ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azaporc 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Azaperone 40 mg/ml

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.
Do not administer more than 5 ml per injection site.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 18 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle 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

Serumwerk Bernburg AG (logo)

14. MARKETING AUTHORISATION NUMBERS

Vm 20631/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azaporc 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Azaperone 40 mg/ml

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

For intramuscular use.
Do not administer more than 5 ml per injection site.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 18 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once broached use by_____

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG (logo)

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Azaporc 40 mg/ml solution for injection for pigs

2. Composition

Each ml contains:

Active substance:

Azaperone	40.0 mg

Excipients:

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

A clear, pale yellow aqueous solution.

3. Target species

Pigs

4. Indications for use

A neuroleptic sedative:

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.

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 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 or ingestion 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.
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.
Wash hands after use.

Pregnancy and lactation:
The product can be used in pregnant and lactating animals.

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.
Repeat dosing in Vietnamese Pot Bellied pigs may result in death due to absorption of the initial dose in fat.

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:	Increased salivation*, tremor*, panting* Reversible penile prolapse in boars

*(at high doses). These side effects disappear spontaneously and leave no lasting damage.

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> <the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system {national system details}.
To be completed nationally

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

For intramuscular use.

Administer strictly by intramuscular injection, behind the ear. A long hypodermic needle should be used and the injection given as closely behind the ear as possible and perpendicular to the skin. There is a risk of injecting part of the drug into the fat, if heavy animals are injected with a short needle into the neck. In this case, the injection may have insufficient effect.
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

A dose of 1 mg/kg should not be exceeded in boars as a higher dose may cause the penis to be extruded, which may then be damaged.

The product is injected once-only behind the ear.

After treatment the animal should be left alone in a quiet environment.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

The rubber stopper may be safely punctured up to 50 times. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

9. Advice on correct administration

The full efficacy of the product cannot be expected if the product was administered into the fat tissue.

10. Withdrawal periods

Meat and offal: 18 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the bottle 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 carton and on the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater. These measures should help to protect the environment.

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.
FOR UK(NI) ONLY: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement.

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 20631/3000

Cardboard box with 1 x 100 ml

15. Date on which the package leaflet was last revised

07/2022

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:
Serumwerk Bernburg AG
Hallesche Landstrasse 105B
06406 Bernburg
Germany

<Local representatives> <and contact details to report suspected adverse reactions>:

To be completed nationally.

<17. Other information>

To be completed nationally.

Approved: 08 March 2023