LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

bottle label

Grey shaded text should only appear once on the packaging.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azaporc 40 mg/ml solution for injection for pigs
Azaperone

2. STATEMENT OF ACTIVE SUBSTANCES

Azaperone 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 18 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

Once broached use by_____

11. SPECIAL STORAGE CONDITIONS

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

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

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

Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20631/3000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

Grey shaded text should only appear once on the packaging.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azaporc 40 mg/ml solution for injection for pigs
Azaperone

2. STATEMENT OF ACTIVE SUBSTANCES

Azaperone 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 18 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

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

Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20631/3000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET

PACKAGE LEAFLET:

Azaporc 40 mg/ml Solution for Injection for Pigs

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

Marketing authorisation holder and manufacturer responsible for batch release:
Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azaporc 40 mg/ml solution for injection for pigs
Azaperone

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

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.

4. INDICATION(S)

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. ADVERSE REACTIONS

Salivation, tremor and panting may occur at high doses. These side effects disappear spontaneously and leave no lasting damage.
In boars a reversible prolapse of the penis may occur.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

<u>Aggressive behaviour (devouring of piglets, re-grouping), obstetrics:</u>

2 mg azaperone/kg body weight, corresponding to 1 ml of the product per 20 kg body weight

<u>Stress:</u>

- 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 PERIOD(S)

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.

Shelf-life after first opening the container: 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 WARNING(S)

Special warnings for each target species:
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 use in animals:
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 (symptoms, emergency procedures, antidotes):
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

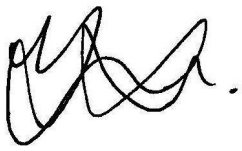
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. OTHER INFORMATION

Nature and composition of immediate packaging:
Clear glass bottle type II sealed with a siliconised bromobutyl rubber stopper and a bordered aluminium-plastic cap.
Package size: Cardboard box with 1 x 100 ml



Approved: 12 August 2021