

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box (50 ml, 100 ml))**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Sedanol 40 mg/ml solution for injection for pigs

Azaperone

**2. STATEMENT OF ACTIVE SUBSTANCES**

Azaperone 40 mg/ml

**3. PACKAGE SIZE**

50 ml  
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**

**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**

VetViva Richter 

**14. MARKETING AUTHORISATION NUMBERS**

Vm 57446/4014

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (100 ml clear glass vial with chlorobutyl rubber stopper and alu caps)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Sedanol 40 mg/ml solution for injection

Azaperone

**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 by ...

**7. SPECIAL STORAGE PRECAUTIONS**

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

VetViva Richter (logo)

**9. BATCH NUMBER**

Lot {number}

100 ml

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS (50 ml clear glass vial with chlorobutyl rubber stopper and alu caps)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Sedanol



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Azaperone 40 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, use within 28 days by....

50 ml

VetViva Richter (logo)

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Sedanol 40 mg/ml solution for injection for pigs

**2. Composition**

Each ml contains:

**Active substance:**

Azaperone 40 mg

**Excipients:**

Sodium metabisulfite (E 223)	2.0 mg
Methyl parahydroxybenzoate (E 218)	0.5 mg
Propyl parahydroxybenzoate	0.05 mg

Clear, pale yellow to yellow solution.

**3. Target species**

Pigs

**4. Indications for use**

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

**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.

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.

## 6. Special warnings

### 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.

### 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 unarmoured 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:

Can be used during pregnancy and lactation.

### 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  $\alpha$ -adrenolysis).
- Amplification of tachycardia caused by adrenolytic agents.
- Simultaneous use with  $\alpha$ - and  $\beta$ -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.

### <Special restrictions for use and special conditions for use:>

### 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 (cannot be estimated from the available data):  
Increased salivation<sup>1</sup>; Tremor<sup>1</sup>; Panting<sup>1</sup>; Penile prolapse<sup>2</sup>.

<sup>1</sup>At the highest dose recommended. These side effects disappear spontaneously and leave no lasting damage.

<sup>2</sup>Reversible.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>, e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

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.

## **9. Advice on correct administration**

Refer to section "Dosage for each species, routes and method of administration".

## **10. Withdrawal periods**

Meat and offal: 18 days

## **11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton box after "Exp." The expiry date refers to the last day of that month. Shelf life after first opening the immediate packaging: 28 days

## **12. Special precautions for disposal**

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 applicable national collection systems. These measures should help to protect the environment.

"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 57446/4014

### Package sizes:

1 x 50 ml, 1 x 100 ml

Not all pack sizes may be marketed.

### **15. PID link (Do not print heading)**

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

Tel: +43 (0)664 8455326

E-mail: [adverse.events@vetviva.com](mailto:adverse.events@vetviva.com)

### **17. Other information**

POM-V

Veterinary medicinal product subject to prescription

*Gavin Hall*

Approved: 30 January 2025