

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Isoxsuprine Hydrochloride 3% w/w

Excipient: Glucose monohydrate

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

Pot of 300 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

A peripheral vasodilator indicated in horses with Navicular disease where a vasodilator would be beneficial.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Treatment should be continued over a 12 week period according to the following schedule for a 500kg horse. 10g twice daily for 6 weeks then 10g once daily for 3 weeks then 10g alternate days for 3 weeks.

Administer in a small quantity of feed on an empty stomach 30 minutes before feeding (3 level 5ml measures = 10g). Add to feed immediately before administration. Discard any remaining medicated feed.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to pregnant mares or following arterial haemorrhage. Do not administer within 14 days post-partum. Not to be given to horses intended for human

consumption. 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.

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

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store below 25°C in a dry place away from animal feedstuffs. Reseal container after use.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

POM-V

To be supplied only on veterinary prescription

For animal treatment only

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

Keep out of reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Buckingham Industrial Park
Buckingham
MK18 1PA

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4026

17. MANUFACTURER'S BATCH NUMBER

Approved: 03/05/2018

J. Berg

NOT MARKETED