# SUMMARY OF PRODUCTS CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypnorm Solution for Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| **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 |

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Mice, rats, rabbits and guinea pigs.

### 4.2 Indications for use, specifying the target species

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.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

i. Special precautions for use in animals

In common with the use of other anaesthetic agents in small mammals, it is essential to maintain normothermia during any procedure.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid all contact with skin, eyes and mouth.
Wash off splashes from skin or eyes immediately.
Wash hands and/or exposed skin after use/handling and before eating, drinking or smoking.
In case of accidental self-injection seek medical attention immediately and show the product label and/or pack leaflet to the doctor.

iii. Other precautions

None.

## 4.6 Adverse reactions (frequency and seriousness)

None according to available data.

## 4.7 Use during pregnancy, lactation or lay

No information available on use during pregnancy or breast feeding.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

Hypnorm

*Mice:* 0.01 ml/30 g body weight (0.105 mg/kg body weight fentanyl citrate and 3.333 mg/kg body weight fluanisone) by intraperitoneal injection.

*Rats*: 0.4 ml/kg body weight (0.126 mg/kg body weight fentanyl citrate and 4 mg/kg body weight fluanisone) by intramuscular or intraperitoneal injection.

*Rabbits*: 0.5 ml/kg body weight (0.158 mg/kg body weight fentanyl citrate and 5 mg/kg body weight fluanisone) by intramuscular injection.

*Guinea pigs*: 1 ml/kg body weight (0.315 mg/kg body weight fentanyl citrate and 10 mg/kg body weight fluanisone) by intramuscular injection.

The duration of sedation and immobilisation is approximately 30-60 minutes. Analgesic effects may persist.

Hypnorm - benzodiazepine combinations
Hypnorm and Diazepam

*Mice:* 0.01 ml Hypnorm/30 g body weight (0.105 mg/kg body weight fentanyl citrate and 3.333 mg/kg body weight fluanisone) by intraperitoneal injection with 5 mg/kg body weight diazepam by intraperitoneal injection.

*Rats*: 0.3 ml Hypnorm/kg body weight (0.095 mg/kg body weight fentanyl citrate and 3 mg/kg body weight fluanisone) by intramuscular injection with 2.5 mg/kg body weight diazepam by intraperitoneal injection.

*Rabbits*: 0.3 ml Hypnorm/kg body weight (0.095 mg/kg body weight fentanyl citrate and 3 mg/kg body weight fluanisone) by intramuscular injection with 2 mg/kg body weight diazepam by intraperitoneal or intravenous injection.

*Guinea pigs*: 1 ml Hypnorm/kg body weight (0.315 mg/kg body weight fentanyl citrate and 10 mg/kg body weight fluanisone) by intramuscular injection with 2.5 mg/kg body weight diazepam by intraperitoneal injection.

This combination of drugs provides good surgical anaesthesia with muscle relaxation for about 20-40 minutes.

Hypnorm and midazolam

Clinical experience has shown that at appropriate dilutions, midazolam is miscible with Hypnorm. Midazolam 5 mg/ml and Hypnorm are each diluted with an equal volume of Water for Injection prior to mixing. The resulting mixture contains 1.25 mg/ml midazolam, 2.5 mg/ml fluanisone and 0.079 mg/ml fentanyl citrate and is administered as a single intraperitoneal injection.

*Mice:* 10 ml/kg body weight

*Rats:* 2.7 ml/kg body weight

*Guinea Pigs:* 8 ml/kg body weight

*Rabbits:* 0.3 ml Hypnorm/kg body weight (0.095 mg/kg body weight fentanyl citrate and 3 mg/kg body weight fluanisone) by intramuscular injection with 2.0 mg/kg body weight midazolam by intraperitoneal injection.

This combination of drugs provides good surgical anaesthesia with muscle relaxation for about 20-40 minutes.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

If respiratory depression occurs, administration of a reversing agent and oxygen may be required.
Reversing agents: Narcotic antagonists such as naloxone or partial agonists such as buprenorphine.

## 4.11 Withdrawal period

Do not use in rabbits intended for human consumption.

## 5. PHARMACOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Analgesics, Opioids, Phenylpiperidine derivatives

**ATC Vet Code:** QN01AH51

The product is a neuroleptanalgesic for use in mice, rats, rabbits and guinea pigs. Fentanyl is an analgesic of the morphine type. Fluanisone is a neuroleptic of the butyrophenone group.

## 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Lactic acid
Water for injection

## 6.2 Incompatibilities

None known.

## 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 Years.
Shelf-life after opening the immediate packaging: 28 days

## 6.4 Special precautions for storage

Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.

## 6.5 Nature and composition of immediate packaging

10 ml colourless glass type I vial with rubber bromobutyl bung secured by an

aluminium overseal.
Available in cartons containing 1 x 10 ml vial or 5 x 10 ml vials.
Not all pack sizes may be marketed.

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER(S)

**Vm** 41760/4000

## 9. DATE OF FIRST AUTHORISATION

**Date:** 26 July 1995

## 10. DATE OF REVISION OF THE TEXT

**Date:** December 2012

## 11. PROHIBITION OF SALE, SUPPLY AND/OR USE

This product falls within the regime of Controlled Drugs Schedule 2

**APPROVED** T. NASH **20/07/15**