SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Large Animal Diprevon Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:	mg/ml
Diprenorphine	3.0
(as Diprenorphine hydrochloride	3.26)
Preservative:	
Chlorocresol	1.0
Colouring Agent:	
Methylthioninium chloride	0.1

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear blue aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and deer.

4.2 Indications for use, specifying the target species

To reverse neuroleptanalgesia induced by etorphine hydrochloride.

4.3 Contraindications

Do not use intramuscularly except in the circumstances of an emergency where intravenous injection is not possible.
Do not dilute or mix with any other substances.
Do not use in animals intended for animal consumption.

4.4 Special warnings for each target species

Animals MUST be kept stabled, protected from extremes of temperature and under close supervision for at least 24 hours, particularly for the first 8 hours following administration.
Care must be taken to avoid hypothermia or hyperthermia (see above).
Protect horses eyes from sun or bright light following administration.

4.5 Special precautions for use

i) Special precautions for use in animals

None known.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Spillages should be dealt with AFTER PUTTING ON SUITABLE HEAVY DUTY RUBBER GLOVES, neoprene or nitrile of minimum thickness 0.5 mm, using a copious quantity of water, which can then be flushed down a running sink. Broken glass should be washed and disposed of in a recognised manner.
The product may induce a hallucinatory state after accidental self-administration.
TO AVOID ACCIDENTAL SELF-INJECTION, the following procedure should be adopted:

(a) Use two sterile needles, one to fill the syringe from the vial and one to inject the patient. Once the required dose has been withdrawn from the vial, the syringe should be removed from the needle. A separate sterile needle should be inserted into the injection site and the syringe connected to it. Both needles should be discarded into a closed container.
(b) Wear surgical gloves.
(c) Do not pressurise vial contents.
(d) An eye and skin wash should be readily available for use following any exposure.

Wash off splashes from skin and eyes immediately.
Should accidental self-injection occur, seek medical advice immediately.
Do not drive.

4.6 Adverse reactions (frequency and seriousness)

Signs of tachycardia, hypertension and mild tranquillisation may be seen following remobilisation.
Since the product is used strictly as an antidote, the product literature for the agonist should be referred to.
Recurrence of excitement, ‘walking’ and ‘head-pressing’ six to eight hours after remobilisation. These effects may be reversed by a further half-dose administered subcutaneously.

4.7 Use during pregnancy, lactation or lay

There is no evidence of testing in such situations.

4.8 Interaction with other medicinal products and other forms of interaction

Do not dilute or mix with any other substances (see section 4.3, Contraindications).

4.9 Amounts to be administered and administration route

A volume equal to the total volume of Large Animal Etorphilon Solution for Injection injected previously should be given intravenously as soon as possible after the required period of restraint is complete. Recovery should then take place with minimal disturbance and noise. Animals should be kept under frequent surveillance during recovery.
A further half-dose may be used subcutaneously after the initial intravenous dose if required.

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

No specific target organ toxicity has been recorded in studies using repeat doses at relatively high dosages.

4.11 Withdrawal period(s)

Must not be administered to animals intended for human or animal consumption.
Not to be used in horses for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antidotes
ATCvet code: QV03AB92

5.1 Pharmacodynamic properties

Diprenorphine hydrochloride is an opioid antagonist used to specifically reverse the neuroleptanalgesic effects of etorphine hydrochloride. Used alone, diprenorphine hydrochloride can act as an agonist and may induce a hallucinatory state.

5.2 Pharmacokinetic particulars

No information.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Methylthioninium chloride
Hydrochloric acid (dilute), sodium hydroxide (for pH adjustment)
Water for injections

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 first opening of the immediate packaging: 1 day.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
Following withdrawal of the first dose, use remainder of the product within one day.
Discard unused material.

6.5 Nature and composition of immediate packaging

Clear glass (Type II) vials containing 10.5 ml, closed with a chlorobutyl rubber stopper and aluminium crimped seal.

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

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

Abbeyvet Export LLP
Sherburn Enterprise Park
Aviation Way
Sherburn-in-Elmet
Leeds
LS25 6NB
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 21757/4001

9. DATE OF FIRST AUTHORISATION

22 September 2009

10 DATE OF REVISION OF THE TEXT

22 September 2009