

Synoglide™

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 intra-articular administration.

Product Description

Synoglide is a sterile, viscoelastic hydrogel microparticle (HMP) suspension formulated with highly purified biopolymers (bovine gelatin 1.70% and oxidized cellulose 0.25%) in phosphate-buffered saline. It appears as a clear, colorless to slightly yellow gel and is supplied in a single use pre-filled Luer-Lock syringe containing 2.0mL of product.

Indication

Synoglide is indicated for intra-articular injection for the management of non-infectious causes of osteoarthritis in horses.

Contraindications

Do not inject Synoglide into joints or surrounding tissues (including skin) showing signs of infection, severe inflammation, or effusion. Avoid use in horses with known hypersensitivity to any product components.

Warnings

- For intra-articular use only.
- Do not inject into blood vessels.
- Do not exceed the recommended maximum dosage per joint.
- Do not inject the contents of the same syringe into different joints.
- Do not mix with any other product.
- Do not re-sterilize or reuse.
- Do not use if the syringe or packaging is damaged or opened.
- Do not use after the expiration date printed on the packaging.
- Discard any solution remaining in the syringe.

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Precautions

The safety of the product was not assessed in pregnant and lactating mares. This product has not been tested in horses under 3 years of age.

Method of Administration

Synoglide must be administered via intra-articular injection by a licensed veterinarian. The product should be allowed to reach room temperature (20–25°C / 68–77°F) before use. Use within 24 hours at room temperature or discard.

Dose Recommendation

The following maximum dosage recommendations are provided based on joint size:

- Tibiotarsal – 2mL
- Tarsometatarsal – 1mL
- Metacarpophalangeal – 1 mL

Peri- and Operative Procedures

Sedate or restrain the horse. Clip the hair overlaying the joint to be injected. Using strict aseptic technique, wash and disinfect thoroughly around the injection site to avoid contamination.

A sterile 19–21 G hypodermic Luer-Lock compatible needle should be placed intra-articularly, and synovial fluid should be observed to confirm correct placement. Care should be taken to avoid damage to intra-articular tissue, as this may result in transient swelling lasting 24–48 hours.

Take the grip from the box and attach firmly by clicking it onto the syringe.

Remove the protective cap from the Synoglide syringe and firmly attach the Luer-Lock syringe to the needle and inject volume appropriate for that specific joint.

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During injection, stop if backpressure is encountered.

Use a new syringe for each joint.

After completing the injection, withdraw the needle and syringe and dispose of them according to accepted veterinary medical practice and applicable local, state, and federal regulations.

Post-Operative Procedures

A cold pack and/or light bandage may be applied to the injection site. As with other intra-articular injections, a rest period of 48 hours and a gradual return to work over a week is recommended.

Information to the Owner

The veterinarian should inform the horse owner about indications, possible side effects, precautions, and expected outcomes.

Complications

As with any intra-articular procedure, infection risk exists. Use strict aseptic technique. Possible adverse effects include acute aseptic synovitis (joint flare), transient pain at the injection site, swelling, local heat, mild inflammation, or hypersensitivity.

Complaints

Please report any product complaints or adverse events to American Regent, Inc, Animal Health at 1-888-354-4857.


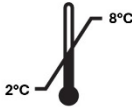

















Storage

Store in a refrigerator between 2°C (36°F) and 8°C (46°F) in dry conditions. Do not freeze. Protect from direct sunlight. Do not store unsealed syringes for later use. Discard any solution remaining in the syringe following the required dose.

Symbols

Symbols used on the packaging conform to ISO 15223-1:2021 standards.

Synoglide™

Symbol	Definition	Symbol	Definition
	Sterilized using irradiation		Temperature limits
	Manufacturer		Do not re-use
	Date of manufacture		Consult instruction for use
	Country of origin: Belgium		Caution, The user must consult cautionary information and warnings
	Use-by date		Medical Device
	Serial Number		Single sterile barrier system
	Do not re-sterilize		Single sterile barrier system inside protective packaging
	Do not use if package is damaged		Magnetic resonance Safe (compatible)
	Keep away from sunlight		Medical device contains biological tissue derivatives of animal origin.
	Unique Device Identifier		

Information

Manufactured by:

Allegro N.V./S.A.

Synoglide™

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B-4000 Liège, Belgium
<https://allegro.bio/>

Distributed by:

American Regent Inc. Animal Health
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Product Code: 99-2020

Revision: 11/2025