Version 9, 10/2021

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Azaporc 40 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Azaperone 40.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium metabisulfite (E223)	2.0 mg
Methyl parahydroxybenzoate (E218)	0.5 mg
Propyl parahydroxybenzoate	0.05 mg
Tartaric acid	/
Sodium hydroxide (for pH-adjustment)	/
Water for injections	/

A clear, pale yellow aqueous solution

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

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.

3.3 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.

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The product can be used in pregnant and lactating animals.

3.8 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").

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 18 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05AD90.

4.2 Pharmacodynamics

Azaperone is a neurolepticum from the group of butyrophenones, which is used for pigs due its sedative and anti-aggressive effects.
It blocks central and peripheral dopamine receptors and causes dosage-dependent sedation. Higher dosages trigger extrapyramidal-motor symptoms, such as catalepsy. An apomorphine-antagonising antiemetic effect has been demonstrated. Restraint of the hypothalamic heat-regulating centre in combination with a simultaneous expansion of the peripheral blood vessels causes a slight decrease in temperature. Azaperone counteracts the respiratory depressive effect of opiates and results in deeper breathing of the pigs after therapeutic dosages. With the elimination of the inhibiting effect of dopamine, a prolactin release occurs and after continued use, particularly with rats, changes to the pituitary gland, female reproductive organs and mammary glands occur.
Azaperone still influences the central and peripheral noradrenergic system. It causes a minor bradycardia with reduced cardiac output and a dilatation of the peripheral blood vessels with a decrease in blood pressure. In high concentrations, azaperone antagonises histamine and serotonin.

In pigs, sedation for 1 to 3 hours takes effect within 5 to 10 minutes after therapeutic dosages. All azaperone effects subside after 6 to 8 hours.

4.3 Pharmacokinetics

Parentally administered azaperone distributes quickly and reaches maximum values in the blood, brain and liver after 30 minutes. Levels reached in the brain are 2 to 6 times higher than in the blood. The maximum plasma concentration of the total of azaperone and its metabolites occurs after 45 minutes. Elimination from the plasma takes place in two phases with half-life values of 20 and 150 minutes for azaperone and 1.5 and 6 hours for azaperone and metabolites.
Azaperone is metabolised quickly. Only about 12 % of the dosage remains unchanged 4 hours after subcutaneous injection. The main metabolite azaperol arises with reduction of the butanone component. Its concentration is higher in most body tissues than that of azaperone, but azaperone is more prevalent at the injection site. Additional degradation paths in pigs are the hydroxylation of the pyridine ring and oxidative dearylation, as a result of which an N-formylation of the piperazine ring can occur. The metabolite patterns are the same in the various body tissues; only azaperone and azaperol were found at the injection site.
Azaperol has about ¼ of the sedative and about 1/30 of the temperature-reducing effect, α-(4-fluorphenyl)-1-piperazine butanone about 1/10 of the neuroleptic effect of azaperone.

In pigs, azaperone is eliminated 70 - 90 % via the kidneys and 1 - 6 % via the faeces within 48 hours after therapeutic dosages.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 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

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14 July 2022

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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