A stride forward

- Easily administered via intramuscular injection
- Well tolerated in clinical trials
- Clinical improvement up to 6 months post-treatment

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The challenges of treating navicular syndrome

- conditions affecting the navicular bone and its adjacent soft tissue structures often occur in both front feet
- are most typically seen in mature riding horses
- can lead to significant and even disabling forelimb lameness
- can be accompanied by an imbalance in the bone remodelling process
- can be very challenging to treat due to the complexity of the bone resorptive process

A: Radiograph healthy navicular bone
B: Radiograph diseased navicular bone
C: MRI healthy navicular bone
D: MRI diseased navicular bone

WATCH ONLINE TO LEARN MORE ABOUT NAVICULAR SYNDROME

UNDERSTANDING NAVICULAR SYNDROME: www.dechra.co.uk/what-is-NS
DIAGNOSING NAVICULAR SYNDROME: www.dechra.co.uk/diagnosing-ns
Introducing Osphos, the new intramuscular bisphosphonate from the innovators in equine health

Osphos 51 mg/ml clodronic acid solution is administered by simple intramuscular injection.

It is the only intramuscular product licensed for the alleviation of clinical forelimb lameness associated with the bone resorptive processes of the navicular bone in adult horses.

With Osphos the benefits are clear…
With Osphos the benefits are clear

**Clinical improvement** up to 6 months post-treatment

- Horses with navicular syndrome positively respond to treatment with Osphos
- Lameness in 74.7% of horses improved by at least one grade at 56 days after treatment
- Osphos has proven efficacy at 6 months post-treatment in 65.8% of cases

**Well tolerated** in clinical trials

- Side effects recorded during clinical field trials in horses treated with Osphos have all been mild and transient

[Watch Online](www.dechra.co.uk/intro-osphos)
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.

**Easily administered via intramuscular injection**

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 with a maximum of 15 ml per horse

**Solution for IM injection**

Clodronic acid 51 mg/ml

Intramuscular injection provides a quick and easy route of administration, and a full dose can be administered in minutes.
Osphos uses the bisphosphonate Clodronic acid to help restore the balance between resorption and remodelling in diseased bone.

Did you know clodronic acid:

- is rapidly absorbed when administered by the intramuscular route
- has a strong affinity for hydroxyapatite crystals in bone
- preferentially accumulates in areas where bone metabolism is most active
- inhibits osteoclast activity

This helps to reduce mineral loss.

How Osphos works

Combats excessive bone resorption

WATCH ONLINE

HOW BISPHOSPHONATES WORK:
www.dechra.co.uk/how-osphos-works
More information about Osphos

Whether you are looking to explain the treatment to a client or want to learn more about Osphos, our website is packed full of videos and information.

www.dechra.co.uk/osphos

- About navicular syndrome
- How to diagnose
- Bisphosphonates
- Osphos product information
- Administering Osphos
- Complementary care

THIS BROCHURE OFFERS GREAT DIGITAL EXPERIENCES USING THE LAYAR APP | DOWNLOAD THE FREE APP. FIND THE LAYAR SYMBOL AND SCAN THE PAGE
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Osphos 51 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml contains:
Active substance:
Clodronic acid 51 mg/ml (Equivalent to clodronate disodium tetrhydrate 74.98 mg)
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for injection.
Clear, colourless solution, practically free from visible particles.

4. CLINICAL PARTICULARS
4.1 Target species
Horses.

4.2 Indications for use, specifying the target species
For the alleviation of clinical footlimb lameness associated with the bone resorption processes of the distal sesamoid (navicular bone) in adult horses.

4.3 Contraindications
Do not administer intravenously.
Do not administer to horses less than 4 years of age, due to the absence of data regarding use in growing animals.
Do not administer to horses with impaired renal function.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species
The veterinary medicinal product should be used only after a proper diagnosis combining a complete orthopaedic clinical examination including local analgesia and appropriate imaging techniques, in order to identify the cause of pain and the nature of bone lesions.
Clinical improvement in lameness grade may not be accompanied by radiographic changes in the appearance of the navicular bone.

4.5 Special precautions for use
Special precautions for use in animals:
Use caution when administering bisphosphonates to horses with conditions affecting mineral or electrolyte homoeostasis, e.g. hyperkalaemic periodic paralysis, hypocalcaemia.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection of this product may increase the risk of obstructed labour in pregnant women and affect fertility in men.
Care should be taken when handling the product to avoid self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
In a clinical field study, administration of clodronic acid at 1.19 mg/kg to 142 horses resulted in the following frequency of adverse reactions: muzziness, lip licking, yawning and cola were common, head bobbing, transient swelling at the injection site, pawing the ground, hares and prunts were uncommon.
The frequency of adverse reactions is defined using the following conventions:
- common (more than 1 but less than 10 animals in 100 animals displaying adverse reactions during the course of one treatment)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)

4.7 Use during pregnancy and lactation
Laboratory studies in rats and rabbits have shown evidence of maternotoxic effects, especially during late gestation stages. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or fetotoxic effects.
The safety of the veterinary medicinal product has not been studied in pregnant or lactating mares.
The use of the product during pregnancy or lactation in mares is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction
The pharmacokinetic profile after a single intramuscular administration of 765 mg clodronic acid in horses dosaged with navicular syndrome is characterised by rapid absorption of clodronic acid and a longer terminal elimination phase. The plasma half-life is approximately 11.8 ± 12.5 hours (mean ± standard deviation), Cmax is 7.5 ± 1.7 µg/mL and time to maximum concentration (Tmax) is approximately 0.6 hours.

5. PHARMACOLOGICAL PROPERTIES
Clodronic acid is a general bisphosphonate that inhibits bone resorption by binding to hydroxyapatite crystals (inhibiting their formation and dissolution), and by direct cellular effects on osteoclasts (inhibiting osteoclast cell function). It has a high affinity for solid-phase calcium phosphate and therefore accumulates in bone, where it inhibits the formation, aggregation and dissolution of calcium phosphate crystals. Bound to bone matrix, clodronic acid enters resorbing osteoclasts, alters their morphology and reduces the number of active osteoclasts, regardless of the cause of osteoclast activity. Clodronic acid increases bone mass by inhibiting bone resorption and retarding bone turnover.

5.1 Pharmacodynamic properties
The pharmacokinetic profile after a single intravenous administration of 765 mg clodronic acid in horses dosaged with navicular syndrome is characterised by rapid absorption of clodronic acid and a longer terminal elimination phase. The plasma half-life is approximately 11.8 ± 12.5 hours (mean ± standard deviation), Cmax is 7.5 ± 1.7 µg/mL and time to maximum concentration (Tmax) is approximately 0.6 hours.

5.2 Pharmacokinetic particulars
The pharmacokinetic profile after a single intravenous administration of 765 mg clodronic acid in horses dosaged with navicular syndrome is characterised by rapid absorption of clodronic acid and a longer terminal elimination phase. The plasma half-life is approximately 11.8 ± 12.5 hours (mean ± standard deviation), Cmax is 7.5 ± 1.7 µg/mL and time to maximum concentration (Tmax) is approximately 0.6 hours.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life
Shelf life of the veterinary medicinal product as packaged for sale, 2 years.
For single use only; any remaining product should be discarded.

6.4 Special precautions for storage
Keep the container in the outer carton.
Do not store above 30°C.

6.5 Nature and composition of immediate packaging
Clear glass (type I) vial with chlorobutyl rubber stopper, an aluminium seal and a plastic flip-off cap containing 15 ml of clodronic acid solution.
Each cardboard box contains 1 vial.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
Dechra Limited
Snaygill Industrial Estate, Keighley Road, Skipton
North Yorkshire, BD21 2KX United Kingdom

8. MARKETING AUTHORISATION NUMBER
UK: Vm 004154/0466
IE: VPA 10795/029/001

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02 September 2015

10. DATE OF REVISION OF THE TEXT
September 2015