

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypnorm Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances	% w/v
Fentanyl citrate	0.0315
(equivalent to fentanyl)	(0.0200)
Fluanisone	1.0000

Excipients

Methyl parahydroxybenzoate	0.180
Propyl parahydroxybenzoate	0.020

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5. TARGET SPECIES

Mice, rats, rabbits and guinea pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Guinea Pigs and Rabbits: Intramuscular injection

Mice and Rats: Intraperitoneal injection

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

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 *[Distribution category]*

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animal Medics UK Ltd
310 Chester Road
Hartford
Cheshire
CW8 2AB
UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41760/4000

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypnorm Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substances	% w/v
Fentanyl citrate	0.0315
(equivalent to fentanyl)	(0.0200)
Fluanisone	1.0000

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Guinea Pigs and Rabbits: Intramuscular injection

Mice and Rats: Intraperitoneal injection

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

PACKAGE LEAFLET FOR:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypnorm Solution for Injection

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

Active substances	% w/v
Fentanyl citrate (equivalent to fentanyl)	0.0315 (0.0200)
Fluanisone	1.0000

Excipients

Methyl parahydroxybenzoate	0.180
Propyl parahydroxybenzoate	0.020

4. INDICATION(S)

Neuroleptanalgesic for mice, rats, rabbits and guinea pigs.

Hypnorm alone produces satisfactory surgical anaesthesia for minor operations and diagnostic techniques for which muscle relaxation is not required.

It may be used in reduced quantities in conjunction with benzodiazepines to produce anaesthesia with muscle relaxation for major surgery.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Mice, Rats, Guinea pigs and Rabbits

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

Guinea Pigs and Rabbits: Intramuscular injection

Mice and Rats: Intraperitoneal injection

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

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

15. OTHER INFORMATION

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Vm 41760/4000

Approved: 04/01/2018

