Synamid®

Instruction For Use

10099-001 December 2020

contura vet

Manufactured by: Contura International A/S,
Sydmarken 23, 2860 Soeborg, Denmark

contura vet

Strandbygaard

Kunde: **Contura International A/S**
Vare: **10099-001 IFU Synamid US**

Format: **70 x 210 mm**
Side-antal: **12 sider - 6-fløjet**

Dato: **18/11 2020**
Ordrenr.: **2205907**

Korrektur: **1**

SORT CYAN MAGENTA YELLOW

Godkendelse fra kunde:
Contura International A/S

Godkendt **JA** ☐ **NEJ** ☐

Godkendt af:

Dato: _____ / _____ 2020

Godkendelsen dækker: Format, design, tekst, fonte, billeder, farveseparation og Ean-kode.

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

Synamid® is a non-resorbable, injectable, transparent, hydrophilic gel, for intra-articular administration in dogs only.

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

Synamid® 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 21-23-gauge hypodermic needle.

Indication

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

Contraindications

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

Warnings

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

Precautions

Synamid® is not recommended for use in dogs with acute/chronic diseases receiving treatment with systemic corticosteroids or antibiotics.

The injection site should undergo surgical skin disinfection prior to treatment.

Medical history records addressing ongoing infections, concomitant medication, surgery, etc. must be reviewed before injection to prevent possible infections.

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

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

Synamid® 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.

Dose Recommendation

The following dosage recommendations have been made, based on observed clinical responses to administration:

Joint	Size of dog	Dose to be administered
Large: Shoulder, elbow, hip and stifle	< 20kg	0.5 mL
	< 20kg	1 mL
Medium: Carpus and Tarsus	< 20kg	0.25 – 0.5 mL
	< 20kg	0.5 – 1 mL
Small: Interphalangeal joint	All patients	0.01 – 0.1 mL

A single injection of the above advised volume is considered adequate administration to achieve effect.

Concurrent treatment of multiple joints can be performed.

Peri-Operative Procedures

1. Sedate the dog.
2. Clip the hair overlaying the joint to be injected and surgically prepare a suitable area around the point of injection.

   Aseptic technique must be used to avoid contamination of the sterile Synamid® syringe and injection site.
3. A 21-23G hypodermic needle should be placed into the intra-articular cavity, taking care to avoid unnecessary damage of the intra-articular tissue, as this may result in diffuse swelling lasting for 24-48 hours.
4. Remove the protective tip cap from the Synamid® syringe.
5. Once the clinician is confident of correct placement of the needle within the joint cavity, the syringe is firmly attached into the luer lock socket on the 21-23 gauge hypodermic needle. Make certain that the syringe is correctly mounted prior to injection.
6. If more than 1 mL of Synamid® is required for the joint, detach the empty Synamid® syringe from the hypodermic needle and repeat the process until the required dose is delivered.
7. Upon completion, withdraw the hypodermic needle and syringe and dispose in accordance with accepted medical practice and applicable local, state and federal requirements.

Post-Operative Procedures

A cold pack can be applied on the injection site in case of oedema. Local or systemic corticosteroids should not be administered to the animal within two weeks of injection of Synamid®, since this may mask a possible infection.

The animal should be rested for 48 hours after treatment and then be on a restricted exercise schedule for 4 weeks post injection. After this period, the animal should gradually return to normal exercise levels.

Non-steroidal anti-inflammatory drugs (NSAIDs) can be

administered for pain relief and to reduce swelling.

Allergic reactions to Synamid® have not been observed.

Complications

As with any intra-articular procedure, a Synamid® injection carries a risk of infection. Standard precautions and strict aseptic injection technique are essential. In the event of infection, follow your normal practice protocols for joint infection. 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. 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 dog should be informed about the indications, expected results, contraindications,

precautions, warnings, and potential complications. The owner of the dog should be advised that in case of complications, the veterinarian who performed the Synamid® injections should be contacted immediately for necessary treatment.

Owners should be counselled that one or more repeat Synamid® 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

Synamid® must be stored 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.
Contura Vet Limited, Riverside One, Sir John Rogerson's Quay, Dublin 2, Ireland.

Keep away from direct sunlight.

Do not re-sterilize.

Do not freeze.

Do not use if package is damaged.

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