HAMBA WORM SYRUP®

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM
HAMBA WORM SYRUP® (Syrup)

COMPOSITION:
Each 5 ml of HAMBA WORM SYRUP contains:
Piperazine citrate equivalent to 750 mg piperazine hydrate.
Contains Sugar: Sucrose 2208 mg
Excipients: Erythrosine (CI 45430), ethanol 96 % rebate, glycerol, peppermint oil, purified water and Sunset Yellow (CI 15985).

CATEGORY AND CLASS:
A 12 Anthelmintics

PHARMACOLOGICAL ACTION:
Piperazine is an anthelmintic against roundworms (Ascaris) and threadworms (Enterobius).
In roundworms piperazine produces narcosis. The worms are then easily 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.

INDICATIONS:
HAMBA WORM SYRUP is indicated for the elimination of roundworm and threadworm.

CONTRAINDICATIONS:
The use of HAMBA WORM SYRUP is contraindicated in patients who have exhibited hypersensitivity to piperazine or to any component of the preparation.
HAMBA WORM SYRUP is contraindicated in patients with epilepsy or severe renal impairment.

WARNINGS AND SPECIAL PRECAUTIONS:
HAMBA WORM SYRUP should be given with caution to patients with neurological disturbances, mild to moderately impaired renal function or hepatic impairment.
If your general state of health worsens while taking this medicine, a doctor or pharmacist should be consulted.
HAMBA WORM SYRUP can cause drowsiness, dizziness and blurred vision which may have an effect on your ability to drive and use machines.
Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase- isomaltase insufficiency should not take HAMBA WORM SYRUP.
Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:
The anthelmintic effects of piperazine and pyrantel may be antagonised when the two compounds are used together.
HAMBA WORM SYRUP may enhance the adverse effects of phenothiazines such as chlorpromazine.

HUMAN REPRODUCTION:
Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:
For the elimination of roundworm.
A single dose of 30 ml of the syrup taken preferably before the evening meal will produce complete clearance of ascaris from the gut in older children and adults.
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 bodymass 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 kg	3 medicine measures daily (15,0 ml)

In rare instances it may be necessary to repeat the course after one week. In the case of adults the dosage should then be increased in proportion to the bodymass.
No special diet is required. It is often advisable to examine all members of a household and treat all positive cases at the same time, to prevent transmission of the worms and re-infestation.
If a dose is missed, skip the missed dose. Do not double the dose.

SIDE EFFECTS:
Blood and the lymphatic system 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, chloreiform 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Toxic effects may be produced with prolonged treatment with large dosages. Dizziness, blurred vision or nausea may be experienced under these conditions. Treatment is symptomatic and supportive.

IDENTIFICATION:
An orange coloured syrup.

PRESENTATION:
In bottles of 50 ml.

STORAGE INSTRUCTIONS:
Store in a well-closed container at or below 25 °C. Protect from light.
KEEP OUT OF REACH OF CHILDREN
Do not keep or use expired medicines.
Do not share medicines prescribed for you with others.

REGISTRATION NUMBER:
H892 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Avid Brands S.A. (Pty) Ltd
Suite 9, Hillcrest Office Park
2 Old Main Road,
Hillcrest, 3610

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
17 February 2017

HAMBA WORM SYRUP®

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM EN DOSERVORM:
HAMBA WORM SYRUP® (Stroop)

SAMESTELLING:
Elke 5 ml van HAMBA WORM SYRUP bevat:
Piperasiensitraat ekwivalent aan 750 mg piperasienhidraat.
Bevat Suiker: Sukrose 2208 mg
Onaktiewe bestanddele: Eritrosien (CI 45430), etanol 96 % rabat, gliserol, pepermentolie, gesuiwerde water en Sunset Yellow (CI 15985).

KATEGORIE EN KLAS:
A 12 Anthelmintika

FARMAKOLOGIESE AKSIE:
Piperasien is 'n anthelmintikum teen rondewurms (Ascaris) en haarwurms (Enterobius). Piperasien veroorsaak narkose by rondewurms. Die wurms word dan maklik verdryf vanaf hul posisie deur beweging van die dermkanaal, en in die ontlasting uitgeskei. Min is bekend rakende die meganisme van werking van piperasien by haarwurms.

INDIKASIES:
HAMBA WORM SYRUP is aangedui vir die eliminasie van rondewurm en haarwurm.

KONTRA INDIKASIES:
Die gebruik van HAMBA WORM SYRUP is teenaangedui by pasiënte wat hipersensitiwiteit vir piperasien of vir enige van die komponente van die preparaat getoon het.
HAMBA WORM SYRUP is teenaangedui by pasiënte met epilepsie of ernstige nierinkorting.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
HAMBA WORM SYRUP moet met omsigtigheid gegee word aan pasiënte met neurologiese versteurings, ligte tot matige ingekorte nierfunksie of hepatiese ontoereikendheid.
Indien u algemene gesondheidstoestand vererger tydens die inname van hierdie medikasie, moet 'n dokter of apteker gekonsulteer word.
HAMBA WORM SYRUP kan lomerigheid, duiseligheid, en dowwe visie veroorsaak, wat 'n effek op u vermoë om te bestuur en masjinerie te gebruik, kan hê.
Bevat sukrose. Pasiënte met seldsame oorerflike toestande soos fruktose intoleransie, glukose-galaktose wanabsorpsie of sukrase-isomaltase ontoereikendheid, moet nie HAMBA WORM SYRUP neem nie.
Bevat sukrose wat 'n effek op die glukemiese beheer van pasiënte met diabetes mellitus kan hê.

INTERAKSIES:
Die antihelmintiese effekte van piperasien en pirantel kan geantagoniseer word wanneer die twee komponente saam gebruik word.
HAMBA WORM SYRUP kan die newe effekte van fenotiasiene, soos chloorpromasien, vererger.

MENSLIKE REPRODUKSIE:
Veiligheid in swangerskap en laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Vir die eliminasie van rondewurm.
'n Enkeldosis van 30 ml van die stroop, verkieslik geneem voor aandete, sal volledige opruiming van ascaris uit die dermkanaal in ouer kinders en volwassenes tot gevolg hê. By babas en kinders wat onder 19,0 kg weeg, is die ooreenstemmende dosis 4 medisynemates (20 ml).
Geen vas- of ander addisionele maatreëls is nodig nie, maar in gevalle van konstipasie, moet 'n soutpurgeermiddel gegee word die volgende oggend.

Vir die eliminasie van haarwurm.
Gee daagliks, na 'n maaltyd vir sewe dae.
Die mees effektiewe dosis is van 50 tot 70 mg piperasien per kg liggaamsmassa per dag.

Doseringskedule vir die behandeling van haarwurm:

Ouderdom	Gewig	Dosis
Moet vir sewe dae volgehou word		
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 medisynemaat daagliks (7,5 ml)
7 – 13 jaar	19,0 – 38,0 kg	2 medisynemate daagliks (10,0 ml)
13 jaar tot volwassene bo	38 kg	3 medisynemate daagliks (15,0 ml)

In seldsame gevalle mag dit nodig wees om die kursus na een week te herhaal. In die geval van volwassenes, moet die dosis dan verhoog word in verhouding met die liggaamsmassa.
Geen spesiale dieet is nodig nie. Dit is dikwels raadsaam om al die lede van 'n huishouding te ondersoek en al die positiewe gevalle terselfdertyd te behandel, om oordrag van die wurms en herinfestasie te voorkom.
Indien 'n dosis gemis is, slaan die gemiste dosis oor. Moenie die dosis verdubbel nie.

NEWE EFFEKTE:
Bloed en limfatiese sisteem versteurings
Frekwensie onbekend: Hemolitiese anemie, trombositopenie, epistakse, hemoptise.
Immuunsisteem versteurings
Minder dikwels: Veluitslag, urtikarie.
Frekwensie onbekend: Brongospasma, Stevens-Johnson-sindroom, angioedeem, serumsiekte-agtige ongesteldheid, hipersensitiwiteit vaskulitis.
Senuweestelsel versteurings
Minder dikwels: Hoofpyn
Frekwensie onbekend: Slaperigheid, duiseligheid, nistagmus, gebrek aan spierkoördinasie, swakheid, ataksie, parestesie, miokloniese kontraksies, spiersametrekkingsbewegings, bewing, konvulsies, refleksverlies.
Oogversteurings
Minder dikwels: Verbygaande visieversteurings soos dowwe visie, katarakvorming.
Gastroïntestinale versteurings
Minder dikwels: Naarheid, braking, diarree, maagpyn.
Hepatobiliêre versteurings
Frekwensie onbekend: Virale hepatitis-agtige reaksies.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN:
Toksiese effekte kan geproduseer word deur langdurige behandeling met hoë dosisse. Duiseligheid, dowwe visie of naarheid kan onder hierdie toestande ondervind word.

IDENTIFIKASIE:
'n Oranjekleurige stroop.

AANBIEDING:
In bottels van 50 ml

BERGINGSINSTRUKSIES:
Berg in 'n diggeslote houer by of benede 25 °C. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS
Moenie vervalde medisynes hou of gebruik nie.
Moenie medisyne wat vir u voorgeskryf is met ander deel nie.

REGISTRASIENOMMER:
H892 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIE-SERTIFIKAAT:
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