

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Portela 6.4 mg solution for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 1 ml contains:

Active substances:

relfovetmab*: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 of age.

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 transient or persistent anti-drug antibodies (immunogenicity), including neutralising anti-drug antibodies.

In clinical studies, a small proportion of cats developed anti-drug antibodies after one or multiple doses. At the proposed commercial dose (0.5 mg relfovetmab per kg body weight), the incidence of anti-drug antibodies ranged from approximately 2% to 4%.

Due to the limited number of animals developing anti-drug antibodies, the impact of immunogenicity on safety or efficacy could not be determined. No adverse events directly attributable to anti-drug antibodies were identified. No information is available for treatment periods 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:

As the following conditions were not studied in clinical trials, the safety of relfovetmab has not been established in cats with intervertebral disc disease, recent injuries resulting in neurologic deficit(s) or lameness due to neoplasia, primary neurologic or immunologic disorders, infection, recent joint trauma, non-healed fractures, or ligament ruptures within six months.

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 radiographically.

The efficacy and safety of the veterinary medicinal product have not been studied in cats weighing less than 2.5 kg or more than 13.7 kg.

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 neurologic 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 nerve growth factor 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.

This veterinary medicinal product may cause eye irritation. Avoid contact with the eyes. In case of accidental contact with eyes, rinse thoroughly with water. If irritation persists, seek medical advice and show package leaflet or the 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

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.

Cats have no reported equivalent of human rapidly progressive osteoarthritis.

No interactions were observed in clinical trials where this veterinary medicinal product was administered concomitantly with veterinary medicinal products including anaesthetics, systemic antimicrobials, endectocides, psycholeptics, anti-inflammatory medications and ectoparasiticides. 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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	6.4 mg
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 to administer a single dose. In those cases, withdraw the content from each required vial into the same syringe and administer as a single subcutaneous injection.

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 5-fold the maximum recommended dose once every three months over a six-month period in one study, and up to 23-fold the maximum recommended dose, dosed monthly (3-fold increased dosing frequency compared to the clinical dosing schedule), for seven consecutive doses in a separate six-month study. Relfovetmab exposure increased in proportion to the dose administered in both studies. 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 has been found to be elevated in the osteoarthritic joints of cats. Following a noxious stimulus, inflammatory cytokines and NGF are released by tissues of the joint. 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 mediated cell signalling reduces neurite outgrowth, neurogenic inflammation, inflammatory degradation mediators such as matrix metalloproteinases and has demonstrated to provide relief from pain associated with osteoarthritis (OA).

Clinical trials:

In a randomised, double masked, multi-centre clinical trial, the efficacy of relfovemab was evaluated in cats with naturally occurring OA that were treated every three months at the approved label dose (0.5 - 1.25 mg/kg). Relfovetmab significantly reduced pain as assessed by cat owners using Client-Specific Outcome Measures (CSOM), by veterinarians using a categorical pain assessment and improved subjective scores of quality of life, temperament and happiness of the cats. 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 ≥ 2 in the total CSOM score and no increase in any individual score, was achieved in 73.0%, 79.5% and 81.6% of the relfovetmab-treated cats and in 46.8%, 41.5% and 42.2% 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. Relfovetmab was demonstrated to provide analgesic effect within 3 days in a clinical trial in cats with naturally occurring OA.

4.3 Pharmacokinetics

In laboratory cats with naturally occurring OA, when relfovetmab was administered at the approved label 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.

In a 6-month single dose clinical trial for safety and efficacy of relfovetmab in cats with OA, the elimination half-life was approximately 9 days. However, due to the infrequent sampling during this study, this calculated half-life may not be as accurate as that determined in the laboratory study (5.4 days). 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.

Immunogenicity:

In a 9-month repeat dose clinical trial for safety and efficacy at the approved label dose (0.5 - 1.25 mg/kg) in adult cats with OA, immunogenicity was infrequently observed (2% of treated cats). Immunogenicity may have no effect or may result in a decrease in efficacy. There were no adverse events related to the immunogenicity findings.

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 UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5215

8. DATE OF FIRST AUTHORISATION

17 July 2026

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

July 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 29 July 2026