PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Cat XL Film-coated TABLETS Round and Tapewormer

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Drontal Cat XL Film-coated Tablet contains two active substances: 30 mg praziquantel and 345 mg pyrantel embonate. Each tablet also contains 2.6 mg of a colouring agent called titanium dioxide (E171).

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

2 tablets for cats / 1 tablet per 6 kg 8 tablets for cats / 1 tablet per 6 kg 16 tablets for cats / 1 tablet per 6 kg 48 tablets for cats / 1 tablet per 6 kg 96 tablets for cats / 1 tablet per 6 kg

5. TARGET SPECIES

Cats.

6. INDICATION(S)

Drontal Cat XL Film-coated Tablets can be used to treat roundworms and tapeworms commonly found in cats in the UK and Ireland.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Give 1 tablet for every 6 kg (13 lb 4 oz) bodyweight. For oral administration only. **Read the package leaflet before use.**

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not give Drontal Cat XL Film-coated Tablets:

- If your cat is receiving other medicines containing piperazine.
- If your cat is pregnant.
- To kittens under 6 weeks of age.

User Warnings

Always wash your hands after giving your cat Drontal Cat XL Film-coated Tablets.

10. EXPIRY DATE

Expiry date: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original packaging. Do not remove tablets from the foil strip until they are required for use. Do not use after the expiry date stated on the foil strip.

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

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

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

For animal treatment only.

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

Keep out of the 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

Vm 08007/4163

17. MANUFACTURER'S BATCH NUMBER

Batch No.: {number}

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

<u>UK only</u>		
Vm 08007/4163	NFA-VPS	
Vetoquinol UK Limited Steadings Barn Pury Hill Business Park Nr. Alderton		
Towcester		
Northamptonshire		

NN12 7LS

IE only

VPA 10021/30/2

CAM

Bayer Ltd

Animal Health Division
The Atrium
Blackthorn Road
Dublin 18, Ireland
Tel: 01 299 9313

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS BLISTER STRIP

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Cat XL Film-coated TABLETS

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"

For animal treatment only.

Contains 2 tablets.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

DISPENSING ENVELOPE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Cat XL Film-coated TABLETS Round and Tapewormer

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Drontal Cat XL Film-coated Tablet contains two active substances: 30 mg praziquantel and 345 mg pyrantel embonate. Each tablet also contains 2.6 mg of colouring agent called titanium dioxide (E171).

3. PHARMACEUTICAL FORM

Tablets for cats / 1 tablet per 6 kg

4. PACKAGE SIZE

5. TARGET SPECIES

Cats.

6. INDICATION(S)

Drontal Cat XL Film-coated Tablets can be used to treat roundworms and tapeworms commonly found in cats in the UK and Ireland.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The number of tablets needed to treat your cat depends on your cat's weight. Give 1 tablet for every 6 kg (13 lb 4 oz) bodyweight.

Give the tablet(s) to your cat by placing directly in the cat's mouth, but if necessary, hide the medicine in the cat's food.

For oral administration only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not give Drontal Cat XL Film-coated Tablets:

- If your cat is receiving other medicines containing piperazine.
- If your cat is pregnant.
- To kittens under 6 weeks of age.

User Warnings

Always wash your hands after giving your cat Drontal Cat XL Film-coated Tablets

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original packaging. Do not remove tablets from the foil strip until they are required for use. Do not use after the expiry date stated on the foil strip.

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

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

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

For animal treatment only.

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

Keep out of the 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

Vm 08007/4163

17. MANUFACTURER'S BATCH NUMBER

UK only			
Vm 08007/4163	NFA-VPS		
Vetoquinol UK Limite Steadings Barn Pury Hill Business P Nr. Alderton Towcester Northamptonshire NN12 7LS			
<u>IE only</u>			
VPA 10021/30/2	CAM		
Bayer Ltd Animal Health Division The Atrium Blackthorn Road Dublin 18, Ireland Tel: 01 299 9313	on		
Name of Cat:			
Cat Owner's Name:			
Address:			
Supplied by:			
Calendar labels			
Drontal 1 = 6 kg	Drontal 1 = 6 kg	Drontal 1 = 6 kg	Drontal 1 = 6 kg

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR: DRONTAL CAT XL FILM-COATED TABLETS

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

UK

Marketing Authorisation Holder:

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

ΙE

Marketing Authorisation Holder:

Bayer Limited, Animal Health Division, The Atrium, Blackthorn Road, Dublin 18, Ireland. Tel 01 299 9313

Manufacturer:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

The name of this veterinary medicine is: Drontal Cat XL Film-coated Tablets

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

What is in Drontal Cat XL Film-coated Tablets?

Each Drontal Cat XL Film-coated Tablet is a white to yellowish tablet containing two active substances: 30 mg praziquantel and 345 mg pyrantel embonate. Each tablet also contains 2.6 mg of a colouring agent called titanium dioxide (E171).

4. INDICATION(S)

What is Drontal Cat XL Film-coated Tablets used for?

Drontal Cat XL Film-coated Tablets can be used to treat roundworms and tapeworms commonly found in cats in the UK and Ireland. The product is effective against the following types of roundworm and tapeworm: *Toxocara cati, Toxascaris leonina, Dipylidium caninum, Taenia taeniaeformis*.

Roundworms and tapeworms are parasites that live in the gut. If left untreated they can cause your cat to become unwell. Treating your cat regularly will reduce the risk of other animals and humans being exposed to worm infections.

5. CONTRAINDICATIONS

Do not give Drontal Cat XL Film-coated Tablets:

- If your cat is receiving other medicines containing piperazine.
- If your cat is pregnant.
- To kittens under 6 weeks of age.

6. ADVERSE REACTIONS

Possible side effects

Mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur in extremely rare cases.

If you notice any serious effects, please consult your veterinary surgeon.

7. TARGET SPECIES

Target species: This veterinary medicine is for use in cats.

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

How many tablets should I give to my cat?

The number of tablets needed to treat your cat depends on your cat's weight. Give 1 tablet for every 6 kg (13 lb 4 oz) bodyweight.

If your cat weighs less than 6 kg (13 lb 4 oz) you can use Drontal Cat Film-coated Tablets, which are intended for use in smaller cats.

9. ADVICE ON CORRECT ADMINISTRATION

How do I give Drontal Cat XL Film-coated Tablets?

Give the tablet(s) to your cat by placing directly in the cat's mouth but if necessary hide the medicine in the cat's food.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

How to store Drontal Cat XL Film-coated Tablets

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not remove tablets from the foil strip until they are required for use.
- Store in the original packaging.
- Do not use after the expiry date stated on the foil strip and outer packaging.

12. SPECIAL WARNING(S)

For Animal Treatment Only

- Your cat can become infected with tapeworms by eating fleas, mice or other small rodents. If fleas are not controlled or your cat often hunts, it may become re-infected with worms.
- If your cat has been taken overseas, it is recommended that they are treated with a veterinary medicine containing praziquantel (e.g. Drontal Cat XL Filmcoated Tablets) before entering the UK or Ireland.

User warnings

Always wash your hands after giving your cat Drontal Cat XL Film-coated Tablets.

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

Disposing of unwanted Drontal Cat XL Film-coated Tablets

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

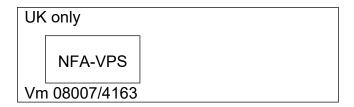
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

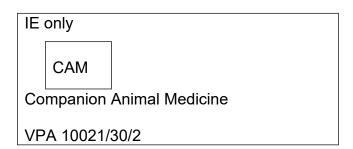
November 2020

15. OTHER INFORMATION

Drontal Cat XL Film-coated Tablets are available in cartons containing 2, 8, 16, 48 and 96 tablets. Not all pack sizes may be marketed.

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





Approved 05 November 2020