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 APPLICABLE

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

Equi Pharma Ltd. Aspen lodge Notabile Road Mriehel Birkirkara BKR 1870 Malta

16. MARKETING AUTHORISATION NUMBER(S)

IE: VPA 10439/002/001

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 20mg 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

9. NAME OF MARKETING AUTHORISATION HOLDER

THE WORDS "FOR ANIMAL TREATMENT ONLY"

Equi Pharma Ltd

8.

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.