Arthramid® Vet

Instruction For Use

Caution

Federal law restricts this device to sale by or on the order of a licensed veterinarian and it must be used under the supervision of a licensed veterinarian for the application of intra-articular administration.

Product Description

Arthramid® Vet is a non-resorbable, injectable, transparent, hydrophilic gel, for intra-articular administration in horses only.

Arthramid® Vet consists of a backbone of cross-linked polyacrylamide, with water molecules loosely bound to the polymer matrix. Nominal proportions of the Arthramid® Vet gel are 2.5% cross-linked polyacrylamide and 97.5% non-pyrogenic water for injection. Arthramid® Vet is biocompatible and non-biodegradable and is sterilized by moist heat.

Arthramid® Vet is supplied in a pre-filled, sterile, 1 mL syringe sealed with a luer lock fitting. It is intended to be injected with a sterile 16-23-gauge hypodermic needle.

Indication

Arthramid® Vet is indicated for the management of non-infectious causes of joint disease in horses, including both early and late stages of osteoarthritis and degenerative joint disease.

Mode of Action

Arthramid® Vet adheres to and becomes incorporated into the synovial lining and the immediate surrounding tissue of the inner capsule by a combination of cell migration and vessel ingrowth, forming a thick, cushion-like membrane consisting of vessel integrated gel covered by a new and hypercellular synovial cell lining.

Arthramid® Vet is intended to improve the symptoms associated with joint disease.

Contraindications

Arthramid® Vet is not to be injected into actively infected joints, infected surrounding joint soft tissues or infected skin overlaying the joint.

Warnings

Arthramid® Vet is not recommended for use in horses with acute/chronic diseases receiving treatment with systemic corticosteroids or antibiotics.

- Do not inject Arthramid® Vet intravascularly. Injection into blood vessels may cause vascular occlusion leading to possible embolism.
- Do not use Arthramid® Vet if the package is opened or damaged.
- Do not re-sterilize Arthramid® Vet.
- Do not mix Arthramid® Vet with any other product.
- Do not use Arthramid® Vet in combination with any other products intended for intra-articular injection, for a period of no less than 30 days.

Precautions

It is recommended that the injection site is disinfected.

Anamnesis data of ongoing infections, concomitant medication, surgery, etc. must be reviewed before injection to prevent possible infections.

Do not use Arthramid® Vet after the expiration date printed on the packaging.

After use, syringes and needles should be handled as potential biohazards. Dispose in accordance with accepted medical practice and applicable local, state and federal requirements.

Method of Administration

Arthramid® Vet must be administered by a qualified veterinarian trained in these types of procedures.

Arthramid® Vet is administered via percutaneous infiltration into the articular cavity of the affected joint delivering the required volume as advised depending on the joint being injected.

Administration and Dose

1. Sedate or restrain the horse.

2. Clip the hair overlaying the joint to be injected. For antisepsis, wash and disinfect thoroughly in a radius o 3 inches round the injection site. Injection of Arthramid® Vet may be performed under local anaesthesia.

Aseptic technique must be used to avoid contamination of the sterile Arthramid® Vet syringe and injection site. Due to Arthramid® Vet's unique mode of action, the following dosage recommendations have been made, based on observed clinical responses to administration;

- Distal Interphalangeal (DIP/ Coffin) - 1-2 mls
- Metacarpo/tarso-phalangeal (Fetlock) - 2 mls
- Carpus – 2 mls
- Tarso-metatarsal (TMT)/ Distal-intertarsal (DIT) - 1 ml
- Tarsocrural - 2-3 mls
- Shoulder - 3 mls
- Stifles - 1-2 ml per compartment or 3-4 mls for medial-femorotibial joint

A single injection of the above advised volumes is considered adequate administration to achieve effect. Published clinical trials indicate horses that partially respond to an initial treatment may benefit from a second dose at 4 to 6 weeks later.

Safety Studies indicate that concurrent treatment of multiple joints in the same animal is safe.

Peri-Operative Procedures

Remove the protective tip cap from the Arthramid® Vet syringe. The syringe is firmly attached into the luer lock socket on the 16-23-gauge hypodermic needle. Make certain that the syringe is correctly mounted prior to use.

Post-Operative Procedures

An ointment can be applied on the injection site immediately after treatment. A cold pack can be applied on the injection site in case of an oedema. A bandage should be applied around the injection site if possible. Local or systemic corticosteroids should not be administered to the animal within two weeks of injection of Arthramid® Vet, since this may mask a possible infection. The animal should be rested for 48 hours after the treatment.

Non-steroidal anti-inflammatory drugs (NSAIDs) can be administered for pain relief and to reduce swelling. Allergic reactions to Arthramid® Vet have never been observed.

Complications

As with any intra-articular procedure, an Arthramid® Vet injection carries a risk of infection. Standard precautions and strict aseptic injection technique are essential. In the event of infection, the use of broad-spectrum antibiotics is recommended as a first line treatment. Any use of corticosteroids is contraindicated in case of infection.

Some animals can develop pain within the first few hours post-administration. In addition, there is also a slight risk of haematoma and mild oedema at the site of injection. Within 1-2 weeks after treatment there is a slight risk that the animal may develop a transient oedema and tenderness at the treatment site as the tissue integration is occurring. If not caused by infection, these reactions are self-limiting and will resolve within a couple of weeks.

Information to the Owner

The owner of the horse should be informed about the indications, expected results, contraindications, precautions, warnings, and potential complications. The owner of the horse should be advised that in case of complications, the veterinarian who performed the Arthramid® Vet injections should be contacted immediately for necessary treatment.

Owners should be counselled that one or more repeat Arthramid® Vet injection procedures may be required to achieve a satisfactory level of improvement in disease symptoms.

Complaints

Please report any malfunction or complaints to Contura Vet at **Info@conturavet.com**.

Storage

Arthramid® Vet must be stored between 5°C (41°F) and 25°C (77°F) (air conditioning) protected from direct sunlight. Do not freeze. Do not store unsealed syringes for later use.

Symbols used on packaging

 Refers to instruction for use.

 For single use only. Do not re-use.

Sterile. Sterilized by moist heat.

 Expiry date. Use before the date printed on the label.

Product batch number.

 Manufacturer.

 Keep away from direct sunlight.

Do not re-sterilize.

Store between 5°C (41°F) and 25°C (77°F).

 Do not use if package is damaged.

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