

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Portela 2.5 mg solution for injection for cats

Portela 6.4 mg solution for injection for cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 1 ml contains:

### Active substances:

relfovetmab\*: 2.5 mg  
6.4 mg

\* Relfovetmab is a felinised anti-nerve growth factor (NGF) monoclonal antibody expressed through recombinant techniques in Chinese hamster ovary (CHO) cells.

### Excipients:

Qualitative composition of excipients and other constituents
Sucrose
Sodium acetate trihydrate
Poloxamer 188
Acetic acid glacial
L-methionine
Disodium EDTA dihydrate
Water for injections

Clear to slightly opalescent solution without any visible particles.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cats.

### 3.2 Indications for use for each target species

For the alleviation of pain associated with osteoarthritis in cats.

### 3.3 Contraindications

Do not use in animals under 12 months.

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 or lactating animals.

### **3.4 Special warnings**

This veterinary medicinal product may induce anti-drug antibodies, including neutralising anti-drug antibodies (immunogenicity). In the clinical trials, the effect of immunogenicity on safety or efficacy could not be determined due to the limited number of animals presenting anti-drug antibodies after either one dose of 0.5 mg relfovetmab per kg of body weight (3/68 cats) or three doses of 0.5-1.25 mg relfovetmab per kg of body weight every 3 months (3/152 cats). No information is available over a treatment period longer than 9 months.

Immunogenicity has not been investigated in cats previously treated with other anti-NGF monoclonal antibodies. Continuation of treatment should be based on the individual response of each animal. If a positive response is not observed, consider alternative treatments.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

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

In the clinical trials, joint radiographs were only taken at screening. Therefore, potential negative effects on the progression of the osteoarthritis have not been investigated.

#### 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-injection may increase the risk of hypersensitivity reactions.

In humans, minor and reversible peripheral neurological signs (for example, paraesthesia, dysesthesia, hypoesthesia) have been reported in a small subset of patients receiving therapeutic doses of human anti-NGF monoclonal antibodies. The frequency of these events is dependent on factors such as dose level and duration of dosing. These events were transitory and reversible upon discontinuation of treatment.

The importance of 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.

If adverse effects occur following accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

#### Special precautions for the protection of the environment:

Not applicable.

### **3.6 Adverse events**

Cats:

Very common (>1 animal / 10 animals treated):	Immediate pain upon injection
Common (1 to 10 animals / 100 animals treated):	Dermatitis
Uncommon (1 to 10 animals / 1 000 animals treated):	Pruritus Skin scabs Injection site swelling Injection site hair loss

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 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.

### 3.8 Interaction with other medicinal products and other forms of interaction

There are no safety data on the concurrent long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) and relfovetmab in cats. In clinical trials in humans, rapidly progressive osteoarthritis has been reported in patients receiving humanised anti-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) NSAIDs concomitantly with an anti-NGF monoclonal antibody.

No laboratory studies on the safety of concomitant administration of this veterinary medicinal product with other veterinary medicinal products have been conducted.

If a vaccine(s) is to be administered at the same time as treatment with the veterinary medicinal product, the vaccine(s) should be administered at a different site to that of the veterinary medicinal product administration.

### 3.9 Administration routes and dosage

Subcutaneous use.

#### Dosage and treatment schedule:

The recommended dose is 0.5-1.25 mg/kg body weight, once every three months.

Dose according to the dosing chart below.

Body weight (kg) of cat	Portela number of vials to be administered	
	2.5 mg vial	6.4 mg vial
2.5 - 5.0	1	-
5.1 - 12.8	-	1

For cats between 12.9 kg and 13.7 kg, the contents of one 2.5 mg vial and one 6.4 mg vial are required. In those cases, withdraw the content from each required vial into the same syringe and administer as a single dose.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Relfovetmab was evaluated in laboratory-based safety studies where the product was dosed up to 5x the maximum recommended dose once every three months over a six-month period in one study, and up to 23x the maximum recommended dose, dosed monthly (3x increased dosing frequency compared to the clinical dosing schedule), for seven consecutive doses in a separate six-month study. These studies identified focal skin reactions (pruritus, abrasions, alopecia, or scabs mostly around the face, base of ears, and neck) that were generally found to increase in incidence with increasing dose.

In case of adverse clinical signs after an overdose, the cat should be treated symptomatically.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QN02BG92

### 4.2 Pharmacodynamics

#### Mechanism of action:

Relfovetmab is a felinised monoclonal antibody (mAb) targeting nerve growth factor (NGF). NGF binds to TrkA receptors located on immune cells to elicit the release of additional proinflammatory mediators, including NGF itself. These inflammatory mediators lead to further peripheral sensitisation involved in pain perception. The inhibition of NGF was demonstrated to provide relief from pain associated with osteoarthritis.

#### Clinical trials:

In a randomised, double masked, multi-centre clinical trial, the efficacy of relfovemab was evaluated in cats with naturally occurring OA (osteoarthritis) that were treated every three months at the recommended dose (0.5 - 1.25 mg/kg). Relfovetmab significantly improved scores as assessed by cat owners using client-specific outcome measures (CSOM), and reduced pain as assessed by veterinarians using a categorical pain assessment. 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.

A total of 153 animals were enrolled in the relfovemab treatment group, and 154 animals were included in the placebo group. Treatment success, defined as a reduction of  $\geq 2$  in the total CSOM

score and no increase in any individual score, was achieved in 72.9%, 78.9% and 79.3% of the relfovetmab-treated cats and in 46.2%, 41.4% and 41.8% of placebo-treated cats assessed three months after one, two and three treatments, respectively. Treatment success on veterinary categorical assessment (VCA), defined as a decrease of  $\geq 1$  score, was achieved in 60.6%, 72.2% and 71.4% of the relfovetmab-treated cats and in 35.5%, 33.1% and 31.9% of placebo-treated cats assessed three months after one, two and three treatments, respectively. Statistically significant difference ( $p < 0.05$ ) compared to placebo treatment was demonstrated after all three treatments for both CSOM- and VCA-based treatment successes. The favourable effect on CSOM score was observed within 3 days in this clinical trial.

### **4.3 Pharmacokinetics**

In laboratory cats with naturally occurring OA, when relfovetmab was administered at the recommended dose (0.5 – 1.25 mg/kg), maximum serum drug concentration ( $C_{max}$ ) following subcutaneous administration was 2.95 mcg/ml and occurred on average 3.6 days post-dosing. Bioavailability by the subcutaneous route was 41.8% and the elimination half-life was 5.4 days. Relfovetmab exposure increased in proportion to dose between 1.25 – 6.25 mg/kg.

In a 9-month repeat dose clinical trial for safety and efficacy of relfovetmab in cats with OA, no accumulation was observed with repeat dosing.

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

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### **5.2 Shelf life**

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

### **5.3 Special precautions for storage**

Store and transport refrigerated (2 °C – 8 °C).  
Do not freeze.  
Store in the original package.  
Protect from light.

### **5.4 Nature and composition of immediate packaging**

Clear glass type I vials with fluorobutyl rubber stopper and aluminium overseal with propylene flip-off disk.

Pack sizes:

Cardboard box with 1 vial of 1 ml.  
Cardboard box with 2 vials of 1 ml.  
Cardboard box with 6 vials of 1 ml.

Not all pack sizes may be marketed.

**5.5 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.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium

**7. MARKETING AUTHORISATION NUMBER(S)**

EU/2/25/353/001-006

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 27/10/2025.

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**ANNEX II**

**OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

## **SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:**

The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: annually.

The MAH shall provide a written summary of a cumulative analysis (including the review of case narratives), at the level of VeDDRA preferred terms (PT), or groups of PTs as appropriate, for musculoskeletal adverse events, at the time of the submission of the annual statement. The applicant should also provide a cumulative analysis and assessment of adverse event reports of lack of efficacy. The written summary should be recorded within the annual statement.

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Portela 2.5 mg Solution for injection 2.5 – 5.0 kg  
Portela 6.4 mg Solution for injection 5.1 – 12.8 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains 2.5 mg relfovetmab.  
Each ml contains 6.4 mg relfovetmab.

**3. PACKAGE SIZE**

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

**4. TARGET SPECIES**

Cats.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

s.c.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.  
Do not freeze.  
Store in the original package.  
Protect from light.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium

**14. MARKETING AUTHORISATION NUMBERS**

EU/2/25/353/001 (2.5 – 5.0 kg, 2.5 mg, 1 x 1 ml)  
EU/2/25/353/002 (2.5 – 5.0 kg, 2.5 mg, 2 x 1 ml)  
EU/2/25/353/003 (2.5 – 5.0 kg, 2.5 mg, 6 x 1 ml)  
EU/2/25/353/004 (5.1 – 12.8 kg, 6.4 mg, 1 x 1 ml)  
EU/2/25/353/005 (5.1 – 12.8 kg, 6.4 mg, 2 x 1 ml)  
EU/2/25/353/006 (5.1 – 12.8 kg, 6.4 mg, 6 x 1 ml)

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**VIAL – 1 ML**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Portela

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

relfovetmab

2.5 mg

6.4 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use immediately.

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Portela 2.5 mg solution for injection for cats

Portela 6.4 mg solution for injection for cats

### 2. Composition

#### Active substances:

Each vial of 1 ml contains 2.5 mg or 6.4 mg relfovetmab\*.

\* Relfovetmab is a felinised anti-nerve growth factor (NGF) monoclonal antibody expressed through recombinant techniques in Chinese hamster ovary (CHO) cells.

Clear to slightly opalescent solution without any visible particles.

### 3. Target species

Cats.

### 4. Indications for use

For the alleviation of pain associated with osteoarthritis in cats.

### 5. Contraindications

Do not use in animals under 12 months.

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 or lactating animals.

### 6. Special warnings

#### Special warnings:

This veterinary medicinal product may induce anti-drug antibodies, including neutralising anti-drug antibodies (immunogenicity). In the clinical trials, the effect of immunogenicity on safety or efficacy could not be determined due to the limited number of animals presenting anti-drug antibodies after either one dose of 0.5 mg relfovetmab per kg of body weight (3/68 cats) or three doses of 0.5-1.25 mg relfovetmab per kg of body weight every 3 months (3/152 cats). No information is available over a treatment period longer than 9 months.

Immunogenicity has not been investigated in cats previously treated with other anti-NGF monoclonal antibodies. Continuation of treatment should be based on the individual response of each animal. If a positive response is not observed, consider alternative treatments.

#### Special precautions for safe use in the target species:

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

In the clinical trials, joint radiographs were only taken at screening. Therefore, potential negative effects on the progression of the osteoarthritis have not been investigated.

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-injection may increase the risk of hypersensitivity reactions.

In humans, minor and reversible peripheral neurological signs (for example, paraesthesia, dysesthesia, hypoesthesia) have been reported in a small subset of patients receiving therapeutic doses of human anti-NGF monoclonal antibodies. The frequency of these events is dependent on factors such as dose level and duration of dosing. These events were transitory and reversible upon discontinuation of treatment.

The importance of 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.

If adverse effects occur following accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:

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.

Do not use in pregnant or lactating animals.

Fertility:

Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:

There are no safety data on the concurrent long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) and relfovetmab in cats. In clinical trials in humans, rapidly progressive osteoarthritis has been reported in patients receiving humanised anti-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) NSAIDs concomitantly with an anti-NGF monoclonal antibody.

No laboratory studies on the safety of concomitant administration of this veterinary medicinal product with other veterinary medicinal products have been conducted.

If a vaccine(s) is to be administered at the same time as treatment with the veterinary medicinal product, the vaccine(s) should be administered at a different site to that of the veterinary medicinal product administration.

Overdose:

Relfovetmab was evaluated in laboratory-based safety studies where the product was dosed up to 5x the maximum recommended dose once every three months over a six-month period in one study, and up to 23x the maximum recommended dose, dosed monthly (3x increased dosing frequency compared to the clinical dosing schedule), for seven consecutive doses in a separate six-month study. These studies identified focal skin reactions (pruritus, abrasions, alopecia, or scabs mostly around the face, base of ears, and neck) that were generally found to increase in incidence with increasing dose.

In case of adverse clinical signs after an overdose, the cat should be treated symptomatically.

### Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## **7. Adverse events**

Cats:

Very common (>1 animal / 10 animals treated):	Immediate pain upon injection
Common (1 to 10 animals / 100 animals treated):	Dermatitis
Uncommon (1 to 10 animals / 1 000 animals treated):	Pruritus Skin scabs Injection site swelling Injection site hair loss

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## **8. Dosage for each species, routes and method of administration**

Subcutaneous use.

### Dosage and treatment schedule:

The recommended dose is 0.5-1.25 mg/kg body weight, once every three months.

Dose according to the dosing chart below.

Body weight (kg) of cat	Portela number of vials to be administered	
	2.5 mg vial	6.4 mg vial
2.5 - 5.0	1	-
5.1 - 12.8	-	1

For cats between 12.9 kg and 13.7 kg, the contents of one 2.5 mg vial and one 6.4 mg vial are required. In those cases, withdraw the content from each required vial into the same syringe and administer as a single dose.

## **9. Advice on correct administration**

None.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store and transport refrigerated (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. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

## **12. Special precautions for disposal**

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

EU/2/25/353/001-006

Clear glass type I vials with fluorobutyl rubber stopper and aluminium overseal with propylene flip-off disk.

Cardboard box with 1, 2 or 6 vials of 1 ml.

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Zoetis Belgium  
Rue Laid Burniat 1  
1348 Louvain-La-Neuve  
Belgium

**België/Belgique/Belgien**  
Tél/Tel: +32 (0) 800 99 189  
[pharmvig-belux@zoetis.com](mailto:pharmvig-belux@zoetis.com)

**Lietuva**  
Tel: +370 610 05088  
[zoetis.lithuania@zoetis.com](mailto:zoetis.lithuania@zoetis.com)

**Република България**  
Тел: +359 888 51 30 30  
[zoetisromania@zoetis.com](mailto:zoetisromania@zoetis.com)

**Česká republika**  
Tel: +420 257 101 111  
[infovet.cz@zoetis.com](mailto:infovet.cz@zoetis.com)

**Danmark**  
Tlf: +45 70 20 73 05  
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[infoqr@zoetis.com](mailto:infoqr@zoetis.com)

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Tel: +370 610 05088  
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Tel.: +36 1 224 5200  
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Tel: +356 21 465 797  
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**Nederland**  
Tel: +31 (0)10 714 0900  
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**Sverige**  
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