UMBULALI NTSHULUBE

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 ingredientsof 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

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Access to the corresponding Professional Information
https://www.avidbrands.co.za
Contact information:
Email: info@avidbrands.com
Telephone: 0860 104 061

UMBULALI NTSHULUBE

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S0

UMBULALI NTSHULUBE, 937,50 mg per 5 ml elikser
Piperasien sitraat
Bevat suiker: Sukrose 2 208 mg

Lees die hele blaadjie sorgvuldig deur want dit bevat belangrike inligting vir u.
UMBULALI NTSHULUBE is beskikbaar sonder 'n dokter se voorskrif vir u om 'n geringe siekte te behandel. Nietemin, moet u UMBULALI NTSHULUBE versigtig gebruik om die beste resultate daaruit te verkry.

- Bewaar hierdie blaadjie. Dit mag nodig wees vir u om dit weer te lees.
- Moenie UMBULALI NTSHULUBE met enige ander persoon deel nie.
- Raadpleeg u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter sien indien u simptome vererger of nie verbeter binne 'n paar dae nie.

Wat is in hierdie blaadjie
1. Wat UMBULALI NTSHULUBE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u UMBULALI NTSHULUBE gebruik
3. Hoe om UMBULALI NTSHULUBE toe te dien
4. Moontlike newe effekte
5. Hoe om UMBULALI NTSHULUBE te bewaar
6. Inhoud van die pak en ander inligting

1. Wat UMBULALI NTSHULUBE is en waarvoor dit gebruik word
UMBULALI NTSHULUBE word gebruik om wurminfestasies te behandel.
Dit word gebruik vir die eliminasie (verwydering) van rondewurms en draadwurms.

2. Wat u moet weet voordat u UMBULALI NTSHULUBE neem
Moenie UMBULALI NTSHULUBE neem:
- Indien u hipersensitief (allergies) is vir piperasien sitraat of vir enige van die bestanddele van UMBULALI NTSHULUBE nie (gelys in afdeling 6).
- Indien u epilepsie het nie.
- Indien u ernstige nierskade het nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met UMBULALI NTSHULUBE:
- Indien u allergies is vir tartrasien of aspirien, aangesien allergiese-tipe reaksies, insluited asma, mag voorkom.
- Indien u senuweestelsel versteurings het.
- Indien u nierprobleme het.
- Indien u ingekorte lewerfunksie het.

Indien u gesondheid agteruitgaan terwyl u UMBULALI NTSHULUBE gebruik, gaan sien 'n dokter of apteker.

Kinders
- Kinders onder een jarige ouderdom kan slegs UMBULALI NTSHULUBE neem indien dit deur 'n dokter aanbeveel word.

Ander medisynes en UMBULALI NTSHULUBE
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne toedien. (Dit sluit komplementêre of tradisionele medisynes in).
- Moenie UMBULALI NTSHULUBE saam met ander ontwurmingsmedisynes gebruik nie.
- UMBULALI NTSHULUBE kan die newe effekte van fenotiasiene soos chloorpromasien vererger.

Swangerskap en Borsvoeding:
Indien u swanger is of borsvoed, dink dat u swanger mag wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.
Swangerskap:
Indien u swanger is, moenie UMBULALI NTSHULUBE gebruik tensy u dokter u aangesê het om dit te neem nie.
Borsvoeding:
Indien u borsvoed, neem 'n dosis van UMBULALI NTSHULUBE onmiddellik na borsvoeding, en moet dan nie borsvoed vir die volgende 8 ure nie. Melk borste uit en gooi die borsmelk gedurende hierdie tyd weg.

Bestuur en gebruik van masjinerie
UMBULALI NTSHULUBE kan lomerigheid, duiseligheid en dowwe visie veroorsaak. Moenie bestuur of masjinerie gebruik totdat u weet hoe UMBULALI NTSHULUBE u affekteer nie.

UMBULALI NTSHULUBE bevat Brilliant Blue (C.I. 42090), etanol, gliserol, peperment olie, gesuiwerde water, sukrose en tartrasien.
- Indien u vertel is deur u dokter dat u 'n intoleransie het vir sommige suikers, kontak u dokter voordat u UMBULALI NTSHULUBE neem.
- UMBULALI NTSHULUBE bevat sukrose, wat 'n effek mag hê op die beheer van u bloedsuiker indien u diabetes mellitus het.

3. Hoe om UMBULALI NTSHULUBE te neem
Moenie medisynes wat vir u voorgeskryf is met enige ander persoon deel nie.
Gebruik altyd UMBULALI NTSHULUBE presies volgens hierdie inligtingstuk of volgens u dokter, apteker of verpleegkundige se instruksie. Maak by u dokter, apteker of verpleegkundige seker indien u onseker is.
Vir die Eliminasie van Rondewurms.
Volwassenes en kinders wat 19,0 kg of meer weeg moet 'n enkeldosis van 30 ml (6 medisynemate) van UMBULALI NTSHULUBE neem voor aandete.
Vir babas en kinders wat minder as 19,0 kg weeg, is die dosis 20 ml (4 medisynemate) van UMBULALI NTSHULUBE voor aandete.
In gevalle van konstipasie, moet 'n soutwater lakseermiddel gegee word die volgende oggend.
Vir die Eliminasie van Draadwurms.
Neem UMBULALI NTSHULUBE daagliks na 'n maaltyd vir sewe dae.
Doseringskedule Vir Die Behandeling Van Draadwurms:

Ouderdom	**Gewig**	**Dosis**
		Moet volgehou word vir sewe dae
9 – 24 maande	6,5 – 9,5 kg	½ medisynemaat daagliks (2,5 ml)
2 – 4 jaar	9,5 – 12,5 kg	1 medisynemaat daagliks (5,0 ml)
4 – 7 jaar	12,5 – 19,0 kg	1½ medisynemate daagliks (7,5 ml)
7 – 13 jaar	19,0 – 38,0 kg	2 medisynemate daagliks (10,0 ml)
13 jaar tot volwassene	bo 38,0 kg	3 medisynemate daagliks (15,0 ml)

Indien nodig, kan die kursus herhaal word na een week.
Daar word aanbeveel dat alle lede van 'n huishouding ondersoek moet word en dat alle positiewe gevalle behandel word op dieselfde tyd om die verspreiding van die wurms en herinfestasie te voorkom.

Indien u meer UMBULALI NTSHULUBE neem as wat u moes:
'n Oordosis van UMBULALI NTSHULUBE kan duiseligheid, dowwe visie of naarheid veroorsaak.
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.
Indien u vergeet om UMBULALI NTSHULUBE te neem:
Moenie die dosis verdubbel nie. Slaan die dosis wat gemis is oor en gaan voort met die volgende dosis soos aangedui.

4. Moontlike newe effekte
UMBULALI NTSHULUBE kan newe effekte veroorsaak.
Nie alle newe effekte wat vir UMBULALI NTSHULUBE aangemeld is, word in hierdie blaadjie ingesluit nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ervaar terwyl UMBULALI NTSHULUBE gebruik word, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.
Indien enige van die volgende newe effekte voorkom, hou op om UMBULALI NTSHULUBE te gebruik en kontak u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal:
- kortheid van asem, stywe bors,
- veluitslae, jeukende vel, tintelende sensasie van die vel,
- aanvalle, verlies van spierkoördinasie, swakheid, rukking, bewing, verlies van reflekse, onwillekeurige oogbeweging,
- simptome wat soortgelyk is aan lewerinflammasie (hepatitis), weens infeksie wat veroorsaak word deur 'n virus soos koors, uitslag, moegheid, naarheid, braking, swak aptyt, gewrigpyn en hoofpyne,
- neusbloeding en ophoes van bloed,

Hierdie is almal ernstige newe effekte en u mag dringende mediese aandag benodig.
Vertel u dokter indien u enige van die volgende opmerk:
- slaperigheid, duiseligheid,
- hoofpyn,
- naarheid, braking, diarree, maagpyn,
- dowwe visie en vertroebeling van die lens in die oog.

Indien u enige newe effekte opmerk wat nie in hierdie blaadjie genoem is nie, stel asseblief u dokter of apteker in kennis.
Aanmelding van newe effekte
Indien u newe effekte ervaar, praat met u dokter, apteker of verpleegster. U kan ook newe effekte aanmeld by SAHPRA via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe effekte aan te meld, kan u help om meer inligting oor die veiligheid van UMBULALI NTSHULUBE te verskaf.

5. Hoe om UMBULALI NTSHULUBE te bewaar
- Bewaar by of benede 25 °C.
- Hou die bottel dig toe en beskerm teen lig.
- Hou die bottel in die buitenste karton tot voor gebruik.
- Moenie na die verstryk van die vervaldatum wat op die ettiket gedruk is, gebruik nie.

Bewaar alle medisyne buite die bereik van kinders.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in dreine of riolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat UMBULALI NTSHULUBE bevat
- Die aktiewe bestanddeel is pipersasien sitraat 937,50 mg per 5 ml van elikser.
- Die ander bestanddele is Brilliant Blue (C.I. 42090), etanol, gliserol, peperment olie, gesuiwerde water, sukrose en tartrasien.

Hoe UMBULALI NTSHULUBE lyk en inhoud van die pak
UMBULALI NTSHULUBE is 'n appelgroen, dik elikser met 'n peperment reuk en geur, wat verskaf word in 50 ml helder plastiekbottels met 'n wit dop.
Houer van Registrasiesertifikaat
Avid Brands S.A. (Edms) Bpk
Suite 9, Hillcrest Office Park
2 Old Main Straat, Hillcrest, 3610
Hierdie blaadjie was laas hersien op
14 Junie 2022
Registrasienommer
H925 (Wet 101/1965)
Toegang tot die ooreenstemmende Professionele Inligting
https://www.avidbrands.co.za
Kontakinligting:
E-pos: info@avidbrands.com, Telefoon: 0860 104 061