A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Single-syringe folding box, carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SynVet-50; 50 mg solution for injection for horses Sodium hyaluronate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One 2.5 ml syringe contains 50 mg sodium hyaluronate

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

2.5 ml

5. TARGET SPECIES

Horse

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

50 mg / 2.5 ml solution for intra-articular injection

for horses Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: zero days Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use

10. EXPIRY DATE

EXP: mm/yyyy

Partly used syringe should be discarded

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

Store in the original container
Store in a dry place

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF

For animal treatment only. To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Equimed Ltd
Jeffcott
2 Hilliards Court, Chester Business Park
Chester
CH4 9PX

16. MARKETING AUTHORISATION NUMBER(S)

Vm 25297/4000

17. MANUFACTURER'S BATCH NUMBER

Lot: 000000/0

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Primary label on single dose syringe (packed and sterilized in blister)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SynVet-50
Synvet 20
mg

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot: 000000/0

7. EXPIRY DATE

EXP: mm/yyyy

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

9. NAME OF MARKETING AUTHORISATION HOLDER

Equi Pharma Ltd

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister, primary label can be seen through the front part of the blister with the above given information

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SynVet-50; 50 mg solution for injection for horses Sodium hyaluronate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg / 2.5 ml solution

3. ROUTE(S) OF ADMINISTRATION

For i.a. use

4. WITHDRAWAL PERIOD

Milk and offal: 0 days
Milk: 0 hours

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Equi Pharma Ltd

6. Batch Number

7. Expiry Date

EXP mm/yyyy

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET
SynVet-50; 50 mg solution for injection for horses
Sodium hyaluronate

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE OF BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Equimed Ltd
Jeffcott
2 Hilliards Court, Chester Business Park
Chester
CH4 9PX

Manufacturer for batch release:
Croma Pharma Gesellschaft m.b.H.
Cromazeile 2
A-2100
Leobendorf
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SynVet-50; 50 mg solution for injection for horses
Sodium hyaluronate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

SynVet-50 is a sterile, colorless, clear solution

containing: Each 2.5 ml syringe contains:

Active substance:
Sodium hyaluronate 50 mg

4. INDICATION(S)

For adjunctive intra-articular treatment of joint disease associated with non-infectious synovitis in horses.

5. CONTRAINDICATIONS

Do not use in cases of joint infections.
Do not use in cases of known hypersensitivity to exogenous sodium hyaluronate or to any of the excipients of the product.

6. ADVERSE REACTIONS

The most commonly reported adverse reaction are transient mild swelling and/or heat occurring in approximately 2.7% of the treated joints. These self-limiting local signs typically resolve spontaneously within 48 hours. However, since the early signs of septic arthritis may be similar, it is advised that a thorough clinical examination and monitoring are carried out if these clinical signs occur. Consideration should be given to appropriate further investigations.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

7. TARGET SPECIES

Horse

8. DOSAGE and ROUTE(S) OF ADMINISTRATION

For single intra-articular injection: 2.5 ml intra-articularly into medium sized and large joints of horses. More than one joint may be treated at the same time.

If necessary, re-treatment of the joint can be considered at 2-3 weeks after the first-treatment.

9. ADVICE ON CORRECT ADMINISTRATION

A sterile dressing and clean bandage should be applied after injection, as appropriate for the particular joint treated.

Suggested needle size for intra-articular use: 20G 1,5inch needle (0.9 x 40mm)

10. WITHDRAWAL PERIOD

Meat and offal: zero
days Milk: zero hours

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Store in the original container
Store in a dry place

Single dose syringes made ready for injection shall be used immediately; any unused portion of a syringe is to be discarded

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Keep out of sight and reach of children.

Each syringe is sealed in a polypropylene/paper blister pack.

12. SPECIAL WARNINGS

Excess synovial fluid should be removed whenever possible prior to injection.
The injection should be administered under strict aseptic conditions through healthy undamaged skin. Appropriate investigations should be carried out in cases of acute, severe lameness to ensure that the joints are free from fractures, OCD fragments and infections.

The treated horse should be box-rested for 2 days before gradually resuming a normal exercise

pattern.

Use during pregnancy and lactation:

The safety of the product has not been established in pregnant and lactating mares. Use only according to the benefit/risk assessment by the responsible veterinarian.

Incompatibilities

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

Interaction with other medical products and other forms of interaction

No data available to the interaction with other medicinal products. It is described that hyaluronic acid competes with other high molecular weight polysaccharides such as chondroitin sulphate for receptors binding and thus for the uptake in the articular cartilage tissue.

User Warnings

In case of accidental contact with skin, wash with soap and water.
In case of accidental contact with eyes, blurred vision may occur because of the viscous nature of the product. Rinse immediately with plenty of clean water.

In the event of accidental self-injection, seek medical advice immediately and show the package leaflet of the label to the physician.
Wash hand after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

IE: 10439/002/001

Available in single cartons or packs of 6 single cartons overwrapped with plastic film.
Not all pack sizes may be marketed.

IE:VPO

Approved: 04 May 2024