ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stresnil 40 mg/ml Solution for Injection for Pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 40 mg azaperone as active, 2.0 mg sodium metabisulphite (E223) as antioxidant, 0.5 mg methyl parahydroxybenzoate (E218) and 0.05 mg propyl parahydroxybenzoate (E216) as antimicrobial preservatives

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml vial

5. TARGET SPECIES

Pigs
<pictogram of pig head>

6. INDICATION(S)

For the prevention and treatment of stress in pigs

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Indications, dosage and administration: Read package leaflet before use.
For intramuscular use only.
Do not administer more than 5 ml per injection site.

8. WITHDRAWAL PERIOD(S)

Meat and Offal: 18 days.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications:
Use of the product should be avoided in very cold conditions because of a possible risk of cardiovascular collapse due to peripheral vasodilation. A dose of 0.5 ml/20 kg should not be exceeded in boars as a higher dose may cause the penis to be

extended, which may then be damaged. Stresnil is contra-indicated for use in transport or for regrouping of pigs which will be slaughtered prior to the end of the 18 day withdrawal period.

Warnings and precautions: Read the package leaflet before use.

Operator warnings: This is a potent drug - particular care should be taken to avoid accidental self administration. Once the required dose has been withdrawn from the vial, keep the needle guarded until the product is administered.
Alternatively, remove the needle from the syringe and immediately insert it into the injection site.
The syringe can then be connected to the inserted needle.
Wash splashes off the skin and eyes immediately with copious water.
Accidental injection is dangerous - read package leaflet before use.
Wash hands after use.

10. EXPIRY DATE

Use by end: {month/year}

11. SPECIAL STORAGE CONDITIONS

Storage precautions:
Do not store above 25 °C.
Keep the vial in the outer carton.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal:
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

UK ONLY: POM-V
To be supplied only on veterinary prescription

IE ONLY: POM
Prescription only medicine

Veterinary Medicinal Product authorised for use in the UK and Ireland

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

16. MARKETING AUTHORISATION NUMBERS

Vm 00879/4198

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stresnil 40 mg/ml Solution for Injection for Pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
40 mg azaperone as active ingredient, 2.0 mg sodium metabisulphite (E223) (as an antioxidant), 0.5 mg methyl parahydroxybenzoate (E218) and 0.05 mg propyl parahydroxybenzoate (E216) (as antimicrobial preservatives).

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

For the prevention and treatment of stress in pigs

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Do not administer more than 5 ml per injection site.

8. WITHDRAWAL PERIOD(S)

Meat and Offal: 18 days.

9. SPECIAL WARNING(S), IF NECESSARY

For indications, dosage, administration, warnings, precautions and disposal advice:
Read package leaflet before use
For intramuscular use only. Accidental injection is dangerous.

10. EXPIRY DATE

Use by end: {month/year}
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
Once broached, use by: _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the vial in the outer carton.

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.

UK: POM-V
IE: POM

UK ONLY: To be supplied only on veterinary prescription
IE ONLY: Prescription only medicine

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook, RG27 9XA

16. MARKETING AUTHORISATION NUMBERS

Vm 00879/4198

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Stresnil 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:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook, RG27 9XA

Manufacturer responsible for batch release:
Elanco France S.A.S.
26 rue de la Chapelle
68330 Huningue,
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stresnil 40 mg/ml Solution for Injection for pigs

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

Each ml of the sterile, clear, pale yellow aqueous solution for injection contains: as active ingredient: 40 mg azaperone, as excipients: 0.5 mg methyl parahydroxybenzoate (E218) and 0.05 mg propyl parahydroxybenzoate (E216), as antimicrobial preservatives, and 2.0 mg sodium metabisulphite (E223) as antioxidant

4. INDICATION(S)

A neuroleptic sedative for pigs to be used for the treatment of:
i) Aggression
- prevention of fighting
- treatment of aggression in sows
ii) Stress, including transport-related stress
iii) Obstetric conditions e.g., cessation of parturition due to excitation, as an obstetric aid in manual delivery, inversion of the vagina, prolapse of the uterus, pathological straining.
iv) Premedication in local and general anaesthesia

5. CONTRAINDICATIONS

The use of the product should be avoided in very cold conditions because of a possible risk of cardiovascular collapse due to peripheral vasodilation.
A dose of 0.5 ml/20 kg should not be exceeded in boars as a higher dose may cause the penis to be extruded, which may then be damaged.
Stresnil is contraindicated for use in transport or for re-grouping of pigs which will be slaughtered prior to the end of the 18-day withdrawal period.

6. ADVERSE REACTIONS

Salivation and panting may occur at high doses. These side effects disappear spontaneously and leave no lasting damage.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs
For animal treatment only.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Method of administration
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. 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.

Dosage
It is important to adhere to the recommended dose. Aggression may only be curbed temporarily or not at all if the dose is too low.
If the dose is too high, aggression may recur after awakening.
Exact dosage will depend on the type and duration of the procedure and concomitant medication.

I. Aggression
Prevention and cure of fighting (including regrouping of piglets, porkers or fattening pigs): 1 ml/20 kg (2 mg/kg).
Pigs from different litters or pens may be brought together into one pen immediately after administration. All animals should be treated. After a few minutes, they lie down together for about 2 hours, irrespective of their origin.
Afterwards, violent fights are unlikely to occur.
During the time of treatment, untreated animals should not be admitted to the run.
The product will not prevent aggressiveness in non-castrated adult boars. Newly weaned piglets may be treated together with other routine treatments on arrival at the fattening unit.
Fighting animals become quiet shortly after injection. The animals are unlikely to fight even after the effect of the drug has worn off.
Treatment of aggression in sows i.e. in sows that do not accept their new-born piglets, or bite them: 1 ml/20 kg (2 mg/kg).
The sow will accept her piglets 1/2 to 1 hour after administration and will also accept piglets from other litters.

II. Stress
Restlessness, anxiety, nervousness, excitation, e.g. because of pain: 0.5-1ml/20 kg (1-2 mg/kg).
The dosage should be adapted to the degree of excitation. If the animal is very nervous, the product may be given in divided doses at 15 minute intervals.
Transport of boars: 0.5 ml/20 kg (1 mg/kg).
The animals should not be brought together within the first half hour following injection because they are still likely to be aggressive; they should be left alone in a quiet environment during the induction period (approximately 30 minutes).
The dose of 0.5 ml/20 kg (1 mg/kg) should not be exceeded as a higher dose may cause the penis to be extruded, which may then be damaged.
Transport of weaners: 1 ml/100 kg to 1 ml/20 kg (0.4–2 mg/kg).
Administer 15–30 minutes before transport to reduce mortality and weight loss during transport. The dose can be increased up to 1 ml/20 kg (2 mg/kg) in order to prevent fighting during transport. Allow adequate space for animals to lie down and ensure that the lorry is adequately ventilated.

III. Obstetrics: 1 ml/20 kg (2 mg/kg)
For use in cessation of parturition due to excitation, as an obstetric aid during manual delivery, inversion of the vagina, prolapse of the uterus, pathological straining.

IV. Premedication in local and general anaesthesia: 0.5-1 ml/20 kg (1-2 mg/kg)
For example in blood sampling, diagnostic examination and minor therapeutic interventions under local anaesthesia (castration, cryptorchidism and prolapse of the rectum, inguinal hernia, wound treatment, insertion of nose rings in boars and sows, etc).

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and Offal: 18 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the vial in the outer carton.
Do not store above 25 °C.
Do not use after the expiry date stated on the label and carton. The date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.
Discard unused material.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special warnings for target species
If the dose exceeds that recommended, aggression may result on reawakening. In boars overdosing (>1 mg/kg) may cause the penis to be extruded, which may then be damaged.
Salivation and panting may occur at high doses.
Repeat dosing in Vietnamese Pot Bellied pigs too soon, because of absorption of the initial dose in fat, has resulted in death. 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 for use in animals
After treatment the animal should be left alone in a quiet environment. Insufficient results may be obtained if the animal is disturbed or chased during the induction period.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This is a potent drug - particular care should be taken to avoid accidental self-administration.
It is recommended that, once the required dose has been withdrawn from the vial, the needle should be kept guarded until the product is administered. Alternatively, the needle should be removed from the syringe and immediately inserted into the injection site, and the syringe should be connected to it.
Wash off splashes from skin and eyes immediately.
In the case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.
Wash hands after use.

Use during pregnancy or lactation
Can be used in pregnant and lactating animals, and in particular obstetric conditions e.g. cessation of parturition due to excitation or as an obstetric aid to manual delivery.

Interaction with other medicinal products and other forms of interaction
When given as premedication for general anaesthesia, the dosage of anaesthetic should be reduced because of the potentiating effect of azaperone.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

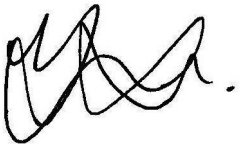
15. OTHER INFORMATION

PACK SIZE
100 ml glass vials.

UK ONLY
Legal category: POM-V
To be supplied only on veterinary prescription
Vm 00879/4198

IE ONLY
Legal category: POM
Prescription only medicine
VPA 22020/007/001

Veterinary medicinal product authorised for use in the UK and Ireland.



Approved: 18 March 2021