

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

UMBULALI NTSULUBE 937,50 mg Elixir

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Piperazine citrate equivalent to 750 mg piperazine hydrate.

Contains sugar: Sucrose 2208 mg

Contains TARTRAZINE

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Elixir

An apple-green, thick liquid with a peppermint odour and flavour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

UMBULALI NTSULUBE is indicated for the elimination of roundworm and threadworm.

4.2 Posology and method of administration

Posology:

For the Elimination of Roundworm.

A single dose of 6 medicine measures (30 ml) of the syrup taken preferably before the evening meal will produce complete clearance of ascarides from the gut in adults and children weighing 19,0 kg or more.

For infants and children weighing under 19,0 kg, the corresponding dose is 4 medicine measures (20 ml).

No fasting or other supplementary measures are necessary, but in cases of constipation, a saline purgative should be given the following morning.

For the Elimination of Threadworm.

Administer daily after food for seven days.

The most effective dose is from 50 to 70 mg of piperazine per kg of body mass per day.

Dosage Schedule For The Treatment Of Threadworm:

Age	Weight	Dosage
		To be continued for seven days
9 - 24 months	6,5 – 9,5 kg	½ medicine measure daily (2,5 ml)
2 – 4 years	9,5 – 12,5 kg	1 medicine measure daily (5,0 ml)
4 – 7 years	12,5 – 19,0 kg	1½ medicine measures daily (7,5 ml)
7 – 13 years	19,0 – 38,0 kg	2 medicine measures daily (10,0 ml)
13 years to adult	over 38,0 kg	3 medicine measures daily (15,0 ml)

In rare instances it may be necessary to repeat the course after one week.

No special diet is required.

Attention to general cleanliness is important in order to prevent reinfection from untreated cases. It is advisable to examine all members of a household and treat all positive cases at the same time, to prevent transmission of the worms and reinfestation.

If you miss a dose, skip the missed dose. Do not double doses.

Method of administration:

For oral use only.

4.3 Contraindications

UMBULALI NTSHULUBE is contraindicated in:

- patients who are hypersensitive to piperazine or to any of the excipients listed in section 6.1.
- patients with epilepsy or severe renal impairment.

4.4 Special warnings and precautions for use

UMBULALI NTSHULUBE should be given with caution to patients with neurological disturbances, mild to moderately impaired renal function or hepatic impairment.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take UMBULALI NTSHULUBE.

Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

UMBULALI NTSHULUBE contains FD & C Yellow No 5 (Tartrazine) which may cause allergic type reactions (including bronchial asthma) in certain susceptible individuals.

Although the overall incidence of tartrazine sensitivity in the general population is currently thought to be low, it is frequently seen in patients who have aspirin sensitivity.

4.5 Interaction with other medicinal products and other forms of interaction

The anthelmintic effects of piperazine, as in UMBULALI NTSHULUBE, and pyrantel may be antagonized when the two medicines are used together.

UMBULALI NTSHULUBE may enhance the adverse effects of phenothiazines such as chlorpromazine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Use of UMBULALI NTSHULUBE during pregnancy is not recommended, especially during the first trimester, unless immediate treatment with UMBULALI NTSHULUBE is essential.

Breastfeeding

Piperazine, as in UMBULALI NTSHULUBE, is distributed into breast milk.

Mothers are advised to take a dose after breastfeeding then not to breastfeed for 8 hours during which period milk should be expressed and discarded at the regular feeding times.

Fertility

There is no data available on the effects of UMBULALI NTSHULUBE on fertility.

4.7 Effects on ability to drive and use machines

UMBULALI NTSHULUBE can cause drowsiness, dizziness and blurred vision which may have an effect on your ability to drive and use machines.

4.8 Undesirable effects

Blood and lymphatic disorders

Frequency unknown: Haemolytic anaemia, thrombocytopenia, epistaxis, haemoptysis.

Immune system disorders

Less frequent: Skin rashes, urticaria

Frequency unknown: Bronchospasm, Stevens-Johnson syndrome, angioedema, serum-sickness-like illness, hypersensitivity vasculitis

Nervous system disorders

Less frequent: Headaches.

Frequency unknown: Somnolence, dizziness, nystagmus, muscular incoordination, weakness, ataxia, paraesthesia, myoclonic contractions, choreiform movements, tremor, convulsions, loss of reflexes.

Eye disorders

Less frequent: Transient visual disturbances such as blurred vision, cataract formation.

Gastrointestinal disorders

Less frequent: Nausea, vomiting, diarrhoea, abdominal pain

Hepato-biliary disorders

Frequency unknown: Viral hepatitis-like reactions.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

Toxic effects may be produced with prolonged treatment with large dosages.

Dizziness, blurred vision or nausea experienced under these conditions should cease when treatment is discontinued. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anthelmintics, ATC code: P02CB01

Piperazine is an anthelmintic against roundworms (*Ascaris*) and threadworms (*Enterobius*).

In roundworms piperazine produces narcosis. The worms are then dislodged from their position by movement of the gut and expelled in the faeces.

Little is known about the mode of action of piperazine on threadworms.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant Blue (C.I. 42090)

Ethanol

Glycerol

Peppermint oil

Purified water

Sugar: Sucrose 2208 mg

TARTRAZINE (C.I. 19140)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a well-closed container at or below 25 °C. Protect from light.

6.5 Nature and contents of container

50 ml clear PVC bottle with white cap.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Avid Brands S.A. (Pty) Ltd

Suite 9, Hillcrest Office Park

2 Old Main Road

Hillcrest, 3610

8. REGISTRATION NUMBER

H925 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION

Not applicable

10. DATE OF REVISION OF THE TEXT

17 July 2020