PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenvet 5 % w/w Premix for Medicated Feeding Stuff

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains 50 mg Flubendazole

Excipients:
Titanium dioxide
Lactose monohydrate
Sodium lauryl sulphate

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

Polyethylene/PET bag of 2 kg.

5. TARGET SPECIES

Pheasant, partridge, chicken, goose, and turkey.

6. INDICATION(S)

Flubendazole is a broad spectrum anthelmintic, effective against mature and immature stages and eggs of the following nematodes of chickens, turkeys, geese, partridges and pheasants.

In the gastrointestinal tract:	*Ascaridia galli, Heterakis gallinarum, Capillaria* spp*., Amidostomum anseris* and *Trichostrongylus tenuis.*
In the respiratory tract:	*Syngamus trachea*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

For oral administration only.

For incorporation into dry feed at a registered mill.
A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products, must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

Pheasants and partridges:
1.2 kg of the product is incorporated into 1 tonne of feeding stuff to provide 60g flubendazole per tonne of feed. Treat for 7 consecutive days.

Chickens and geese:
600 g of the product is incorporated into 1 tonne of feeding stuff to provide 30g flubendazole per tonne of feed. Treat for 7 consecutive days.

Turkeys:
400 g of the product is incorporated into 1 tonne of feeding stuff to provide 20g flubendazole per tonne of feed. Treat for 7 consecutive days.

On infected premises treatment at 3 weekly intervals may be necessary to control worm infestation.

8. WITHDRAWAL PERIOD(S)

Birds must not be slaughtered for human consumption during treatment.
Chickens, turkeys, geese, partridges and pheasants: Meat :7 days
Chickens eggs: zero days

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings
Accidental ingestion by humans should be avoided. May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Wear overalls, safety glasses and impervious gloves when mixing and handling the product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. If the operations involve potential exposure to dust, wear either a disposable filter and half-mask respirator conforming to European Standard EN149, or a non-disposable respirator to European Standard EN140 fitted with a filter to EN143.

10. EXPIRY DATE

EXP...-….

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Store in tightly closed original containers.
The product will remain stable in the finished feed for eight weeks.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 43877/4010

17. MANUFACTURER’S BATCH NUMBER

Lot

Manufactured by Janssen Pharmaceutica NV or Laboratoria Smeets N.V.
Procured from within the EU and repackaged by the licence holder:
Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

PACKAGE LEAFLET FOR:

Flubenvet 5 % w/w Premix for Medicated Feeding Stuff

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

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

Manufacturers for batch release:

Janssen Pharmaceutica NV
Janssen Pharmaceuticalaan 3
2440 GEEL
Belgium

Laboratoria Smeets N.V.
Neerlandweg 24
2610 ANTWERPEN-WILRIJK
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenvet 5 % w/w Premix for Medicated Feeding Stuff

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

Active substance:
Flubendazole 50 mg/g
Excipients:
Titanium dioxide (E171)
Lactose monohydrate
Sodium lauryl sulphate

4. INDICATION(S)

Flubendazole is a broad spectrum anthelmintic, effective against mature and immature stages and eggs of the following nematodes of chickens, turkeys, geese, partridges and pheasants:

In the gastrointestinal tract: *Ascaridia galli, Heterakis gallinarum, Capillaria* spp*., Amidostomum anseris* and *Trichostrongylus tenuis.*

In the respiratory tract: *Syngamus trachea*

5. CONTRAINDICATIONS

None known

6. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pheasant, partridge, chicken, goose, and turkey.

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

Pheasants and partridges :
1.2 kg of the product is incorporated into 1 tonne of feeding stuff to provide 60g flubendazole per tonne of feed. Treat for 7 consecutive days.

Chickens and geese :
600 g of the product is incorporated into 1 tonne of feeding stuff to provide 30g flubendazole per tonne of feed. Treat for 7 consecutive days.

Turkeys :
400 g of the product is incorporated into 1 tonne of feeding stuff to provide 20g flubendazole per tonne of feed. Treat for 7 consecutive days.

On infected premises treatment at 3 weekly intervals may be necessary to control worm infestation.

9. ADVICE ON CORRECT ADMINISTRATION

For oral administration only.

For incorporation into dry feed at a registered mill.
A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products, must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

10. WITHDRAWAL PERIOD(s)

Birds must not be slaughtered for human consumption during treatment.
Chickens, turkeys, geese, partridges and pheasants: Meat :7 days
Chickens eggs: zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25 °C.
Store in tightly closed original containers.
The product will remain stable in the finished feed for eight weeks.

12. SPECIAL WARNING(S)

For Animal Treatment Only

Overdose
Flubendazole is an analog of mebendazole for which the side effects of overdose include transient gastrointestinal abnormalities.

User Warnings
Accidental ingestion by humans should be avoided. May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Wear overalls, safety glasses and impervious gloves when mixing and handling the product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. If the operations involve potential exposure to dust, wear either a disposable filter and half-mask respirator conforming to European Standard EN149, or a non-disposable respirator to European Standard EN140 fitted with a filter to EN143.

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

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Detailed product information is available on the VMD website which can be located by searching for VMD on gov.uk.

15. OTHER INFORMATION

Polyethylene/PET bag of 2 kg.

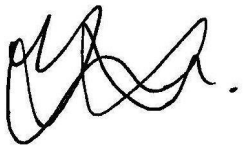
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

For animal treatment only

Adverse events should be reported to the MAPI holder. To report an adverse event, ring [UK telephone number].
To be supplied only on veterinary prescription.

POM-VPS

Vm 43877/4010



Approved: 01 February 2022