ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOLENSIA 7 mg/ml solution for injection for cats
frunevetmab

2. STATEMENT OF ACTIVE SUBSTANCES

Each vial of 1 ml contains 7 mg frunevetmab

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 x 1 ml
2 x 1 ml
6 x 1 ml

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Store in the original package.
Protect from light.

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL – 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOLENSIA 7 mg/ml solution for injection for cats
frunevetmab

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

frunevetmab 7 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
SOLENSIA 7 mg/ml solution for injection for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

or

Zoetis Belgium SA
Unit 5, Sragh Technology Park
Tullamore
Co. Offaly
IRELAND

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOLENSIA 7 mg/ml solution for injection for cats
frunevetmab

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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.

4. INDICATION(S)

For the alleviation of pain associated with osteoarthritis in cats.

5. 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.

6. ADVERSE REACTIONS

Focal skin reactions (e.g. pruritus, dermatitis and alopecia) occurred commonly in studies.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Cats.

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

Subcutaneous use.

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

The product should appear clear to slightly opalescent solution.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid excessive shaking or foaming.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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
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.

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.

Pregnancy and lactation:

Do not use in pregnant and lactating animals.

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.

Overdose (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

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

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Primary packaging: Single dose clear glass Type I vials with bromobutyl rubber stopper and aluminium overseals.

Secondary packaging: cardboard box.

Cardboard box with 1, 2 or 6 vials.

Not all pack sizes may be marketed.

Approved: 17 February 2021