

[Version 8.1,01/2017]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedanol 40 mg/ml solution for injection for pigs
(BG, CZ, DE, EE, ES, HR, HU, IE, IT, LT, LV, PL, PT, RO, SI, SK, UK)

Separon 40 mg/ml solution for injection for pigs
(AT, BE, EL, FR, NL)

Separon vet. 40 mg/ml solution for injection for pigs
(DK, FI, IS, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Azaperone	40 mg
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Excipients:

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

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.

4.5 Special precautions for use

Special precautions for use in animals

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 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 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.

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 interaction

- Azaperone has a potentiating effect on all centrally suppressive substances and hypotensive substances (due to peripheral α -adrenolysis).
- Amplification of tachycardia caused by adrenergic 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.

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.

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)

Meat and offal: 18 days

5. PHARMACOLOGICAL 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 product 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

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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
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Separon 40 mg/ml solution for injection for pigs
(AT, BE, EL, FR, NL)

Separon vet. 40 mg/ml solution for injection for pigs
(DK, FI, IS, NO, SE)

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”
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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)
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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
(BG, CZ, DE, EE, ES, HR, HU, IE, IT, LT, LV, PL, PT, RO, SI, SK, UK)

Separon 40 mg/ml solution for injection for pigs
(AT, BE, EL, FR, NL)

Separon vet. 40 mg/ml solution for injection for pigs
(DK, FI, IS, NO, SE)

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”
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-

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)
--

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
(BG, CZ, DE, EE, ES, HR, HU, IE, IT, LT, LV, PL, PT, RO, SI, SK, UK)

Separon 40 mg/ml solution for injection for pigs
(AT, BE, EL, FR, NL)

Separon vet. 40 mg/ml solution for injection for pigs
(DK, FI, IS, NO, SE)

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
(BG, CZ, DE, EE, ES, HR, HU, IE, IT, LT, LV, PL, PT, RO, SI, SK, UK)

Separon 40 mg/ml solution for injection for pigs
(AT, BE, EL, FR, NL)

Separon vet. 40 mg/ml solution for injection for pigs
(DK, FI, IS, NO, SE)

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
(BG, CZ, DE, EE, ES, HR, HU, IE, IT, LT, LV, PL, PT, RO, SI, SK, UK)

Separon 40 mg/ml solution for injection for pigs
(AT, BE, EL, FR, NL)

Separon vet. 40 mg/ml solution for injection for pigs
(DK, FI, IS, NO, SE)

Azaperone

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

1 ml contains:

Active substance:

Azaperone	40 mg
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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 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 (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

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.