SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen Wormer Granules 888 mg for Adult Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Active substance:
Fenbendazole 888.8 mg

Excipient(s):
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules
A free flowing white to greyish white granular powder

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Dogs
For the treatment of immature and mature stages of Toxacara canis and Taenia hydatigena.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance or the excipients.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

None

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

The product can cause irritation to the skin, eyes and lungs. Direct contact with the skin should be kept to a minimum. Avoid inhalation of granule dust. Wash hands after use. Avoid contact with the eyes. In case of accidental eye contact, irrigate the eyes with plenty of clean water. If irritation persists, seek medical advice. Only use for the bodyweight of animal recommended. The entire contents of the sachet must be directly sprinkled onto food as a single dose. Discard any uneaten medicated feed.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Not recommended.
Seek the advice of a veterinary surgeon before using the product during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only; sprinkled onto food.
For the routine treatment of adult dogs a dosage of 100 mg/kg is recommended.
This equates to approximately 1 whole sachet per 8 kg bodyweight (2 sachets for 16 kg bodyweight; 3 sachets for 24 kg bodyweight etc.).

Sachets must not be divided and stored for future use. If necessary, a suitable alternative product must be selected.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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

Benzimidazoles have a wide margin of safety.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Anthelminthics (Benzimidazoles and related substances)
ATC code: QP52AC13

5.1 Pharmacodynamic properties

Contains fenbendazole which is a member of the benzimidazole family of anthelmintics and has been in veterinary use for a number of years. It acts against parasites by disrupting the formation of microtubules by binding to tubulin in parasitic intestinal cells hence preventing the absorption of glucose, and as a result the parasites are gradually starved to death. Fenbendazole displays preference for parasitic as opposed to mammalian tubulin; this appears to be due to the fact that the formation of the parasitic tubulin-fenbendazole complex is more favourable kinetically under physiological conditions than the mammalian complex.

5.2 Pharmacokinetic particulars

Fenbendazole is only partly absorbed from the intestine and reaches maximum plasma concentration in dogs 4 - 9 hours after oral administration.

Fenbendazole and its metabolites are distributed throughout the body but highest concentrations are found in the liver.

Fenbendazole is metabolised mainly by enzymes of the cytochrome P-450 system in the liver. The major oxidative metabolite is fenbendazole sulfoxide which is further metabolised to fenbendazole sulfone.

Fenbendazole and its metabolites are predominantly excreted via the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone
Sodium laurilsulfate

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Store in a dry place.
Add to feed immediately before administration. Discard any remaining medicated feed.

6.5 Nature and composition of immediate packaging

Sachet consisting of paper, low density polyethylene and foil containing 4g of granules, with a heat-seal closure.
Each carton contains 1, 2, 3, 4 or 5 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

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

C&H Generics Ltd.
c/o Michael McEvoy and Co.
Seville House
New Dock Street
Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 40162/4004

9. DATE OF FIRST AUTHORISATION

02 December 2016

10. DATE OF REVISION OF THE TEXT

July 2023

Approved 19 July 2023