SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOLENSIA 7 mg/ml solution for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Each ml of solution contains:

Frunevetmab* 7 mg

* Frunevetmab is a felinised monoclonal antibody (mAb) expressed through recombinant techniques in Chinese hamster ovary (CHO) cells.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear to slightly opalescent solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

For the alleviation of pain associated with osteoarthritis in cats.

4.3 Contraindications

Do not use in animals under 12 months and/or under 2.5 kg body weight.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals intended for breeding.
Do not use in pregnant and lactating animals.

4.4 Special warnings for each target species

Continuation of treatment should be based on the individual response of each animal. If a positive response is not observed, consider alternative treatments.

This veterinary medicinal product may induce transient or persistent anti-drug antibodies. The induction of such antibodies may reduce the efficacy of the product although this was not observed during the 84 days of the pivotal clinical trial. No information is available for longer duration treatment.

4.5 Special precautions for use

i) Special precautions for use in animals

The safety and efficacy of this product has not been investigated in cats with kidney disease IRIS stages 3 and 4. Use of the product in such cases should be based on a benefit-risk assessment performed by the responsible veterinarian.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection. Repeated accidental self-administration may increase the risk of hypersensitivity reactions.

The importance of Nerve Growth Factor (NGF) in ensuring normal foetal nervous system development is well-established and laboratory studies conducted on non-human primates with human anti-NGF antibodies have shown evidence of reproductive and developmental toxicity. Pregnant women, women trying to conceive, and breastfeeding women should take extreme care to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

iii) Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Cats:

Common (1 to 10 animals / 100 animals treated):	alopecia, dermatitis, pruritus
Rare (1 to 10 animals / 10,000 animals treated):	injection site reaction (e.g. pain and alopecia)[1] skin disorders (e.g. skin scab, skin sore)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[2]

[1] Mild.
[2] In case of such reactions, appropriate symptomatic treatment should be administered.

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 also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in breeding cats. Laboratory studies with human anti-NGF antibodies in cynomolgus monkeys have shown evidence of teratogenic and foetotoxic effects.

Pregnancy and lactation
Do not use in pregnant or lactating animals.

Fertility
Do not use in breeding animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

There are no safety data on the concurrent use of non-steroidal anti-inflammatory drugs (NSAIDs) and frunevetmab in the cat. In clinical trials in humans, rapidly progressive osteoarthritis has been reported in patients receiving humanised anti-Nerve Growth Factor (NGF) monoclonal antibody therapy. The incidence of these events increased with high doses and in those human patients that received long-term (more than 90 days) non-steroidal anti-inflammatory drugs (NSAIDs) concomitantly with an anti-NGF monoclonal antibody. Cats have no reported equivalent of human rapidly progressive osteoarthritis.

If a vaccine is to be administered at the same time as treatment with frunevetmab, the vaccine should be administered at a different site to that of frunevetmab administration to reduce any potential recruitment of immunogenicity (formation of anti-drug antibodies) to the mAb.

4.9 Amount(s) to be administered and administration route

Subcutaneous use.

Avoid excessive shaking or foaming of the solution. Administer the entire content (1 ml) of the vial.

Dosage and treatment schedule:

The recommended dose is 1-2.8 mg/kg bodyweight, once a month.

Dose according to the dosing chart below.

Bodyweight (kg) of cat	**SOLENSIA (7 mg/ml) volume to be administered**
2.5 - 7.0	**1 vial**
7.1 - 14.0	**2 vials**

For cats greater than 7 kg, withdraw the full contents of two vials into the same syringe and administer as a single dose.

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

No adverse reactions were observed in laboratory overdose studies when Solensia was administered for 6 consecutive monthly doses at 5 times the maximum recommended dose.
In case of adverse clinical signs after an overdose the cat should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other analgesics and antipyretics.

ATCvet Code: QN02BG90.

Mechanism of action
Frunevetmab is a felinised monoclonal antibody (mAb) targeting Nerve Growth Factor (NGF). The inhibition of NGF mediated cell signalling has been demonstrated to provide relief from pain associated with osteoarthritis.

Onset of effect
Frunevetmab was demonstrated to provide analgesic effect within 6 days in an acute inflammatory pain laboratory model.

Pharmacokinetics
In a 6-month laboratory study of healthy, adult cats administered frunevetmab every 28 days at doses ranging from 2.8-14 mg/kg, AUC and C_{max} increased slightly less than in proportion to dose. In a laboratory pharmacokinetic study at 3.0 mg/kg bw in cats diagnosed with osteoarthritis, peak plasma drug levels were observed at 3-7 days (t_{max} = 6.2 days) after subcutaneous dosing, the bioavailability was approximately 60% and the elimination half-life was approximately 10 days.

In a field effectiveness study at the label dose in cats with osteoarthritis, steady-state was achieved after 2 doses.

Frunevetmab, like endogenous proteins, is expected to be degraded into small peptides and amino acids via normal catabolic pathways. Frunevetmab is not metabolised by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

Field trials

In clinical trials up to 3 months, treatment of cats with osteoarthritis was demonstrated to have a favourable effect on the reduction of pain assessed by CSOM (Client-Specific Outcome Measures). CSOM is an assessment of an individual cat's response to pain treatment, as assessed by performance of physical activities, sociability and quality of life. The maximum total CSOM score was 15. A total of 182 animals were enrolled in the frunevetmab treatment group and 93 animals included in the placebo group, in the pivotal field trial. Treatment success, defined as a reduction of ≥2 in the total CSOM score and no increase in any individual score, was achieved in 66.70%, 75.91% and 76.47% of the frunevetmab-treated cats and in 52.06%, 64.65% and 68.09% of placebo-treated cats after one, two and three monthly treatments, respectively. Statistically significant difference ($p<0.05$) compared to placebo-treatment was demonstrated after the first and second treatment, but not after the third treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-histidine
D-sorbitol
Polysorbate 20
Water for injections
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Store in the original package.
Protect from light.

6.5 Nature and composition of immediate packaging

Clear glass Type I vials with bromobutyl rubber stoppers and aluminium overseals.

Cardboard box with 1, 2 or 6 vials.

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

Medicines should not be disposed of via wastewater or household waste.

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5004

9. DATE OF FIRST AUTHORISATION

17 February 2021

10. DATE OF REVISION OF THE TEXT

February 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 12 February 2025