused product or waste materials, if any

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Other information

For any information abut this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Dechra Veterinary Products Limited is a trading business of Dechra Pharmaceuticals PLC.

Legal category

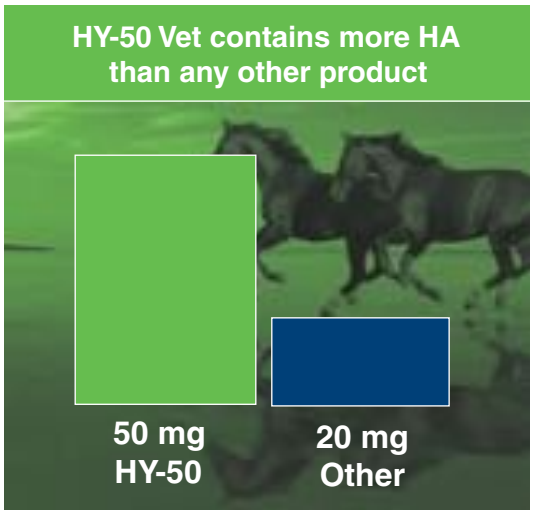
POM-V

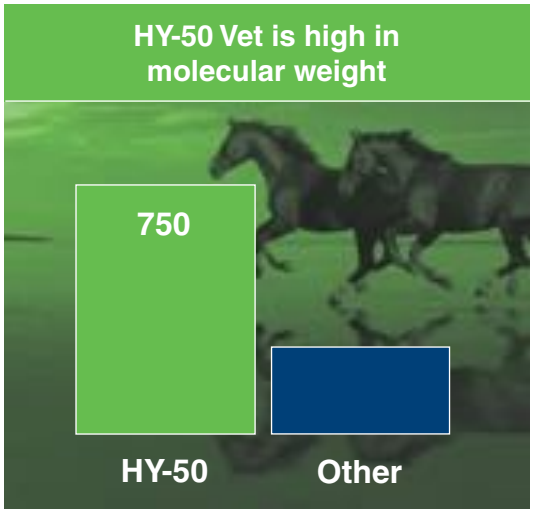
To be supplied only on veterinary prescription.

use medicines responsibly: www.noah.co.uk/responsible

HY-50 Vet Sodium Hyaluronate

for Intra-Articular or Intravenous injection





HY-50 Vet is manufactured by fermentation for a very high purity and is free of pyrogens.

What is Hyaluronic Acid?

- A naturally occurring biopolymer found in all animal connective tissue
- A major component of synovial fluid
- An essential constituent of articular cartilage

Effects of Intra-Articular injection of HA

- Physical and pharmacological activity
- Enhances viscoelasticity of synovial fluid
- Activates the tissue repair process in joint cartilage
- Anti-inflammatory
- Analgesic
- Anti-oxidant

With some of the world's finest competition horses in the UK, it is important that veterinary surgeons have HY-50 Vet available to them. HY-50Vet's high molecular weight, coupled with its unique fermentation and purification processes make it the sodium hyaluronate of choice.

Delivering the highest dose of sodium hyaluronate per ml of all the products currently on the market, HY-50 Vet's manufacturing method produces a highly effective and easy to use injection, free from animal proteins and therefore presenting minimal opportunity for adverse local reaction.

Indicated for the alleviation of joint inflammation and enhancement of joint function, HY-50 Vet is presented in a pre-loaded syringe, delivering 50 mg of sodium hyaluronate per 3 ml; another competitor product gives just 20 mg.

HY-50 Vet is licensed for intra-articular and intravenous use

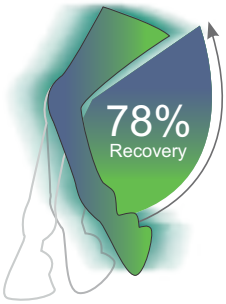
When intra-articular medication is deemed inappropriate or where there is more than one affected joint. HY-50 Vet may be used intravenously. The dose regime is 1 syringe of HY-50 Vet given 3 times at weekly intervals

A study carried out at Oklahoma State University was exported at BEVA Congress 2001.

Efficacy of Intravenously Administered HY-50 Vet in Experimentally Induced Lameness Model

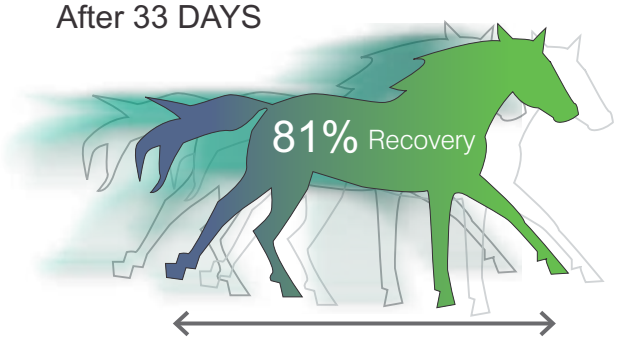
Carpal Flexion

After 33 DAYS



Stride Length

After 33 DAYS

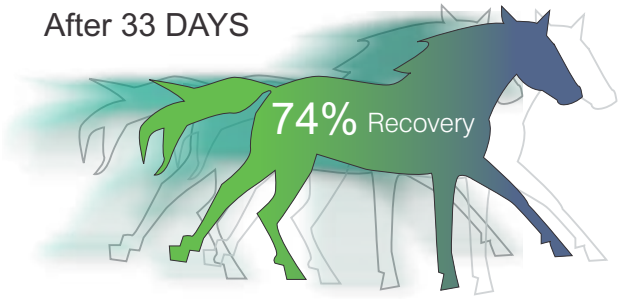


Joint Circumference

After 33 DAYS

Lameness Score

After 33 DAYS



Proceedings BEVA Congress 2001 – Page 203

Comparison of the Intravenous efficacy of two commercial preparations of sodium hyaluronate in the CFA Equine Carpitis model

White G.W., Jordan S.M., Stites D., Jones E.W., Hamm J. and Aviad A. Oklahoma USA

The efficacy of the intravenous route of 2 commercial preparations of sodium hyaluronate was compared in an investigator-blinded study using an equine carpitis model induced by the intra-articular injection of complete Freund's aduvant (CFA). This model has been used successfully to establish the efficacy and optimal dose of many of the drugs currently used to treat equine synovitis and DJD. Twenty-four sound, healthy Quarter Horse type horses, age 2-10 years and weighing 400-500 kg, participated in the study. The model was induced in the left radiocarpal joint of each horse on Day 1. On Day 5, horses were stratified by degree of model-induced deficits in lameness score, stride length, carpal flexion and carpal joint circumference (the primary outcome measures or POM) and allocated randomly into 2 groups of 12 horses. Group 1 received 50mg i.v. of HY-50 (Bexco Pharma Inc) on Days 5, 12 and 19. Group 2 received 40 mg i.v. of competitor HA with an IV license on the same days. Percent recovery of the model-induced deficit was calculated for each subsequent day the POM were recorded (Days 12, 19, 26 and 33). Substantial improvement in 3 out of 4 POM was evident after the first dose, but maximum response did not occur until Days 26 or 33 for each POM. Day 33 percent recoveries were lameness score, 74 and 66%; carpal flexion, 78 and 65%; stride length, 81 and 87% for HY-50 and competitor HA with an IV license, respectively. Joint circumference recovered to only 16% (HY-50) and 19% (competitor HA with an IV license) of premodel values. There were no significant differences between the groups ($P>0.05$, repeated measures univariate analysis of variance) for any POM. It was concluded that when administered by the i.v. route, 40 mg of a competitor HA with an IV license and 50 mg HY-50 were equally effective in the CFA model of carpal synovitis.

Results of a comparative efficacy and safety study.

- Species: Horses / Cattle
- Client: Vet / Clinic
- Category: Pharmaceutical > Sedative – Sedation

Eurovets Code	Size
E005366	20ml

Introduction

Domidine® is an injectable solution for horses and cattle containing 10 mg/ml detomidine hydrochloride. It is available in 20 ml vials.

Domidine® can be administered intramuscularly and intravenously.

Detomidine belongs to the α_2-adrenoceptor agonists. The usefulness of the α_2- adrenoceptor agonist drugs has been recognised in equine and bovine practice for many years.

Indications

Domidine® is indicated for pre-medication prior to administration of injection or inhalation anaesthetics.

Furthermore, **Domidine®** is indicated for the sedation and slight analgesia of horses and cattle, to facilitate physical examinations and treatments, such as minor surgical interventions.

Domidine®, alone or in combination, can be used for:

- Examination (e.g. endoscopy, rectal and gynaecological examinations, X-rays).
- Minor surgical procedures (e.g. treatment of wounds, dental treatment, tendon treatment, excision of skin lumps, teat treatment).
- Before treatment and medication (e.g. stomach tube, horse shoeing).

A comparative efficacy and safety study

In a single dose, 2-way-crossover comparative study, two detomidine - containing formulations, administered intravenously, have been tested in healthy horses under good clinical practice (GCP) conditions.

Scores were given for both formulations, the original product (reference product) and **Domidine®**, the generic product (test product), for the following clinical parameters:

- Position of the head.
- Response to imposed stimuli:
  - Touching inside the ear.
  - Touching the front foot.
  - Clapping hands.

The averages of the individual scores are reflected per product and time and are expressed graphically per scored clinical parameter.

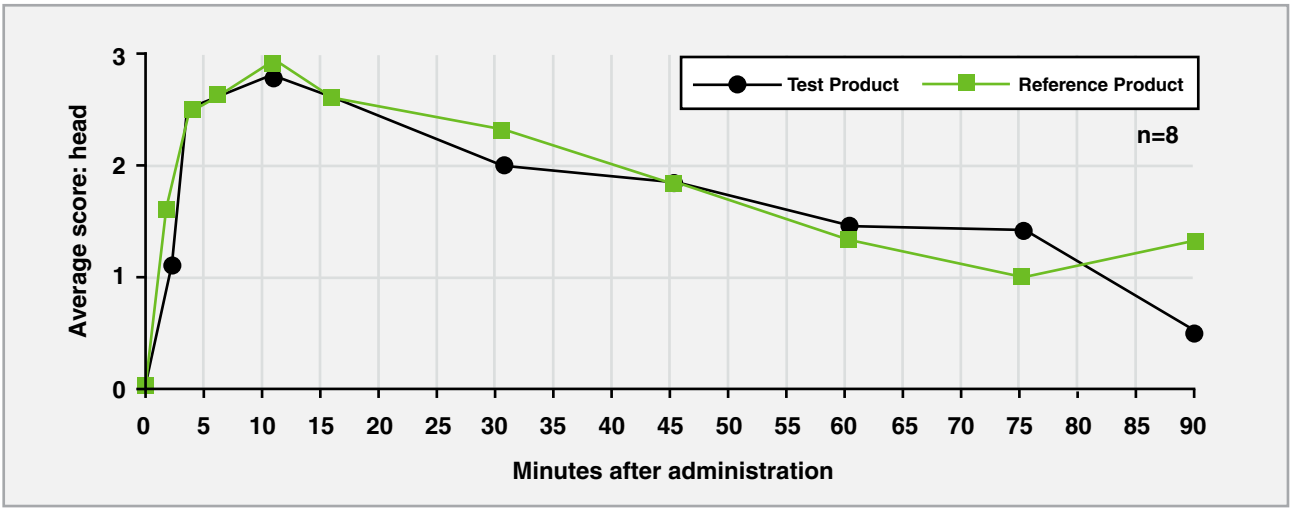
Two parameters related to safety were also observed and scored, namely:

- Ataxia.
- Heart rate.

Efficacy

Position of the head	
Score	**Observation**
0	Normal as before administration
1	Slightly lowered
2	Medium lowered
3	Deeply lowered

Position of the head



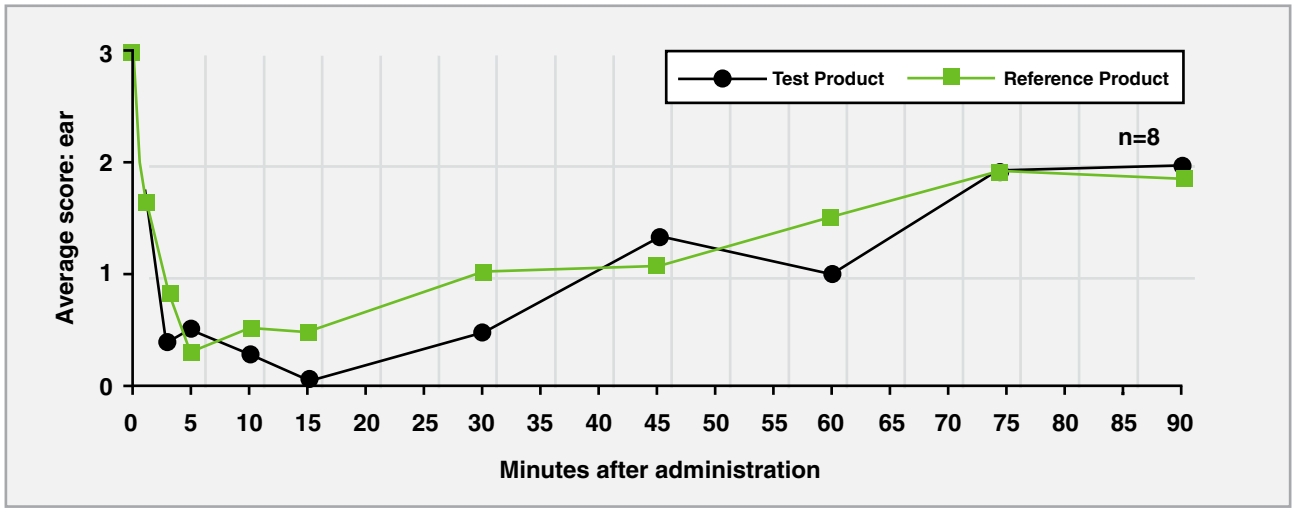
For both products, the maximum effect based on the position of the head was measured 10 minutes after administration. After 15 minutes, the effect started to decrease gradually.

The time-effect curves for both products appeared similar.

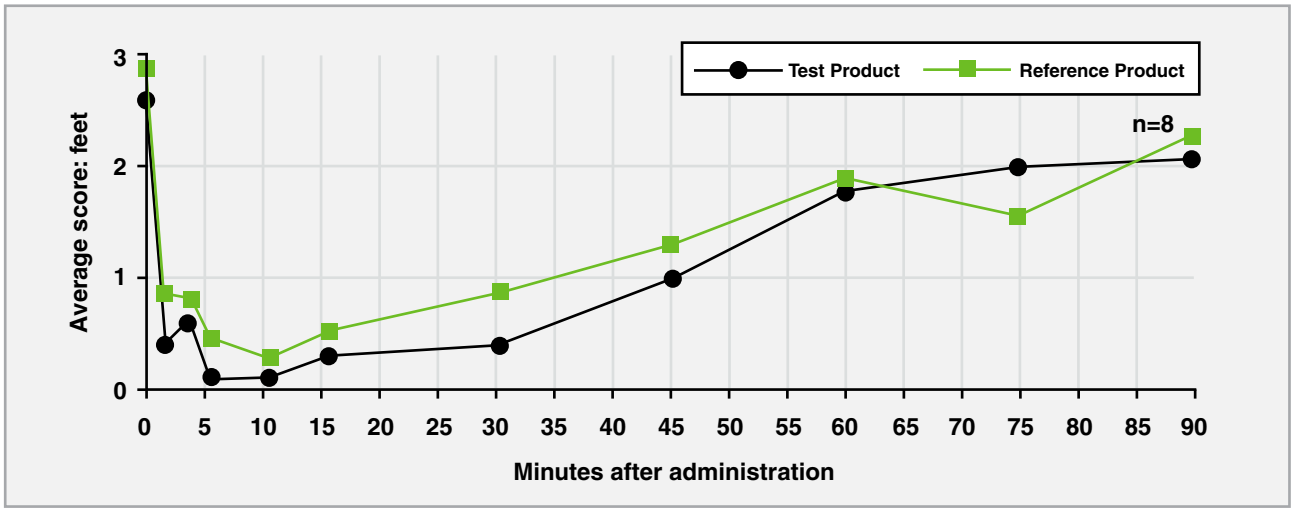
Efficacy (continued)

Response to stimuli	
Score	**Observation**
0	Response
1	Response slow and hesitant
2	Response of medium speed
3	Response marked and rapid

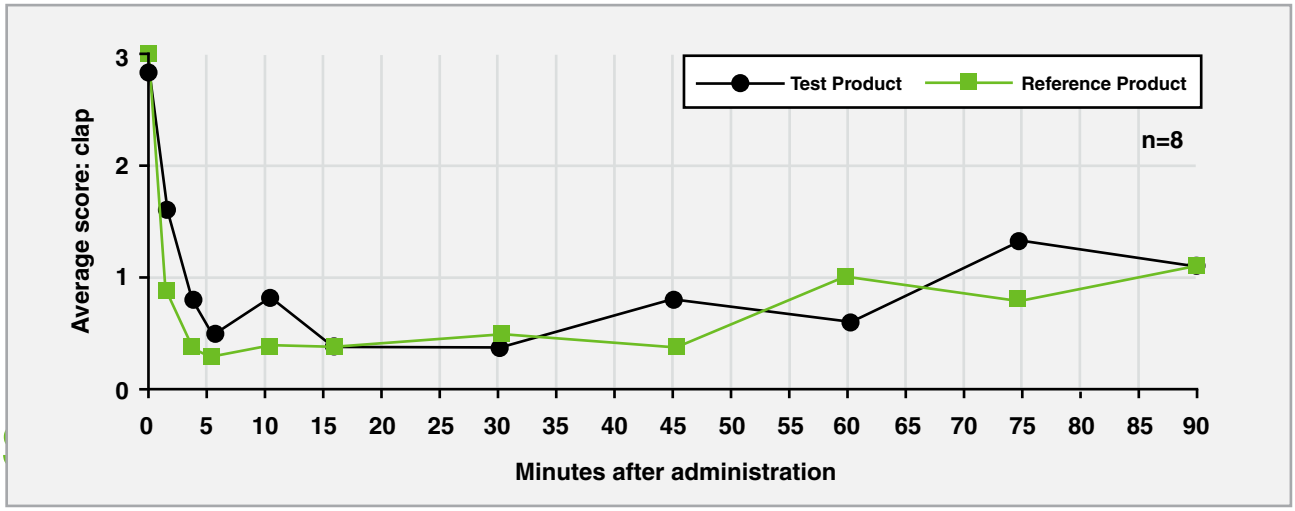
Response to touching inside the ear



Response to touching the front foot



Response to auditory stimulation (clapping hands)



Imposed stimuli

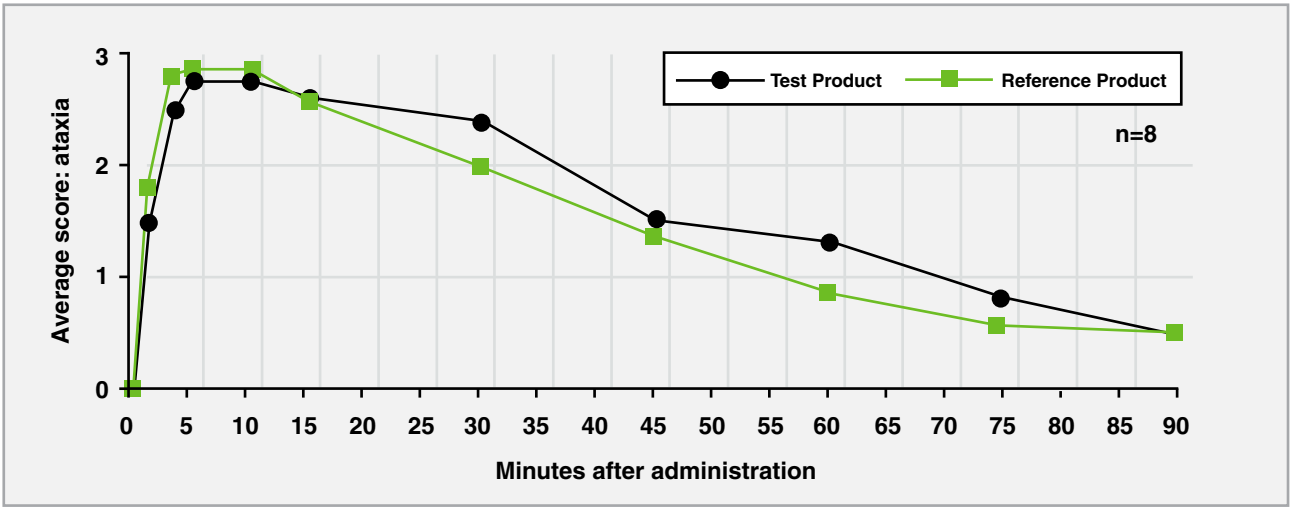
The maximum effect based on the imposed stimuli varied, but in all cases was observed within 5 to 15 minutes after injection. In all cases, a steep decrease was observed within 5 minutes after administration. Depending on the scored parameter, recovery started between 15 to 45 minutes.

All time-effect curves showed the same trend.

Safety

Degree of ataxia	
Score	**Observation**
0	No ataxia
1	Horse stable but swaying
2	Horse swaying and leaning against the wall
3	Horse leaning against the wall, swaying with its hind limbs and its forelimbs buckling at the carpal joints
4	Horse unstable to stand

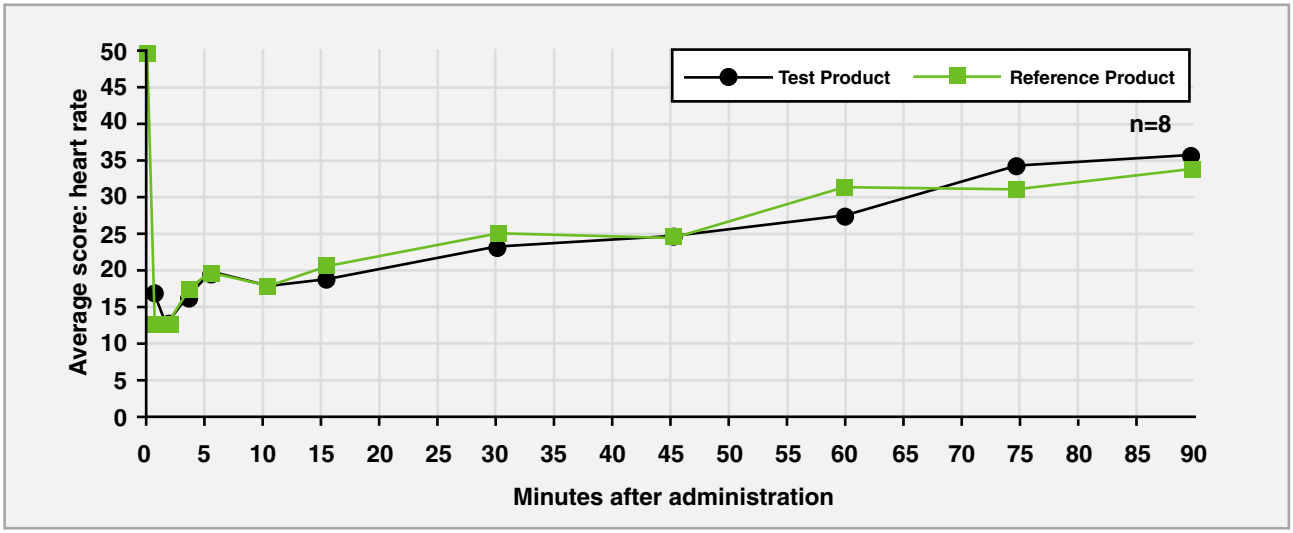
Degree of ataxia



Maximal ataxia was observed 5 minutes after administration. Gradual recovery started within 10 minutes.

The time-effect curves of both products appeared similar.

Heart rate



The heart rate decreased quickly after administration. The lowest average heart beat (13 beats per minute) was measured 1 minute after administration for both products. The lowest individual heart beat recorded was eight beats per minute.

The heart beat remained constant from 5 until 15 minutes after administration, for both products (approximately 20 beats per minute).

Gradual recovery to a (normal) heart rate of 35 and 34 beats per minute, 90 minutes after administration was recorded for the test and the reference product.

The time-effect curves of both products appeared similar.

Administration and combinations

Amounts to be administered and administration route

For intravenous (IV) or intramuscular (IM) administration **Domidine®** should be injected slowly. Onset of effect is more rapid following intravenous administration.

When prolonged sedation and analgesia is required, doses of 40 to 80 µg/kg can be used. The duration of effect is up to 3 hours.

When combining with other products to intensify the sedation or for pre-medication prior to general anaesthesia, doses of 10 to 30 µg/kg can be used.

It is recommended to wait 15 minutes after administration of **Domidine®** before starting the planned procedure.

The bodyweight of the animal to be treated should be determined as accurately as possible to avoid overdosing.

Domidine® in combination with other sedatives and anaesthetics should be used carefully because of possible additive / synergistic effects. Where anaesthesia is induced with a combination of **Domidine®** and ketamine, prior to maintenance with isoflurane, the effects of isoflurane may be delayed and care must be taken to avoid overdosage.

When **Domidine®** is used as a premedicant prior to general anaesthesia, the product may delay the onset of induction. [2]

Dosage in mcg/kg	Dosage in ml/100 kg	Level of sedation	Commencement of effect (min)		Duration of effect (hrs)
			Horse	Cattle	
10-20	0.1-0.2	Light	3-5	5-8	0.5-1
20-40	0.2-0.4	Moderate	3-5	5-8	0.5-1

Conclusions

Both products are considered equally effective and safe.

[1] Boezeman, M.A.H., de Kleyne, J.A.L.M., van Hattum, J.J.C. and Vissers, M.P.M.N, Therapeutic Equivalence and Equal Target Species Safety of Two Detomidine Formulations for Horses, Farma Research Animal Health, Nijmegen, December 2006, page 432 - 437, Dier en Arts.

[2] Steffey E.P. et.al. Vet Anaesthesia Analg. Vol 24, page 23 (2002)

Data sheet

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release
Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, The Netherlands
Distributor: Dechra Veterinary Products.

Name of the veterinary medicinal product
Domidine 10 mg/ml, solution for injection.
Detomidine hydrochloride for horses and cattle.
Domidine vet. (Denmark)
Domidin vet. (Sweden, Finland)

Statement of the active substance and other ingredients
1 ml solution for injection contains:

Active substance:
Detomidine hydrochloride 10.0 mg
This corresponds to 8.36 mg detomidine base

Excipients:
Methyl parahydroxybenzoate (E218) 1.0 mg

Other excipients: up to 1 ml
Clear and colourless solution

Indications
For the sedation and slight analgesia of horses and cattle, to facilitate physical examinations and treatments, such as minor surgical interventions.

Detomidine can be used for:

- Examinations (e.g. endoscopy, rectal and gynaecological examinations, X-rays).
- Minor surgical procedures (e.g. treatment of wounds, dental treatment, tendon treatment, excision of skin tumours, teat treatment).
- Before treatment and medication (e.g. stomach tube, horse shoeing).

For premedication prior to administration of injection or inhalation anaesthetics.

Contraindications
Do not use in animals with cardiac abnormalities or respiratory diseases.
Do not use in animals with liver insufficiency or renal failure.
Do not use in animals with general health problems (e.g. dehydrated animals).
Do not use in combination with butorphanol in horses suffering from colic.
See also 'Special warnings' section – 'Use during pregnancy and lactation and interactions'

Adverse reactions
Injection of detomidine may cause the following side effects:

- Bradycardia
- Transient hypo- and/or hypertension
- Respiratory depression, rarely hyperventilation
- Increase in blood glucose
- As with other sedatives, in rare cases paradoxical reactions (excitation) can develop
- Ataxia
- In horses: Cardiac arrhythmia, atrioventricular and sino-atrial block
- In cattle: Inhibition of rumen motility, tympania, paralysis of the tongue

At doses above 40 µg/kg, the following symptoms can also be observed: sweating, pilo-erection and tremor of muscles, transient penis prolaps in stallions and geldings and mild, transient tympania of rumen and increased salivation in cattle.
In very rare cases horses may show mild symptoms of colic following administration of alpha-2 sympathomimetics because substances of this class transiently inhibit the motility of the intestines. Detomidine should be prescribed with caution in horses which present with signs of colic or impaction.
A diuretic effect is usually observed within 45 to 60 minutes after treatment.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species
Horses and cattle

Dosage for each species, route(s) and method of administration
For intravenous (IV) or intramuscular (IM) administration. The product should be injected slowly. Onset of effect is more rapid following intravenous administration.

Dosage in microgram/kg	Dosage in ml/100 kg	Level of sedation	Commencement of effect (min) Horse	Commencement of effect (min) Cattle	Duration of effect (hrs)
10-20	0.1-0.2	Light	3-5	5-8	0.5-1
20-40	0.2-0.4	Moderate	3-5	5-8	0.5-1

When prolonged sedation and analgesia is required, doses of 40 to 80 microgram/kg bodyweight can be used.
The duration of effect is up to 3 hours.
For combination with other product to intensify the sedation or for premedication prior to general anaesthesia, doses of 10 to 30 microgram/kg can be used.
It is recommended to wait 15 minutes after the detomidine administration before starting the planned procedure.

Advice on correct administration
The bodyweight of an animal to be treated should be determined as accurately as possible to avoid overdosing.

Withdrawal period
Horse (meat and offal) 2 days
Horse (milk) 12 hours
Cattle (meat and offal) 2 days
Cattle (milk) 12 hours

Special storage precautions
Keep out of the reach and sight of children.
Do not use after the expiry date stated on the label after EXP.
Shelf-life after first opening the container: 28 days.
This veterinary medicinal product does not require any special storage conditions.

Special warning(s)
To avoid aspiration of feed or saliva, cattle should be maintained in upright position following treatment and head and neck of cattle lying down should be lowered.

Special precautions for use in animals
As sedation begins, horses especially may start to sway and lower the head rapidly while they remain standing. Cattle, and especially young cattle, will try to lie down. To prevent injuries the location should therefore be chosen carefully. Especially for horses, precautions should be taken to prevent self-injury.
Animals suffering from a shock or liver or kidney disease should only be treated according to the benefit/risk assessment by the responsible veterinarian. The product should not be used in animals suffering from heart diseases (with pre-existing low heart rate and risk of atrio-ventricular block), respiratory, liver or renal deficiencies, shock or any other extraordinary stress conditions. Detomidine/butorphanol combination should not be used in horses with a history of liver disease or heart abnormalities.
It is recommended that feed should be withheld for at least 12 hours prior to anaesthesia.
Water or food should not be offered to treated animals until the drug effect has passed.
In painful procedures detomidine should be used only in combination with an analgesic or a local anaesthetic.
While waiting for sedation animals should remain in calm surroundings.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet and other product literature to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Irritation, sensitisation, contact dermatitis and systemic effects cannot be excluded after skin contact.
Avoid skin contact and wear impermeable gloves when handling the product.
Wash the exposed skin immediately after exposure with large amounts of water.
In the case of accidental projection of the product into the eyes, rinse abundantly with fresh water. If irritation persists, seek the advice of a physician.
Remove contaminated clothes.
Pregnant women should not handle the product.
ADVICE TO DOCTORS: detomidine is an alpha-adrenoreceptor agonist whose toxicity may cause clinical effects including sedation, respiratory depression and coma, bradycardia and hypotension and hyperglycaemia. Ventricular arrhythmias have also been reported. Treatment should be supportive with appropriate intensive therapy.

Use during pregnancy and lactation
Do not use this product during the last trimester of pregnancy. Use only according to the benefit/risk assessment of the responsible veterinarian during pregnancy.

Interactions with other medicinal products and other forms of interaction
Simultaneous use with other sedatives only after consultation of the warnings and precautions of the product concerned. Detomidine should not be used in combination with sympathomimetic amines such as adrenaline, dobutamine and ephedrine. The concurrent use of certain sulphonamides may cause heart arrhythmias with fatal outcome. Therefore do not use in combination with sulphonamides.
Detomidine in combination with other sedatives and anaesthetics should be used carefully because additive or synergistic effects may be possible. Where anaesthesia is started with a combination of detomidine and ketamine, prior to maintenance with halothane, the effects of halothane may be delayed and care must be taken to avoid overdosage. When detomidine is used as a premedicant prior to general anaesthesia, the product may delay the onset of induction.

Overdose (symptoms, emergency procedures, antidotes)
In the event of an accidental overdose, heart arrhythmias, hypotension, delayed recovery and profound central nervous system and respiratory depression may occur. Should the effects of detomidine become life-threatening, administration of an 2-adrenergic antagonist is recommended.

Special precautions for the disposal of unused product or waste materials
Disposal advice
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Date on which the package leaflet was last approved
November 2006

Other information
Pack sizes: 5, 10 or 20 ml.
Not all pack sizes may be marketed.
For animal treatment only.

POM-V UK: Prescription Only Medicine – Veterinarian
VPO Eire: Veterinary Practitioner Only

To be supplied only on veterinary prescription (UK only).
Veterinary medicinal product authorised for use in UK and Ireland.

Marketing authorisation numbers:
UK Vm 16849/4008
Eire VPA 10989/053/1

NOTES

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