1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedanol 40 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Azaperone 40 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 (E 223)	2.0 mg
Methyl parahydroxybenzoate (E 218)	0.5 mg
Propyl parahydroxybenzoate	0.05 mg
Tartaric acid	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Clear, pale yellow to yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

A neuroleptic sedative for pigs:
For the use in animals with aggressive behaviour
- following re-grouping
- in sows (devouring of piglets by the sow)

For the use in animals with stress and prevention of stress
- cardiovascular stress
- transport-related stress

Obstetrics
As pre-medication in local or general anaesthesia
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.

Do not use in case of transport and re-grouping of pigs if they 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.
Injection into adipose tissue may lead to apparent insufficient effect.
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.
Do not re-inject if the animal is unresponsive to the initial dose, allow full recovery before re-injecting on a different day.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 veterinary medicinal 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 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 (cannot be estimated from the available data):	Increased salivation[1]; Tremor[1]; Panting[1]; Penile prolapse[2].

[1] At the highest dose recommended. These side effects disappear spontaneously and leave no lasting damage.
[2] Reversible.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

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.
To be given 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 insignificant effect.
Do not re-inject if the animal is unresponsive to the initial dose, allow full recovery before re-injecting on a different day.

Aggressive behaviour (re-grouping, devouring of piglets), obstetrics
2 mg azaperone/kg bodyweight (i.e. 1 ml veterinary medicinal product per 20 kg bodyweight)

Stress
– Cardiovascular stress
  0.4 mg azaperone/kg bodyweight (i.e. 0.2 ml veterinary medicinal product per 20 kg bodyweight)

– Transport-related stress
  Transport of piglets, weaners and boars
  1.0 mg azaperone/kg bodyweight (i.e. 0.5 ml veterinary medicinal product per 20 kg bodyweight)

  Transport of sows and fattening pigs
  0.4 mg azaperone/kg bodyweight (i.e. 0.2 ml veterinary medicinal product per 20 kg bodyweight)

Premedication in local and general anaesthesia, nutritional muscular dystrophy
1 – 2 mg azaperone/kg bodyweight (i.e. 0.5 – 1 ml veterinary medicinal product per 20 kg bodyweight)

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. Do not administer more than 5 ml per injection site.

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 rubber stopper can be punctured a maximum of 20 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 butyrophenone neuroleptic agent that is used in pigs for its sedative and antiaggressive effects.
It is a central and peripheral dopamine receptor blocker producing dose-related sedation. Higher doses produce extrapyramidal motoric symptoms including catalepsy. An apomorphin-antagonistic antiemetic effect has been demonstrated. Inhibition of the hypothalamic heat regulation centre and concurrent dilation of peripheral blood vessels lead to a small decrease in temperature. Azaperone counteracts the respiratory depressant effect of opiates and given to pigs at therapeutic doses it produces deeper breathing. The elimination of the inhibitory effect of dopamine gives rise to prolactin release and, following chronic administration, to changes in the pituitary gland, female reproductive organs and mammary glands, especially in rats.
Azaperone also has effects on the central and peripheral noradrenergic system. It causes slight bradycardia with reduced cardiac output and dilation of peripheral blood vessels with a drop in blood pressure. At high concentrations, azaperone antagonises histamine and serotonin.

In pigs, the duration of sedation is 1 – 3 hours and onset of sedation and anti-aggressive effects is within 5 – 10 minutes after therapeutic doses. All effects of azaperone have worn off after 6 – 8 hours.

4.3 Pharmacokinetics

Parenterally administered azaperone distributes rapidly and attains peak concentrations in the blood, brain and liver after 30 minutes. The levels attained in the brain are 2- to 6-fold higher than those in the blood. The time to peak plasma concentrations of azaperone and its metabolites is 45 minutes post-dose. Elimination from plasma is biphasic with half-lives of 20 and 150 minutes for azaperone and of 1.5 and 6 hours for azaperone including metabolites.
Azaperone is rapidly metabolised. Four hours after subcutaneous administration, only about 12 % of the dose is present as unchanged drug. The major metabolite azaperol is produced by reduction of the butanone. Its concentration is higher than that of azaperone in most body tissues whilst the azaperone concentration is higher at the injection site. Other metabolic pathways in pigs include hydroxylation of the pyridine group and oxidative dearylation, which may result in N-formylation of the piperazine ring. Metabolite patterns are similar across different body tissues whilst only azaperone and azaperol were detected at the injection site.
Azaperol has about ¼ of the sedative effect and approximately 1/30 of the temperature-lowering effect of azaperone, and α-(4-fluorophenyl)-1-piperazine butanone has approximately 1/10 the neuroleptic effect of azaperone.

After administration of therapeutic doses of azaperone to pigs, 70 – 90 % and 1 – 6 % of a dose are excreted within 48 hours via the kidneys and in faeces, respectively.

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 in 100 ml vial: 3 years
Shelf life of the veterinary medicinal product as packaged for sale in 50 ml vial: 2 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Clear glass vial type I (Ph. Eur.) with chlorobutyl rubber stopper type I (Ph. Eur.) and aluminium pull off or aluminium/plastic flip off cap.

Package size: Cardboard box with 1 x 50 ml, 1 x 100 ml
Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA23462/012/001

8. DATE OF FIRST AUTHORISATION

28/02/2020

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

23/09/2024

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 (https://medicines.health.europa.eu/veterinary).