## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strantel 230/20 mg Flavoured Film-Coated Tablets for Cats (IT, UK)
Strantel Clément Thékan 230/20 mg Film-Coated Tablets for Cats (FR)
Wormaway 230/20mg Flavoured film-coated tablets for cats (IE)
Exitel Kat 230/20 mg Flavoured Film Coated Tablets for Cats (NL)
CESTAGUARD Cat, Tablets for Cats (RO)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

**Active substances:**

Pyrantel embonate 230 mg
Praziquantel 20 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| **Core tablet:** |
| Maize starch |
| Microcrystalline cellulose |
| Crospovidone |
| Magnesium stearate |
| Colloidal anhydrous silica |
| **Film coat** |
| Grilled meat flavour |
| Opadry II White consisting of Polyvinyl Alcohol, Titanium Dioxide (E171), Macrogol 3350 and Talc (E553b) |

A white to off white round, biconvex coated tablet with a breakline on one side and plain on the other side.
The tablet can be divided into two equal parts.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cats.

### 3.2 Indications for use for each target species

For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms:

**Roundworms:** *Toxocara cati, Toxascaris leonina.*

**Tapeworms:** *Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis.*

## 3.3 Contraindications

Do not use in kittens less than 6 weeks of age.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

## 3.4 Special warnings

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*.

Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration in cats. Local epidemiological information and the living conditions of the cat should be taken into account. It is also important to remove sources of possible re-infection such as fleas and mice.

Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

Animals in a poor condition or heavily infested, which can be manifested by symptoms such as diarrhoea, vomiting, presence of parasites in faeces and vomit, poor hair condition, should be examined by a veterinarian prior to the product administration. For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

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

In the interests of good hygiene, persons administering the tablets directly to the cat, or by adding them to the cat's food, should wash their hands afterwards.

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

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

### 3.6 Adverse events

Cats.

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Digestive tract disorders (e.g. vomiting and/or hypersalivation).<br>Neurological disorders (e.g. ataxia and muscle tremors). |

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 the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy.

Can be used during lactation.

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

Do not use simultaneously with piperazine compounds.

### 3.9 Administration routes and dosage

Oral use.

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

*Dosage*

The recommended dose is: 20 mg/kg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel in a single administration. This is equivalent to 1 tablet per 4 kg bodyweight.

| Body weight | Tablets |
|---|---|
| 1.0 - 2.0 kg. | ½ |
| 2.1 - 4.0 kg. | 1 |
| 4.1 - 6.0 kg. | 1 ½ |
| 6.1 - 8.0 kg. | 2 |

The tablet should be given directly to the cat, but if necessary can be disguised in food.
In ascarid infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3 weeks after weaning. If signs of disease persist or appear, consult a veterinary surgeon.

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

After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

**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 :**
QP52AA51

**4.2 Pharmacodynamics**

This veterinary medicinal product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The veterinary medicinal product contains two active substances, as follows:

**1.** Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative

and

**2.** Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative.

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow expulsion from the gastro-intestinal (GI) system by peristalsis.

Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both in vitro and in vivo studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolization of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

In this fixed combination, pyrantel is active against the following ascarids: *Toxocara cati*, and *Toxascaris leonina*. Praziquantel is effective against tapeworms in particular *Dipylidium caninum* and *Taenia taeniaeformis.*

Since it contains praziquantel, the veterinary medicinal product is effective against *Echinococcus multilocularis.*

### 4.3 Pharmacokinetics

Praziquantel is rapidly absorbed, metabolized and distributed in the body. It is also believed to be excreted back into the intestinal lumen by the mucous membrane.
Following administration of the veterinary medicinal product to cats, peak plasma concentrations of praziquantel were achieved by approximately 2 hours.
Pyrantel is poorly absorbed so it is expected that a large proportion of the administered dose remains in the GIT where it exerts its therapeutic effect and it is excreted largely unchanged in the faeces.
Following administration of the veterinary medicinal product to cats, peak plasma concentrations of pyrantel were achieved by approximately 3 hours.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Not applicable.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Unused half tablets must be discarded.

### 5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

### 5.4 Nature and composition of immediate packaging

The veterinary medicinal product is presented in either:

Individual blisters made up of a PVC/PE/PCTFE white opaque copolymer and a 20µm heatseal lacquer/aluminium containing 2, 4, 6, 8, 10, 12, 14, 16, 18 or 20 tablets.
or
Individual blisters made up of 45µm PVC/aluminium/orientated polyamide and a 20µm heatseal lacquer/aluminium containing 2 or 8 tablets.

The blisters are packed into cartons containing either: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
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

Chanelle Pharmaceuticals Manufacturing Limited

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

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

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

FR: Veterinary medicinal product subject to prescription.
IE, IT, RO, UK(NI): Veterinary medicinal product not subject to prescription.

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

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

## A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**{CARTON FOR PACK SIZES OF 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42 AND 44 TABLETS AND ABOVE}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Wormaway 230/20mg Flavoured film-coated tablets (IE)
Exitel Kat 230/20 mg Flavoured Film Coated Tablets (NL)
CESTAGUARD Cat, Tablets (RO)

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

## 3. PACKAGE SIZE

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128,136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets

## 4. TARGET SPECIES

Cats

## 5. INDICATIONS

For products not subject to veterinary prescription:

For the treatment of mixed infections caused by gastrointestinal roundworms and tapeworms.

## 6. ROUTES OF ADMINISTRATION

Oral use.

1 tablet per 4 kg bodyweight.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Unused half tablets must be discarded.

## 9. SPECIAL STORAGE PRECAUTIONS

## 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

Chanelle Pharmaceuticals Manufacturing Limited.

## 14. MARKETING AUTHORISATION NUMBERS

## 15. BATCH NUMBER

Lot {number}

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

**{BLISTER FOIL TEXT}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strantel (IT, UK)
Strantel Clément Thékan (FR)
Wormaway (IE)
Exitel Kat (NL)
CESTAGUARD Cat (RO)

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Unused half tablets must be discarded.

**B. PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Strantel 230/20 mg Flavoured Film-Coated Tablets for Cats. (IT, UK)
Strantel Clemént Thékan 230/20 mg Film-Coated Tablets for Cats (FR)
Wormaway 230/20mg Flavoured film-coated tablets for cats (IE)
Exitel Kat 230/20 mg Flavoured Film Coated Tablets for Cats (NL)
CESTAGUARD Cat, Tablets for Cats (RO)

## 2. Composition

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

A white to off white round, biconvex coated tablet with a breakline on one side and plain on the other side.

The tablet can be divided into two equal parts.

## 3. Target species

Cats.

## 4. Indications for use

For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms:

**Roundworms:** *Toxocara cati*, *Toxascaris leonina,*

**Tapeworms:** *Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis.*

## 5. Contraindications

Do not use in kittens less than 6 weeks of age.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

## 6. Special warnings

Special warnings:

Fleas serve as intermediate hosts for one common type of tapeworm – Dipylidium caninum.

Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration in cats. Local epidemiological information and the living conditions of the cat should be taken into account. It is also important to remove sources of possible re-infection such as fleas and mice.

Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

Special precautions for safe use in the target species:

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals. Animals in a poor condition or heavily infested, which can be manifested by symptoms such as diarrhoea, vomiting, presence of parasites in faeces and vomit, poor hair condition, should be examined by a veterinarian prior to the veterinary medicinal product administration. For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

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

In the interests of good hygiene, persons administering the tablets directly to the cat, or by adding them to the cat's food, should wash their hands afterwards.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Pregnancy and lactation:

Do not use during pregnancy.

Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with piperazine compounds.

Overdose:

After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

## 7. Adverse events

Cats.

| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): |
|---|
| Digestive tract disorders (e.g. vomiting and/or hypersalivation).<br>Neurological disorders (e.g. ataxia (incoordination) and muscle tremors). |

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.

*Dosage*

The recommended dose is: 20 mg/kg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel in a single administration. This is equivalent to 1 tablet per 4 kg bodyweight.

| Body weight | Tablets |
|---|---|
| 1.0 - 2.0 kg. | ½ |
| 2.1 - 4.0 kg. | 1 |
| 4.1 - 6.0 kg. | 1 ½ |
| 6.1 - 8.0 kg. | 2 |

The tablet should be given directly to the cat, but if necessary can be disguised in food.

In ascarid infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3 weeks after weaning. If signs of disease persist or appear, consult a veterinary surgeon.

## 9. Advice on correct administration

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

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Unused half tablets must be discarded.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

FR: Veterinary medicinal product subject to prescription.
IE, IT, RO, UK(NI): Veterinary medicinal product not subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Blisters packed into cartons containing either: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets.

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 reactions:

Chanelle Pharmaceuticals Manufacturing Limited.
Loughrea,
Co. Galway,
Ireland.
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.