[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sediron 40 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 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 (E 218)	0.5 mg
Propyl parahydroxybenzoate	0.05 mg
Tartaric acid	
Sodium hydroxide (for pH adjustment)	
Water for injections	

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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 cases of hypersensitivity to the active substance or to any of the excipients.

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 for transport or re-grouping of pigs which will be slaughtered prior to the end of the withdrawal period.

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.

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 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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersalivation[1] Tremor[1] Panting[1] Penile prolaps[2]

[1] at the highest dose recommended; disappear spontaneously and leave no lasting damage;
[2] reversible; in boars;

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

Intramuscular use.

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)

To be given strictly by intramuscular injection, behind the ear.
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.

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 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.

The rubber stopper can be punctured a maximum of 100 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Aggressive behaviour may occur during awakening in case of overdose.
Repeated 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:

QNO5AD90

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 postdose. 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 substance. The major metabolite azaperol is produced by butanone reduction. 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: 30 months
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 (Type II Ph. Eur.) vials closed with a bromobutyl rubber stopper and sealed with an aluminium cap with central tear off or coloured flip off.

Pack sizes:
Cardboard box containing 1 vial of 100 ml.

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

LIVISTO Int'l, S.L.

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

{MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sediron 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:
Azaperone 40.0 mg

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.

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

LIVISTO Int’l, S.L.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sediron 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:
Azaperone 40.0 mg

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
For intramuscular use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 18 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once opened use by…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LIVISTO Int'l, S.L.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Sediron 40 mg/ml solution for injection for pigs

2. Composition

1 ml contains:

Active substance:

Azaperone	40.0 mg

Excipients:

Sodium metabisulfite (E223)	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 cases of hypersensitivity to the active substance or to any of the excipients.

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 for transport or re-grouping of pigs which will be slaughtered prior to the end of the withdrawal period.

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.

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 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.

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 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”).

Overdose:
Aggressive behaviour may occur during awakening in case of overdose.
Repeated dosing in Vietnamese Pot Bellied pigs may result in death due to absorption of the initial dose in fat.

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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersalivation[1]
Tremor[1]

Panting[1]
Penile prolaps[2]

[1] at the highest dose recommended; disappear spontaneously and leave no lasting damage;
[2] reversible; in boars;

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: {national system details}.

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

Intramuscular use.

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)

To be given strictly by intramuscular injection, behind the ear.
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 100 times.

9. Advice on correct administration

Please refer to section “Dosage for each species, route(s) and method of administration”.
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 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.

10. Withdrawal periods

Meat and offal: 18 days.

11. Special storage precautions

Keep out of the sight and reach of children.

This 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 and carton 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 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 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

XXXXXX

Pack sizes:
Cardboard box containing 1 vial of 100 ml.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29

08290 Cerdanyola del Vallès
(Barcelona), Spain
Tel: +34 934 706 270

Manufacturer responsible for batch release:

Industrial Veterinaria S.A.
C/ Esmeralda, 19
08950 Esplugues des Llobregat
Barcelona
Spain

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Local representatives and contact details to report suspected adverse reactions:

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