# PARTICULARS TO APPEAR ON THE OUTER PACKAGE

# **CARTON**

# 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit TABLETS 50 mg. Tapewormer.

#### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 50 mg praziquantel as active substance.

#### 3. PHARMACEUTICAL FORM

# 4. PACKAGE SIZE

20 tablets 100 tablets

#### 5. TARGET SPECIES

Cats and dogs

# 6. INDICATION(S)

For the elimination of tapeworms (including *Echinococcus* spp.) in cats and dogs.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

#### For oral administration.

1 tablet per 10 kg.

#### 8. WITHDRAWAL PERIOD.

# 9. SPECIAL WARNING(S), IF NECESSARY

Droncit should not be administered to unweaned kittens and puppies, as such animals are rarely infected with tapeworms.

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

#### 10. EXPIRY DATE

Expiry date: {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place. Keep the blister in outer carton. Any part used tablets should be discarded.

# 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For disposal advice, please see pack insert.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

AVM-GSL	CAM	Companion Animal Medicine

FOR ANIMAL TREATMENT ONLY.

#### 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

# 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS
Bayer Ltd
The Atrium
Blackthorn Road
Dublin 18
Ireland
Tel: 01-2999313

NN12 7LS Tel: 01-29993

# 16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4158 VPA 10021/13/1

# 17. MANUFACTURER'S BATCH NUMBER

Batch No.: {number}

Manufactured by: KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324,

D-24106 Kiel, Germany

Manufactured by: KVP, Kiel, Germany

# MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

# **BLISTER STRIPS**

# 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**Droncit** 

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited logo

# 3. EXPIRY DATE

Expiry date: {month/year}

# **4. BATCH NUMBER**

Batch No.: {number}

# 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

ad us. vet.

50 mg Praziquantel

# PARTICULARS TO APPEAR ON THE OUTER PACKAGE DISPENSING ENVELOPE

# 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit TABLETS 50 mg
Tapewormer

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 50 mg praziquantel as active substance.

#### 3. PHARMACEUTICAL FORM

Tablet.

## 4. PACKAGE SIZE

#### 5. TARGET SPECIES

For cats and dogs.

# 6. INDICATION(S)

For the elimination of tapeworms (including *Echinococcus* spp) in dogs and cats.

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

## For oral administration.

1 tablet per 10 kg.

# 8. WITHDRAWAL PERIOD

# 9. SPECIAL WARNING(S), IF NECESSARY

Droncit should not be administered to unweaned kittens and puppies, as such animals are rarely infected with tapeworms.

Do not use in dogs weighing less than 2.5 kg.

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

# 10. EXPIRY DATE

#### 11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Store in a dry place. Any part-used tablets should be discarded.

# 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For further information and disposal advice please see enclosed leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

FOR ANIMAL TREATMENT ONLY.

**AVM-GSL** 

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

#### 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton Towcester Northamptonshire NN12 7LS

# 16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4158

# 17. MANUFACTURER'S BATCH NUMBER

Name of Pet:		
Name of Client:		
Address:		
Date:	Give	Tablets
Supplied by:		

# PACKAGE LEAFLET FOR: DRONCIT TABLETS 50 mg

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

#### MAH:

Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS

#### Manufacturer:

- KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany
- Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit tablets 50 mg

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

Tablets for the treatment of tapeworms in cats and dogs. Each tablet contains 50 mg praziquantel as active substance.

#### 4. INDICATION(S)

#### Uses

For the treatment of adult tapeworms of cats and dogs. The product is effective against both immature and mature forms of adult tapeworms in both cats and dogs.

The product is a highly effective treatment against all the common species of tapeworm infecting cats and dogs in the United Kingdom and Ireland including:

Echinococcus granulosus.

Taenia multiceps, Taenia hydatigena,

Taenia ovis, Taenia pisiformis

Taenia taeniaeformis, Dipylidium caninum.

Droncit is also effective against *Echinococcus multilocularis* (see below).

#### 5. CONTRAINDICATIONS

Do not administer to dogs weighing less than 2.5 kg

Do not administer to unweaned kittens and puppies, as such animals are rarely infected with tapeworms.

#### 6. ADVERSE REACTIONS

#### 7. TARGET SPECIES

Dogs and cats.

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

#### Dosage

5 mg/kg body weight (1 tablet per 10 kg body weight).

	<b>Bodyweight</b>	
Dogs	2.5 – 5.0 kg	½ tablet
	6.0 - 10.0 kg	1 tablet
	11.0 – 20.0 kg	2 tablets
	21.0 – 30.0 kg	3 tablets
	Over 30.0 kg	pro rata
Cats	Adult cats	½ tablet

#### 9. ADVICE ON CORRECT ADMINISTRATION

#### Administration

Droncit Tablets should be given by mouth, preferably by opening the animal's mouth and pushing the tablet over the back of the tongue so that it cannot be rejected. Alternatively, a tablet can be wrapped in a piece of meat or butter and offered to the animal or crushed and mixed with the food.

A single dose is all that is required. However, for dogs in rural areas and for packs of hounds, this dose should be repeated every four weeks to ensure that newly acquired tapeworms are destroyed before reaching maturity. Dosing must be associated with strict control of the dog's diet to ensure that uncooked offal is not eaten.

## 10. WITHDRAWAL PERIOD(S)

#### 11. SPECIAL STORAGE PRECAUTIONS

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Do not store above 25°C. Store in a dry place. Keep the blister in outer carton. Any part-used tablets should be discarded.

# 12. SPECIAL WARNING(S)

#### FOR ANIMAL TREATMENT ONLY

N.B. Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. To avoid reinfection with this parasite, flea control of the animal and its housing should be carried out at the same time. Unless flea control is complete an infected flea population may survive: i.e. re-treatment of the animal may be necessary.

Since it contains praziquantel, the product is effective against *Echinococcus multilocularis*, which does not occur in the UK and Ireland, but is becoming more common in some European countries. As a precautionary measure to prevent establishment of *E. multilocularis* in the UK and Ireland it is recommended that all dogs and cats entering the country be treated with praziquantel.

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

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

Disposal: Dispose of any empty packaging and any remaining product in the household refuse.

#### 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

#### 15. OTHER INFORMATION

UK only			
V 00007/4450	4) (14 00)		
Vm 08007/4158	AVM-GSL		
Votoguinal LIK Limitad			
Vetoquinol UK Limited			
Steadings Barn			
Pury Hill Business Park			
Nr. Alderton			
Towcester			
Northamptonshire			
NN12 7LS			
141412 720			

IE only		
VPA 10021/13/1	CAM	
Companion Animal Medicine Bayer Ltd The Atrium Blackthorn Road Dublin 18 Tel 01-2999313		

# Manufactured by:

KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

Approved: 04 August 2022