# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imoxat 80 mg + 8 mg spot-on solution for large cats.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substances:**

Imoxat for large cats contains 100 mg/ml imidacloprid and 10 mg/ml moxidectin.

Each unit dose (pipette) delivers:

| | Unit dose | Imidacloprid | Moxidectin |
|---|---|---|---|
| Imoxat for large cats (> 4–8 kg) | 0.8 ml | 80 mg | 8 mg |

**Excipients:**

Benzyl alcohol
Butylhydroxytoluene 1 mg/ml (E321).

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution.

Colourless to yellow solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cats.

### 4.2 Indications for use, specifying the target species

**For cats** suffering from, or at risk from, mixed parasitic infections:

- the treatment and prevention of flea infestation (*Ctenocephalides felis*),
- the treatment of ear mite infestation (*Otodectes cynotis*),
- the treatment of notoedric mange (*Notoedres cati*),
- the treatment of the lungworm *Eucoleus aerophilus* (syn. *Capillaria aerophila*) (adults),
- the prevention of lungworm disease (L3/L4 larvae of *Aelurostrongylus abstrusus*),
- the treatment of the lungworm *Aelurostrongylus abstrusus* (adults),
- the treatment of the eye worm *Thelazia callipaeda* (adults),

- the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*),
- the treatment of infections with gastrointestinal nematodes (L4 larvae, immature adults and adults of *Toxocara cati* and *Ancylostoma tubaeforme*).

The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

## 4.3 Contraindications

Do not use in kittens under 9 weeks of age.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.
For ferrets: do not use Imoxat for dogs. Only “Imoxat for small cats and ferrets” (0.4 ml) must be used.

For dogs, the corresponding “Imoxat for dog” product, which contains 100 mg/ml imidacloprid and 25 mg/ml moxidectin, must be used.

Do not use on canaries.

## 4.4 Special warnings for each target species

Please refer to section 4.5.

Brief contact of the animal with water on one or two occasions between monthly treatments is unlikely to significantly reduce the efficacy of the product. However, frequent shampooing or immersion of the animal in water after treatment may reduce the efficacy of the veterinary medicinal product.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. Therefore, the use of this veterinary medicinal product should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species in order to limit the possibility of a future selection for resistance.

The use of the veterinary medicinal product should be based on the confirmed diagnosis of mixed infection (or risk of infection, where prevention applies) at the same time (see also sections 4.2 and 4.9).

## 4.5 Special precautions for use

Special precautions for use in animals

The treatment of cats weighing less than 1 kg should be based on a benefit-risk assessment.

There is limited experience on the use of the veterinary medicinal product in sick and debilitated animals, thus the veterinary medicinal product should only be used based on a benefit-risk assessment for these animals.

Do not apply in the mouth, in the eyes or the ears of the animal.

Care should be taken that the veterinary medicinal product is not ingested by animals and does not come into contact with the eyes or mouth of the recipient and/or other animals.

Consider carefully the correct application method described in section 4.9, especially that the veterinary medicinal product should be applied to the site specified in order to minimise the risk for the animal to lick the veterinary medicinal product.

Do not allow recently treated animals to groom each other. Do not allow treated animals to come into contact with untreated animals until the application site is dry.

In case of accidental oral uptake, symptomatic treatment should be administered. There is no known specific antidote. The use of activated charcoal may be beneficial. It is recommended that cats living in, or travelling to areas endemic for heartworm are treated monthly with the veterinary medicinal product to protect them from heartworm disease.

Whilst the accuracy of diagnosis of heartworm infection is limited, it is recommended that attempts be made to check the heartworm status of any cat aged over 6 months, before beginning prophylactic treatment, as use of the veterinary medicinal product on cats which have adult heartworms may cause serious adverse effects, including death. If adult heartworm infection is diagnosed, the infection should be treated in accordance with current scientific knowledge.

In certain individual cats *Notoedres cati* infestation may be severe. In these severe cases concomitant supportive treatment is necessary as treatment with the veterinary medicinal product alone may not be sufficient to prevent death of the animal.

Imidacloprid is toxic for birds, especially canaries.
Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with skin, eyes or mouth.
Do not eat, drink or smoke during application.
Wash hands thoroughly after use.
After application do not stroke or groom animals until the application site is dry.
In case of accidental spillage onto skin, wash off immediately with soap and water.
People with known hypersensitivity to benzyl alcohol, imidacloprid or moxidectin should administer the veterinary medicinal product with caution. In very rare cases the veterinary medicinal product may cause skin sensitisation or transient skin reactions (for example numbness, irritation or burning/tingling sensation).
In very rare cases the veterinary medicinal product may cause respiratory irritation in sensitive individuals.
If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with water.
If skin or eye symptoms persist, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

The solvent in the veterinary medicinal product may stain or damage certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

## 4.6 Adverse reactions (frequency and seriousness)

Use of the veterinary medicinal product may result in transient pruritus in cats. On rare occasions greasy fur, erythema and vomiting can occur. These signs disappear without further treatment. The veterinary medicinal product may, in rare cases, cause local hypersensitivity reactions. If the animal licks the application site after treatment, neurological signs (most of which are transient) may be observed in very rare cases (see section 4.10).

The veterinary medicinal product tastes bitter. Salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application will minimise licking of the application site.

The veterinary medicinal product may in very rare cases cause at the application site a sensation resulting in transient behavioural changes such as lethargy, agitation, and inappetence.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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).

## 4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Therefore, the use of the product is not recommended in animals intended for breeding or during pregnancy and lactation.

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

During treatment with the veterinary medicinal product no other antiparasitic macrocyclic lactone should be administered.

No interactions between the veterinary medicinal product and routinely used veterinary medicinal products or medical or surgical procedures have been observed.

## 4.9 Amounts to be administered and administration route

Dosage schedule for cats

The recommended minimum doses are 10 mg/kg bodyweight imidacloprid and 1.0 mg/kg bodyweight moxidectin, equivalent to 0.1 ml/kg bodyweight of the veterinary medicinal product.

The treatment schedule should be based on individual veterinary diagnosis and on the local epidemiological situation.

| Weight of cat [kg] | Pipette size to be used | Volume [ml] | Imidacloprid [mg/kg bw] | Moxidectin [mg/kg bw] |
|---|---|---|---|---|
| > 4–8 kg | Imoxat for large cats | 0.8 | 10–20 | 1–2 |

*Flea treatment and prevention (Ctenocephalides felis)*
One treatment prevents future flea infestation for 4 weeks. Existing pupae in the environment may emerge for 6 weeks or longer after treatment is initiated, depending upon climatic conditions. Therefore, it may be necessary to combine animal treatment with environmental treatments aimed at breaking the flea life cycle in the surroundings. This can result in a more rapid reduction in the household flea population. The veterinary medicinal product should be administered at monthly intervals when used as part of a treatment strategy for flea allergy dermatitis.

*Treatment of ear mite infestation (Otodectes cynotis)*
A single dose of the veterinary medicinal product should be administered. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment. Do not apply directly to the ear canal.

*Treatment of notoedric mange (Notoedres cati)*
A single dose of the veterinary medicinal product should be administered.

*Treatment of the lungworm Eucoleus aerophilus (syn. Capillaria aerophila) (adults)*
A single dose of the veterinary medicinal product should be administered.

*Prevention of Aelurostrongylus abstrusus*
The veterinary medicinal product should be administered monthly.

*Treatment of Aelurostrongylus abstrusus*
The veterinary medicinal product should be administered monthly for three consecutive months.

*Treatment of the eye worm Thelazia callipaeda (adults)*
A single dose of the veterinary medicinal product should be administered.

*Heartworm prevention (Dirofilaria immitis)*
Cats in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to treatment with the veterinary medicinal product, the advice provided in section 4.5 should be considered.

For prevention of heartworm disease, the veterinary medicinal product must be applied at regular monthly intervals during the time of the year when mosquitoes (the intermediate hosts which carry and transmit heartworm larvae) are present. The veterinary medicinal product may be administered throughout the year. The first dose may be given after first possible exposure to mosquitoes, but not more than one month after this exposure. Treatment should continue at regular monthly intervals until 1 month after the last exposure to mosquitoes. To establish a treatment routine, it is recommended that the same day or date be used each month. When replacing

another heartworm preventative product in a heartworm prevention programme, the first treatment with the veterinary medicinal product must be given within 1 month of the last dose of the former medication.

In non-endemic areas there should be no risk of cats having heartworm. Therefore, they can be treated without special precautions.

*Roundworm and hookworm treatment (Toxocara cati and Ancylostoma tubaeforme)*
In areas endemic for heartworm, monthly treatment may significantly reduce the risk of re-infection caused by the respective roundworms and hookworms. In areas non-endemic for heartworm, the product can be used as part of a seasonal prevention programme against fleas and gastrointestinal nematodes.

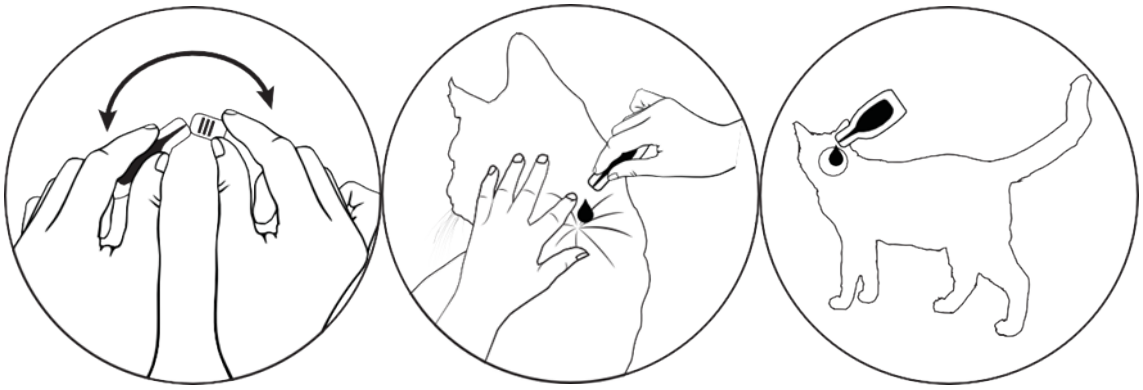
Method of administration

Spot-on use.

For external use only.

Remove one pipette from the package. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Snap back the tip of the pipette to enable the contents to be expelled**.**

Part the fur on the animal's neck at the base of the skull until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette firmly several times to empty its contents directly onto the skin. Application at the base of the skull will minimise the opportunity for the animal to lick the product. Apply only to undamaged skin.



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

Up to 10 times the recommended dose was tolerated in cats with no evidence of adverse effects or undesirable clinical signs.
The veterinary medicinal product was administered to kittens at up to 5 times the recommended dose, every 2 weeks for 6 treatments, and there were no serious safety concerns. Transient mydriasis, salivation, vomiting and transient rapid respiration were observed.
After accidental oral ingestion or overdose, neurological signs (most of which are transient) such as ataxia, generalised tremors, ocular signs (dilated pupils, little

pupillary reflex, nystagmus), abnormal respiration, salivation and vomiting may occur in very rare cases.

### 4.11 Withdrawal period(s)

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents, macrocyclic lactones, milbemycins. ATCvet code: QP54AB52.

### 5.1 Pharmacodynamic properties

Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine. Imidacloprid is active against larval flea stages and adult fleas. Flea larvae in the pet's surroundings are killed after contact with a pet treated with the product. Imidacloprid has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) of the flea. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptors and the postulated poor penetration through the blood-brain barrier in mammals, it has virtually no effect on the mammalian CNS. Imidacloprid has minimal pharmacological activity in mammals.

Moxidectin, 23-(O-methyloxime)-F28249 alpha is a second-generation macrocyclic lactone of the milbemycin family. It is a parasiticide which is active against many internal and external parasites. Moxidectin is active against larval stages (L3, L4) of *Dirofilaria immitis.* It is also active against gastrointestinal nematodes. Moxidectin interacts with GABA and glutamate-gated chloride channels. This leads to opening of the chloride channels on the postsynaptic junction, the inflow of chloride ions and induction of an irreversible resting state. The result is flaccid paralysis of affected parasites, followed by their death and/or expulsion. The veterinary medicinal product has a persistent action and protects cats for 4 weeks after a single application against reinfection with *Dirofilaria immitis.*

### 5.2 Pharmacokinetic particulars

After topical administration of the veterinary medicinal product, imidacloprid is rapidly distributed over the animal's skin within one day of application. It can be found on the body surface throughout the treatment interval. Moxidectin is absorbed through the skin, reaching maximum plasma concentrations approximately 1 to 2 days after treatment in cats. Following absorption from the skin, moxidectin is distributed systemically throughout the body tissues but due to its lipophilicity it is concentrated mainly in the fat. It is slowly eliminated from the plasma as manifested by detectable moxidectin concentrations in plasma throughout the treatment interval of one month.

The mean T ½ in cats ranges between 18.7 and 25.7 days. Studies evaluating the pharmacokinetic behaviour of moxidectin after multiple applications have indicated

that steady state serum levels are achieved following approximately 4 consecutive monthly treatments in cats.

**Environmental properties**

Moxidectin has been classified as persistent, bioaccumulative and toxic in the environment.

See section 6.6.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzyl alcohol
Butylhydroxytoluene (E321)
Propylene carbonate

### 6.2 Major incompatibilities

Not applicable

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

### 6.4 Special precautions for storage

Store in the original package in order to protect from light and moisture.
Do not store above 25°C.

### 6.5 Nature and composition of immediate packaging

Pipette: a white pipette composed of a heat-formed shell composed of (polypropylene (PP)/cyclic olefin copolymer (COC)/ethylene vinyl alcohol (EVOH)/polypropylene(PP) with a snap off cap.
Sachet: polyethylene (PET)/aluminium foil/nylon/low density polyethylene (LDPE)

Pack size: 0.8 ml per pipette
Each cardboard box contains 1 or 3 pipettes in individual foil sachets.

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

The veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

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

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

## 8. MARKETING AUTHORISATION NUMBER

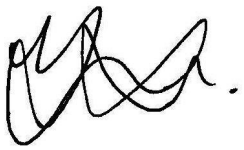
Vm 08749/5029

## 9. DATE OF FIRST AUTHORISATION

25 March 2022

## 10. DATE OF REVISION OF THE TEXT

April 2023



Approved: 28 April 2023