Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedanol 40 mg/ml solution for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Azaperone	40	mg

Excipients:

Sodium metabisulphite (E223)	2.0	mg
Methylparahydroxybenzoate (E 218)	0.5	mg
Propylparahydroxybenzoate	0.05	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, pale yellow to yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the 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.

4.3 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.

4.4 Special warnings for each target species

During onset of action treated animals should be left alone in a quiet environment.

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.

4.5 Special precautions for use

Special precautions for use in animals
Injection into adipose tissue may lead to apparent insufficient effect.

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.

4.6 Adverse reactions (frequency and seriousness)

Salivation, tremor and panting may occur at the highest dose recommended. These side effects disappear spontaneously and leave no lasting damage.
Reversible penis prolapse may occur in boars.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

- 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").

4.9 Amounts to be administered and administration route

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.

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

Stress
- Cardiovascular stress
0.4 mg azaperone/kg bodyweight (i.e. 0.2 ml 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 product per 20 kg bodyweight)
- Transport of sows and fattening pigs
0.4 mg azaperone/kg bodyweight (i.e. 0.2 ml 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 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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Pigs:
Meat and offal: 14 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Psycholeptics, butyrophenone derivatives, azaperone.
ATC vet code: QN05AD90.

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulfite (E223)
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Tartaric acid
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 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.

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

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

7 MARKETING AUTHORISATION HOLDER

Richter Pharma AG
Feldgasse 19
4600 Wels
Austria

8 MARKETING AUTHORISATION NUMBER(S)

VPA10801/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 February 2020

10 DATE OF REVISION OF THE TEXT