ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stresoron 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

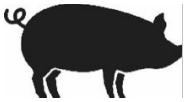
Azaperone 40.0 mg/ml

3. PACKAGE SIZE

50 mL
100 mL

4. TARGET SPECIES

Pigs



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 18 days.

8. EXPIRY DATE

Exp. mm/yyyy
Once broached use within 28 days, use by…

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

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

CP Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

Vm 20916/3020

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

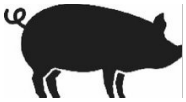
Stresoron 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Azaperone 40.0 mg/ml

3. TARGET SPECIES

Pigs



4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 18 days.

6. EXPIRY DATE

Exp. mm/yyyy

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stresoron

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Azaperone 40.0 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Stresoron 40 mg/ml solution for injection for pigs

2. Composition

Each mL contains:

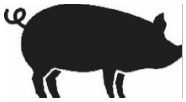
Active substance:
Azaperone: 40.0 mg

Excipients:
Methyl parahydroxybenzoate (E218) – 0.5 mg
Propyl parahydroxybenzoate – 0.05 mg
Sodium metabisulfite (E223) – 2.0 mg

Clear, colourless to slightly yellowish solution.

3. Target species

Pigs



4. Indications for use

1. For the use in animals with aggressive behaviour
   - following re-grouping
   - in sows (devouring of piglets)
2. For the use in animals with stress and prevention of stress
   - cardiovascular stress
   - transport-related stress
3. Obstetrics
4. Premedication for local or general anaesthesia
5. For relief of symptoms in animals with nutritional muscular dystrophy

5. Contraindications

Do not use in very cold conditions as cardiovascular collapse and hypothermia (increased by inhibition of hypothalamic heat regulation centre) due to peripheral vasodilation may occur.
The veterinary medicinal product is contraindicated for use in transport or for re-grouping of pigs which will be slaughtered prior to the end of the withdrawal period.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
During onset of action treated animals should be left alone in a quiet environment.
Insufficient results may be obtained if the animals are disturbed or chased during the induction period.
Injection into adipose tissue may lead to apparent insufficient effect.

Special precautions for safe use in the target species:
Occasional deaths have been observed in Vietnamese Pot Bellied Pigs. It is thought this may be caused by injection into the fat leading to slow induction and tendency to use additional doses, leading to overdosage.
It is important with this breed not to exceed the stated dose.
If the initial dose does not appear to have an effect, allow complete recovery before re-injecting on a different day.
In boars, doses exceeding >1 mg/kg may cause the penis to be extruded, which may then be damaged.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Azaperone, sodium metabisulfite, and methyl and propyl parahydroxybenzoate can cause hypersensitivity reactions. People with known hypersensitivity to azaperone or any of the excipients should avoid contact with the product.
This veterinary medicinal product may be irritant to the skin, eyes and oral mucosa. Avoid contact with the skin, eyes and oral mucosa. Wash any splashes from skin, eyes and oral mucosa immediately with plenty of water.
Seek medical advice if irritation persists.
Accidental self-injection may result in sedation. Care should be taken to avoid accidental self-injection. Only carry this veterinary medicinal product in an unarmed syringe to avoid accidental injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE as sedation may occur.
Studies on laboratory animals given azaperone showed indications of effects on the fetus. The veterinary medicinal product should not be administered by pregnant women. No data is available on the presence of azaperone in the milk of breastfeeding women. Breastfeeding women should handle the veterinary medicinal product with extreme caution. Azaperone may cause central nervous system effects after dermal exposure, including hand-to-mouth contact. Avoid skin contact and hand-to-mouth contact. Wash hands after use.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Azaperone has a potentiating effect on all centrally suppressive substances and hypotensive substances (due to peripheral α-adrenolysis).
- Amplification of tachycardia caused by adrenolytic agents.
- Simultaneous use with α- and β-sympathomimetic substances such as epinephrine (adrenaline) results in hypotension (“adrenaline reversal”).

Overdose:
Aggressive behaviour may occur during awakening in case of overdose.

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

7. Adverse events

Pigs:

Undetermined frequency (cannot be estimated from the available data)	Hypersalivation[1], panting[1], tremor[1] Reversible prolapse of the penis in boars[2]

[1](at high doses). These adverse events resolve spontaneously and do not result in permanent damage
[2] at doses exceeding >1 mg/kg

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Intramuscular use.

Administer strictly by intramuscular injection, only behind the ear.
The product is injected once.
A long hypodermic needle should be used and the injection should be given as close as possible behind the ear and perpendicular to the skin.
Do not administer more than 5 ml per injection site.

Aggressive behaviour (devouring of piglets, re-grouping), obstetrics:
2 mg azaperone/kg body weight, corresponding to 1 ml of the product per 20 kg body weight

Stress:
- Cardiovascular stress:
0.4 mg azaperone/kg body weight, corresponding to 0.2 ml of the product per 20 kg body weight
- Transport related stress of piglets, weaners, boars:
1 mg azaperone/kg body weight, corresponding to 0.5 ml of the product per 20 kg body weight
- Transport-related stress of sows and fattening pigs:
0.4 mg azaperone/kg body weight, corresponding to 0.2 ml of the product per 20 kg body weight

Premedication for local or general anaesthesia, nutritional muscular dystrophy:
1-2 mg azaperone/kg body weight, corresponding to 0.5-1 ml of the product per 20 kg body weight

For the use in boar, see section 6. Special warnings.

After treatment the animal should be left alone in a quite environment.
When heavy animals are injected into the neck with a short needle, there is a risk that some of the drug is injected into the fat. In this case, the injection may have a non-significant effect.

The stopper should not be punctured more than 20 times.

9. Advice on correct administration

See section: “Dosage for each species, routes and method of administration”.

10. Withdrawal periods

Meat and offal: 18 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
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.
Shelf life after first opening the immediate packaging: 28 days.

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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 20916/3020

Colourless glass (Type I) vial closed with a chlorobutyl rubber stopper secured with an aluminum cap.

Pack size:
Cardboard box with 1x100 ml vial.
Cardboard box with 1x50 ml vial.

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.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Tel: +49-(0)5136-6066-0

Local representatives and contact details to report suspected adverse reactions:

{To be completed nationally.}

17. Other information

Gavin Hall

Approved: 07 August 2025