Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Stresnil 40 mg/ml Solution for Injection for Pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance		
Azaperone	40	mg
Excipients		
Methyl parahydroxybenzoate (E218) (antimicrobial preservative)	0.5	mg
Propyl parahydroxybenzoate (E216) (antimicrobial preservative)	0.05	mg
Sodium metabisulphite (E223) (antioxidant)	2.0	mg

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A sterile, clear, pale yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

A neuroleptic sedative for pigs to be used for the prevention and treatment of:

i) Aggression
- prevention of fighting
- treatment of aggression in sows

ii) Stress, including transport-related stress

iii) Obstetric conditions, eg cessation of parturition due to excitation, as an obstetric aid in manual delivery, inversion of the vagina, prolapse of theuterus, pathological straining.

iv) Premedication in local and general anaesthesia.

4.3 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 contra-indicated for use in transport or for re-grouping of pigs which will be slaughtered prior to the end of the 10 day withdrawal period.

4.4 Special warnings for each 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 reinjecting on a different day.

4.5 Special precautions for use

i) 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.

ii) 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.

4.6 Adverse reactions (frequency and seriousness)

Salivation and panting may occur at high doses. These side effects disappear spontaneously and leave no lasting damage.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interactions

When given as premedication for general anaesthesia, the dosage of anaesthetic should be reduced because of the potentiating effect of azaperone.

4.9 Amounts to be administered and administration route

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. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

<u>Dosage</u>

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.

I. Aggression.

i) 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 the injection. The animals are unlikely to fight even after the effect of the drug has worn off.

ii) Treatment of aggression in sows i.e. in sows that do not accept their new-born piglets, or bite them: 1 ml/20 kg (2mg/kg).

The sow will accept her piglets ½ to 1 hour after administration and will also accept piglets from other litters.

II. Stress

i) Restlessness, anxiety, nervousness, excitation, e.g. because of pain: 0.5-1 ml/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.

ii) 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.

iii) Transport of weaners: 1ml/100 kg to 1ml/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).

Exact dosage will depend on the type and duration of the procedure and concomitant medication.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 absorbtion of the initial dose in fat has resulted in death.

4.11 Withdrawal period(s)

Pigs: Meat - 10 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nervous system; antipsychotics
ATCvet code: QN05AD90

5.1 Pharmacodynamic properties

Stresnil is a sedative butyrophenone neuroleptic with pronounced α-adrenergic properties for specific use in pigs.

Stresnil produces a predictable psychomotor sedation without narcosis after intramuscular administration. The degree of sedation is dose-related. Adult animals require comparatively lower doses than half-grown animals. At low doses (0.5 mg/kg), the animal is slightly sedated, yet it can be easily driven. With increasing doses, the animal becomes increasingly drowsy and slow. At 2 mg/kg, it lies down for about 2 hours, can hardly be driven and ceases to be aggressive. The induction period is short. Peak effect is reached after about 15 minutes in young animals and 30 minutes in adult animals. The duration of action is 1-3 hours, depending on the dose and the weight of the animal.

5.2 Pharmacokinetic particulars

Azaperone is rapidly absorbed from the injection site and peak concentrations in plasma occur within 1 hour after administration. The elimination from plasma is fast ($T_{½}$ = 2.5 h), due to the rapid and extensive metabolism and excretion.

The main metabolic pathways are:

1) reduction of the butanone
2) oxidative N-dearylation
3) hydroxylation of the pyridine group

The target tissue for azaperone and its metabolites is the liver. Low residue levels are present in muscle and other edible tissues.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Sodium metabisulphite (E223)
Tartaric acid
Sodium hydroxide (for pH adjustment)
Water for injection

6.2 Major incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Container: colourless glass (Type I) vial
Closure: lacquered natural rubber or bromobutyl rubber bung secured with an aluminium overseal.
Each vial contains 100ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1990
Date of last renewal: 9th July 2010

10 DATE OF REVISION OF THE TEXT

June 2018