

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

UMBULALI NTSHULUBE, 937,50 mg per 5 ml elixir

Piperazine citrate

Contains sugar: Sucrose 2208 mg

Read all of this leaflet carefully because it contains important information for you.

UMBULALI NTSHULUBE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use UMBULALI NTSHULUBE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share UMBULALI NTSHULUBE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What UMBULALI NTSHULUBE is and what it is used for
2. What you need to know before you take UMBULALI NTSHULUBE
3. How to take UMBULALI NTSHULUBE
4. Possible side effects
5. How to store UMBULALI NTSHULUBE
6. Contents of the pack and other information

1. What UMBULALI NTSHULUBE is and what it is used for

UMBULALI NTSHULUBE is used to treat worm infestations.

It is used for the elimination (removal) of roundworm and threadworm.

2. What you need to know before you take UMBULALI NTSHULUBE

Do not take UMBULALI NTSHULUBE:

- If you are hypersensitive (allergic) to piperazine citrate or any of the ingredients of UMBULALI NTSHULUBE (listed in section 6).
- If you have epilepsy.
- If you have serous kidney damage.

Warnings and precautions

Take special care with UMBULALI NTSHULUBE:

- If you are allergic to tartrazine or aspirin as allergic type reactions may occur including asthma.
- If you have nervous system disorders
- If you have kidney problems
- If you have impaired liver function

If your health worsens while taking UMBULALI NTSHULUBE, see a doctor or pharmacist.

Children

- Children under one year of age can only take UMBULALI NTSHULUBE if told to do so by a doctor.

Other medicines and UMBULALI NTSHULUBE

Always tell your healthcare provider if you are administering any other medicine.

(This includes complementary or traditional medicines).

- Do not take UMBULALI NTSHULUBE with other de-worming medicines.
- UMBULALI NTSHULUBE may increase the adverse effects of phenothiazines such as chlorpromazine.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a

baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy:

If you are pregnant do not use UMBULALI NTSHULUBE unless your doctor has told you to do so.

Breastfeeding:

If you are breastfeeding, take a dose of UMBULALI NTSHULUBE immediately after breast feeding, then do not breast feed for the next 8 hours. Express and discard the breast milk during this time.

Driving and using machines

UMBULALI NTSHULUBE may cause drowsiness, dizziness and blurred vision. Do not drive or use machinery until you know how UMBULALI NTSHULUBE affects you.

UMBULALI NTSHULUBE contains Brilliant Blue (C.I. 42090), ethanol, glycerol, peppermint oil, purified water, sucrose and tartrazine.

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking UMBULALI NTSHULUBE.
- UMBULALI NTSHULUBE contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take UMBULALI NTSHULUBE

Do not share medicines prescribed for you with any other person.

Always take UMBULALI NTSHULUBE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

For the Elimination of Roundworm.

Adults and children weighing 19,0 kg or more should take a single dose of 30 ml (6 medicine

measures) of UMBULALI NTSHULUBE before supper.

For infants and children weighing under 19,0 kg the dose is 20 ml (4 medicine measures) of UMBULALI NTSHULUBE before supper.

In cases of constipation, a saline laxative should be given the following morning.

For the Elimination of Threadworm.

Take UMBULALI NTSHULUBE daily after food for seven days.

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) |

If necessary the course may be repeated after one week.

It is recommended to check all members of a household and treat all positive cases at the same time to prevent spread of the worms and reinfestation.

If you take more UMBULALI NTSHULUBE than you should:

An overdose of UMBULALI NTSHULUBE can cause dizziness, blurred vision or nausea.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forgot to take UMBULALI NTSHULUBE:

Do not double the dose. Skip the missed dose and continue with the next dose as directed.

4. Possible side effects

UMBULALI NTSHULUBE can have side effects.

Not all side effects reported for UMBULALI NTSHULUBE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking UMBULALI NTSHULUBE, please consult your health care provider for advice.

If any of the following side effects happen, stop taking UMBULALI NTSHULUBE and tell your doctor or go to the casualty department at your nearest hospital:

- shortness of breath, tight chest,
- skin rashes, itchy skin, tingling sensation of the skin,
- seizures, loss of muscle coordination, weakness, twitching, shaking, loss of reflexes, involuntary eye movement,
- symptoms similar to that of inflamed liver (hepatitis), due to infection caused by a virus, such as fever, rash, tiredness, nausea, vomiting, poor appetite, joint pain, and headaches,
- nose bleeds and coughing up blood,

These are all serious side effects and you may need urgent medical attention.

Tell your doctor if you notice any of the following:

- sleepiness, dizziness,
- headaches,
- nausea, vomiting, diarrhoea, abdominal pain,
- blurred vision and clouding of the lens in the eye.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

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

By reporting side effects, you can help provide more information on the safety of UMBULALI NTSHULUBE.

5. How to store UMBULALI NTSHULUBE

- Store at or below 25 °C
- Keep the bottle tightly closed and protect from light.
- Keep bottle in unit carton until prior to use
- Do not use after the expiry date stated on the label.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What UMBULAI NTSHULUBE contains

- The active substance is piperazine citrate 937,50 mg per 5 ml elixir
- The other ingredients are Brilliant Blue (C.I. 42090), ethanol, glycerol, peppermint oil, purified water, sucrose and tartrazine.

What UMBULALI NTSHULUBE looks like and contents of the pack

UMBULALI NTSHULUBE is an apple-green, thick elixir with a peppermint odour and flavour, supplied in 50 ml clear plastic bottles with a white cap.

Holder of Certificate of Registration

Avid Brands S.A. (Pty) Ltd

Suite 9, Hillcrest Office Park

2 Old Main Road

Hillcrest

3610

This leaflet was last revised in

14 June 2022

Registration number

H925 (Act 101/1965)

Access to the corresponding Professional Information

<https://www.avidbrands.co.za>

Contact information:

Email: info@avidbrands.com

Telephone: 0860 104 061