

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 20% Solution for Injection
Elemental iron as iron dextran

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200mg elemental iron as iron dextran and 0.5% w/v phenol as a preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

Boxes of 5 x 100ml, 10 x 100ml or 12 x 200ml multidose collapsible polyethylene vials.

5. TARGET SPECIES

Piglets.

6. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia in piglets.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by deep intramuscular injection.

Prevention: A single dose of 1 ml (200mg iron) by deep intramuscular injection into the hind limb at 3-4 days of age.

Treatment: 1 ml by deep intramuscular injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, seek urgent medical attention.

Occasional deaths have occurred in piglets following the administration of parenteral iron dextran preparations. These deaths have been associated with maternal dietary deficiency of vitamin E and/or selenium.

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Vials are closed by rubber stoppers and aluminium caps. They are packed in aluminium sachets. Do not open the foil sachet until ready to use the product.

Following withdrawal of the first dose use the product within 28 days. Discard unused material at the latest 28 days after first opening the immediate packaging.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE
[Distribution category]

POM-
VPS

For animal treatment only

To be supplied only on veterinary prescription (UK)

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

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek
Denmark

Distributor: **Virbac Ltd.** Suffolk IP30 9UP - UK

16. MARKETING AUTHORISATION NUMBER(S)

UK only: **Vm 21674/4000**

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 20% Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains 200 mg iron (III) as iron dextran and 0.5% w/v phenol

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

100 or 200 ml

4. ROUTE(S) OF ADMINISTRATION

Solution for injection

Read the package leaflet before use.

For the prevention and treatment of iron deficiency anaemia in piglets.

Administer by deep muscular injection.

5. WITHDRAWAL PERIOD

Meat and offal: 28 days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP.:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

KEEP OUT OF SIGHT AND REACH OF CHILDREN

Protect from light. Do not store above 25°C.

Discard no later than 28 days after opening. Date to discard _/ _/ _

POM – VPS Vm 21674/4000

Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark

UK only: **Vm 21674/4000**

PACKAGE LEAFLET

Uniferon 20% Solution for injection

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

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek
Denmark

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 20%, Solution for Injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each ml contains 200mg elemental iron (Fe) as iron dextran, and 0.5% w/v phenol as a bacteriostat.

4. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia in piglets

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Occasional deaths have occurred in piglets following the administration of parenteral iron dextran preparations. These deaths have been associated with maternal dietary deficiency of vitamin E and/or selenium. In addition, occasional piglet deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system by the iron dextran colloidal solution as it is being absorbed.

7. TARGET SPECIES

Piglets

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Prevention: A single dose of 1 ml (200mg iron) by deep intramuscular injection into the hind limb at 3-4 days of age.

Treatment: 1ml by deep intramuscular injection.

9. ADVICE ON CORRECT ADMINISTRATION

Uniferon 20% w/v solution for injection should be administered to piglets by intramuscular injection. It is advisable to stretch the skin at the injection site with the thumb prior to inserting the needle, to prevent leakage on withdrawal. A 5/8" x 20 SWG hypodermic needle is recommended and the injection should be made at right angles to the skin.

10. WITHDRAWAL PERIOD

Meat and offal: 28 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.

Do not store above 25°C.

Protect from light.

Do not open the foil sachet until ready to use the product.

Following withdrawal of the first dose, use the product within 28 days.

Discard unused material at the latest 28 days after first opening the immediate packaging.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, seek urgent medical attention.

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

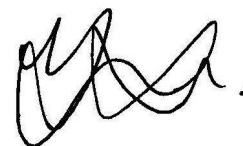
15. OTHER INFORMATION

POM – VPS To be supplied only on veterinary prescription.

Vm 21674/4000

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

Distributor:
Virbac Ltd
Woolpit Business Park
Windmill Avenue, Woolpit, Bury St Edmunds
Suffolk IP30 9UP
UK

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 29 July 2020