Part II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Navilox 3% w/w powder for in-feed use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Isoxsuprine Hydrochloride 3% w/w.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for in-feed use.
Fine white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

Cases of Navicular disease in the horse.

4.3 Contra-indications

Do not administer to pregnant mares or following arterial haemorrhage. Do not administer within 14 days post-partum.

Isoxsuprine may be detected in urine at low levels for long variable periods after administration. No recommendation can therefore be given on withdrawal before competing, and consequently NAVILOX is not recommended for use in competition horses.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

(i) Special precautions for use in animals

None

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

Avoid breathing the powder while mixing with feed.
It is recommended that a dust mask be worn when using this product. Use in a well ventilated area.
Do not eat, drink or smoke while using the product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

At the clinically recommended dose, no side effects have been reported.

4.7 Use during pregnancy, lactation or lay

No studies have been reported on use during pregnancy and lactation. Therefore, use is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

None reported.

4.9 Amounts to be administered and administration route

Administer on an empty stomach, approximately 30 minutes before feeding, by adding to a small quantity of feed.

The optimum dosage regimen is 20mg of Navilox per kilogram of bodyweight (equivalent to 0.6mg Isoxsuprine hydrochloride/kg bodyweight).

Treatment should be continued over a full 12 week period according to the following schedule, for a 500kg horse.

Bodyweight	Navilox	Frequency of Dosage
500kg	10g	Twice daily for 6 weeks
500kg	10g	Once daily for 3 weeks
500kg	10g	Alternate days for 3 weeks

3 level measures = 10g

Add to feed immediately before administration. Discard any remaining medicated feed.

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

Overdose may cause the animal to sweat but no other effects have been reported with oral administration. Animals should be treated symptomatically.

4.11 Withdrawal period(s)

Not to be used in animals intended 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

Isoxsuprine is a phenylethylamine derivative of epinephrine. It is a vasodilator which also stimulates beta-adrenergic receptors. These effects cause direct relaxation of vascular and uterine smooth muscle. Its dilating action is greater on the arteries supplying skeletal muscles than on those supplying the skin. Isoxsuprine also produces positive ionotrophic effects, lowers blood viscosity and inhibits platelet aggregation.

In horses, orally administered Isoxsuprine has been used mainly for its effects on the peripheral circulation, in the treatment of Navicular disease, Podotrochlosis, Sesamoiditis and Arthrosis.

Isoxsuprine hydrochloride acts by improving the blood supply to the Navicular bone and thus treats the underlying blood flow problems associated with Navicular disease.

Pharmacokinetic Properties

After intravenous administration of 0.6mg/kg isoxsuprine to horses, peak plasma concentrations were attained soon after it was given. These decreased over a 12 hour period in a bi-exponential way, with distribution and elimination half-lives of 14 minutes and 2.67 hours respectively.

Isoxsuprine is well absorbed from the gastro-intestinal tract and is excreted in the urine mainly as conjugates.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose Monohydrate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary product as packaged for sale; 2 years.

6.4. Special precautions for storage

Do not store above 25°C. Store in a dry place away from animal feeding stuffs.
Reseal container after use.

6.5 Nature and composition of immediate packaging

The product is packed into 300g white high density polyethylene pots with white high density polypropylene screw tops. A clear polythene bag inner liner is sealed with a tie. Each pot is supplied with a 5ml scoop.

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

Vétoquinol UK Limited
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8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4026

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 January 1991/10 January 2006

10. DATE OF REVISION OF THE TEXT

March 2008