

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box

**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. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

1 x 50 ml

1 x 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:  
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**

-

**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**

VetViva Richter GmbH, 4600 Wels, Austria

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 57446/4014

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

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 for pigs

Azaperone

**2. STATEMENT OF ACTIVE SUBSTANCES**

Azaperone 40 mg/ml

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

1 x 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:  
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 by ...

**11. SPECIAL STORAGE CONDITIONS**

-

**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”**

-

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

VetViva Richter GmbH, 4600 Wels, Austria

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 57446/4014

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**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 40 mg/ml solution for injection for pigs

Azaperone

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Azaperone 40 mg/ml

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1 x 50 ml

**4. ROUTE(S) OF ADMINISTRATION**

For intramuscular use. Do not administer more than 5 ml per injection site.

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period: Meat and offal: 18 days.

**6. BATCH NUMBER**

Lot: {number}

**7. EXPIRY DATE**

EXP: {month/year}

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

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **B. PACKAGE LEAFLET**



## PACKAGE LEAFLET:

Sedanol 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:  
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedanol 40 mg/ml solution for injection for pigs

Azaperone

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

1 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.

### 4. INDICATION(S)

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.

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 the highest dose recommended. These side effects disappear spontaneously and leave no lasting damage.

Reversible penis prolapse may occur in boars.

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.

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 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. 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 8.

## **10. WITHDRAWAL PERIOD(S)**

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 WARNING(S)**

Special warnings for each target species:

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 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:

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 adrenergic agents.
- Simultaneous use with  $\alpha$ - and  $\beta$ -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 materials 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**

September 2023

**15. OTHER INFORMATION**

Pharmacological 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.

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.

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.

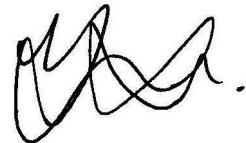
After administration of therapeutic doses of azaperone to pigs, 70 – 90 % and 1 – 6 % of a dose are excreted within 48 hours via the kidneys and in faeces, respectively.

Package sizes:

1 x 50 ml, 1 x 100 ml

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 27 March 2024