PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 22% Equine Granules

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 22.2% w/v Fenbendazole.

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

1 kg

5. TARGET SPECIES

Horses

6. INDICATION(S)

Zerofen 22% Equine Granules is a broad spectrum oral wormer for the treatment of horses and other equines infected with immature and mature roundworms including large redworms (*Strongylus vulgaris, Strongylus edentatus*) and migrating large redworms, benzimidazole susceptible small redworms and encysted mucosal larvae, *Ascarids*, *Oxyuris* and Strongyloides species. Also kills nematode eggs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For routine treatment of horses administer orally 10.2 g Zerofen 22 % Equine Granules per 300 kg bodyweight (= 7.5 mg fenbendazole/kg bodyweight) equivalent to 2 level measuring scoops. Assess bodyweight accurately before calculating the dosage. Treatment should be repeated when natural re-infestation with worms occurs (approximately every 6 to 8 weeks).

Granules should be sprinkled onto concentrate or grain feeds immediately before administration and the full daily dosage given as one administration. Discard any remaining medicated feed.

Dosage Table:

Foals and ponies up to 300 kg bodyweight	2 level scoops
Thoroughbreds and other breeds of horses up to 600 kg bodyweight	4 level scoops
Heavy hunters, heavy draught horses	6 level scoops
Donkeys	1 level scoop

Increased dosing for specific indications:

For the control of benzimidaole susceptible encysted mucosal stages of small strongyles and migrating larval stages of large strongyles administer 10.2 g Zerofen 22 % Equine Granules per 300 kg bodyweight equivalent to 2 level measuring scoops, for 5 consecutive days. Ideally dosage at this rate should be carried out at once a year between the end of October and December. All new arrivals should be treated at this rate whatever the time of year.

For the control of diarrhoea caused by *Strongyloides westeri* in 2 to 3 week old suckling foals administer 10.2 g Zerofen 22 % Equine Granules per 44 kg body weight or 2 level scoops (=50 mg fenbendazole/kg bodyweight).

See package leaflet for further information.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption until 35 days after treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Not to be used in animals hypersensitive to the ingredients.

Pregnant mares and young foals may be safely treated with fenbendazole at therapeutic dosage levels.

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and to reduce the likelihood of anthelmintic resistance developing.

Direct contact with skin should be kept to a minimum. Wash hands after use. Avoid inhalation of granule dust.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Store in a dry place.

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in farm refuse. Used containers should not be recycled.

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

POM-VPS

To be supplied only o veterinary prescription. For animal treatment only

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

KEEP OUT OF THE REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd., Rodney Street, Liverpool L1 9HZ, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4017

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

M.A. Holder: Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool, L1 9HZ, UK.

Manufacturer: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zerofen 22% Equine Granules

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

Contain 22.2% w/v Fenbendazole.

4. INDICATION(S)

Zerofen 22% Equine Granules is a broad spectrum oral wormer for the treatment of horses and other equines infected with immature and mature roundworms including large redworms (Strongylus vulgaris, Strongylus edentatus) and migrating large redworms, benzimidazole susceptible small redworms and encysted mucosal larvae, Ascarids, Oxyuris and Strongyloides species. Also kills nematode eggs.

5. CONTRAINDICATIONS

Not to be used in animals hypersensitive to the ingredients.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Horses

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

For routine treatment of horses administer orally 10.2 g Zerofen 22 % Equine Granules per 300 kg bodyweight (= 7.5 mg fenbendazole/kg bodyweight) equivalent to 2 level measuring scoops. Assess bodyweight accurately before calculating the dosage. Treatment should be repeated when natural re-infestation with worms occurs (approximately every 6 to 8 weeks).

Granules should be sprinkled onto concentrate or grain feeds immediately before administration and the full daily dosage given as one administration. Discard any remaining medicated feed.

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9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption until 35 days after treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach of children. Do not store above 25oC. Store in a dry place.

12. SPECIAL WARNING(S)

Pregnant mares and young foals may be safely treated with fenbendazole at therapeutic dosage levels.

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and to reduce the likelihood of anthelmintic resistance developing.

Direct contact with skin should be kept to a minimum. Wash hands after use. Avoid inhalation of granule dust.

For Animal Treatment Only

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in farm refuse. Used containers should not be recycled.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – VPS To be supplied only on veterinary prescription

Vm 11990/4017

Approved: 04/01/2018