LABELLING

PACKAGE LEAFLET

Quantilex Plus Tablets For Dogs (UK)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quantilex Plus Tablets For Dogs (UK)
Praziquantel/ Febantel/ Pyrantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each yellow, pork flavoured tablet contains:
Active substances:

Praziquantel	50 mg
Pyrantel	50 mg (equivalent to 144 mg pyrantel embonate)
Febantel.	150 mg

The tablets can be divided into two or four equal parts.

4. INDICATION(S)

In dogs: Treatment of mixed infections by nematodes and cestodes of the following species
Nematodes:
Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).
Cestodes:
Tapeworms: *Echinococcus* species, *(E. granulosus, E. multilocularis), Taenia* species, *(T. hydatigena, T. pisiformis, T. taeniformis) Dipylidium caninum* (adult and immature forms).

5. CONTRAINDICATIONS

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases slight and transient digestive tract disorders such as vomiting and /or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.
The recommended dose rates are: 15 mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel.
1 Quantilex Plus tablet per 10 kg (22 lbs) bodyweight. The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

Dosage table:

Bodyweight (kg)	**Tablets**
½ - 2	1/4
3-5	½
6-10	1
11-15	1½
16-20	2
21-25	2½
26-30	3
31-35	3½
36-40	4
>40	1 tablet per 10 kg

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.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible
Discard any unused divided tablets.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Discard any unused divided tablets.

12. SPECIAL WARNING(S)

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Concurrent use with other cholinergic compounds can lead to toxicity.
Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
The combination of praziquantel, pyrantel and febatel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

User Precautions:
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.
In the interests of good hygiene, persons administering the tablets either directly to the dog, or adding them to the dog's food, should wash their hands afterwards.
For animal treatment only.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2023

15. OTHER INFORMATION

NFA VPS Non-food animal medicine-veterinarian, pharmacist, suitable qualified person
2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and 1000 tablets.
Not all pack sizes may be marketed.

Approved 31 January 2024