

**ANNEX III**  
**LABELLING**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Outer Packaging for LDPE vials**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Uniferon 200 mg/ml Solution for Injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains 200 mg elemental iron as iron(III) hydroxide dextran complex and 0.5% w/v phenol as a preservative.

**3. PACKAGE SIZE**

5 x 100ml  
10 x 100 ml  
12 x 200 ml

**4. TARGET SPECIES**

Piglets

**5. INDICATIONS**

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

**6. ROUTES OF ADMINISTRATION**

Intramuscular route.

Prevention: A single injection of 1 ml (200 mg iron) at 1-4 days of age.  
Treatment: A single injection of 1 ml (200 mg iron).

**7. WITHDRAWAL PERIODS**

Withdrawal period:

Meat and offal: zero days.

**8. EXPIRY DATE**

EXP.: {mm/yyyy}

Once opened use within 28 days.

**9. SPECIAL STORAGE PRECAUTIONS**

Store in the original package.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Pharmacosmos A/S

**14. MARKETING AUTHORISATION NUMBER**

UK only: Vm 21674/4000

**15. BATCH NUMBER**

Lot {number}

POM-VPS

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Label**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Uniferon 200 mg/ml Solution for Injection

100 ml

200 ml

**2. STATEMENT OF ACTIVE SUBSTANCES**

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

**3. TARGET SPECIES**

Piglets

**4. ROUTES OF ADMINISTRATION**

Administer by deep muscular injection.

**5. WITHDRAWAL PERIODS**

Withdrawal period:

Meat and offal: zero days.

**6. EXPIRY DATE**

EXP.: {mm/yyyy}

Once opened use within 28 days. Use by...

**7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.

Protect from light.

Do not remove the foil before opening and use.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Pharmacosmos A/S

**9. BATCH NUMBER**

Lot {number}

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Uniferon 200 mg/ml Solution for Injection for Pigs (piglet)

### 2. Composition

Each ml contains:

**Active substance:**

200 mg elemental iron (Fe) as iron(III) hydroxide dextran complex.

**Excipients:**

5 mg phenol as a bacteriostat.

Slightly viscous dark brown solution.

### 3. Target species

Pig (piglet).

### 4. Indications for use

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

### 5. Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.  
Do not use in older pigs as ham staining may occur in animals over 4 weeks of age.

### 6. Special warnings

Special precautions for safe use in the target species:

It is advisable to stretch the skin at the injection site to minimise leakage after withdrawal of the needle. Observe aseptic precautions. Avoid the introduction of contamination during use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Interaction with other medicinal products and other forms of interaction:

None known.

## 7. Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death <sup>1,2</sup> , Hypersensitivity reaction, Injection site skin discolouration <sup>3</sup>
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<sup>1</sup>Associated with genetic factors or deficiency of vitamin E and/or selenium.

<sup>2</sup>Occasional piglet deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

<sup>3</sup>Transient discoloration and calcifications at the injection site.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

UK only:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

Intramuscular route.

Prevention: A single injection of 1 ml (200 mg iron) at 1-4 days of age.

Treatment: A single injection of 1 ml (200 mg iron).

## 9. Advice on correct administration

Uniferon 20% w/v solution for injection should be administered to piglets by intramuscular injection. A 5/8" x 20 SWG hypodermic needle is recommended and the injection should be made at right angles to the skin.

## 10. Withdrawal periods

Meat and offal: zero days

## 11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

Protect from light.

Do not open the foil 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 disposal**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

UK only:

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **14. Marketing authorisation number and pack sizes**

UK only:

Vm 21674/4000

Multidose collapsible polyethylene vials, closed by rubber stoppers and aluminium caps. They are packed in aluminium or transparent foil.

Package size:

5 x 100 ml,  
10 x 100 ml or  
12 x 200 ml

Not all pack sizes may be marketed.

## **15. 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](http://www.gov.uk).

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release:

Pharmacosmos A/S  
Roervangsvej 30  
Holbaek  
4300  
Denmark

## **17. Other information**

UK only:

POM-VPS

*Gavin Hall*

Approved 30 March 2026