1. NAME OF THE MEDICINAL PRODUCT

(BENDAMEX-S) Mebendazole 100mg/5ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Mebendazole USP ……100 mg

Approved Flavor Used

Sodium Methyl Paraben BP…….0.20 % W/V

Sodium Propyl Paraben BP……0.045 % W/V

Excipients with known effect:

Sorbitol 70% Solution BP……350 mg

Sugar S 30 IH…….2500 mg

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension

Off white to cream colored viscous suspension with Banana flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Broad spectrum gastrointestinal anthelmintic indicated for the treatment of:

Enterobius vermicularis (threadworm/pinworm)

Oxyuris vermicularis

Trichuris trichuria (whipworm)

Ascaris lumbricoides (large roundworm)

Ancylostoma duodenal (common hookworm)

Necator americanus (American hookworm)

4.2.Posology and method of administration

Posology

Adults and children over 2 years:

Enterobiasis:

1 x 5 ml (1 dosing cup).

It is highly recommended that a second dose is taken after 2 weeks, if reinfection is suspected.

Ascariasis, trichuriasis, ancylostomiasis, necatoriasis and mixed infections:

1 x 5 ml (1 dosing cup) twice a day for three days.
Children under 2 years:
See section 4.4 Special warnings and precautions for use

Method of administration
Oral use.

4.3.Contraindications

Bendamex-S is contraindicated in pregnancy and in patients who have shown hypersensitivity to the product or any components.

4.4.Special warnings and precautions for use

Not recommended in the treatment of children under 2 years
There have been rare reports of reversible liver function disturbances, hepatitis and neutropenia described in patients who were treated with Mebendazole at standard dosages for indicated conditions. These events, along with glomerulonephritis and agranulocytosis, have also been reported with dosages substantially above those recommended and with treatment for prolonged periods of time.
A case-control study of a single outbreak of Stevens-Johnson syndrome /toxic epidermal necrolysis (SJS/TEN) suggested a possible association with the concomitant use of metronidazole with mebendazole. Although there are no additional data on this potential interaction, concomitant use of mebendazole and metronidazole should be avoided.
Convulsions in children, including in infants below 1 year of age, have been reported very rarely during post-marketing experience (see section 4.8 'Undesirable effects'). Because of the risk of convulsions, Bendamex-S should not be used particularly in children below the age of 1 year. Bendamex-S has not been extensively studied in children below the age of 2 years.
Bendamex-S should only be given to very young children if their worm infestation interferes significantly with their nutritional status and physical development.
Bendamex-S oral suspension contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
Bendamex-S oral suspension 100 mg/5 ml contains Methyl paraben and Propyl paraben which may cause allergic reactions (possibly delayed). It also contains sorbitol solution and sucrose; patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicinal product”.

4.5.Interaction with other medicinal products and other forms of interaction

Concomitant treatment with cimetidine may inhibit the metabolism of mebendazole in the liver, resulting in increased plasma concentrations of the drug.

Concomitant use of mebendazole and metronidazole should be avoided.

4.6.Pregnancy and Lactation

Since Bendamex-S is contraindicated in pregnancy, patients who think they are or may be pregnant should not take this preparation.

Limited data from case reports demonstrate that a small amount of mebendazole is present in human milk following oral administration. Therefore, caution should be exercised when Bendamex-S is administered to breast-feeding women.

4.7.Effects on ability to drive and use machines

Bendamex-S has no influence on the ability to drive and use machines.

4.8.Undesirable effects

The displayed frequency categories use the following convention:

Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1000 to <1/100); Rare (≥1/10,000 to <1/1000); Very rare (<1/10,000), Not known (cannot be estimated from the available data).

System Organ Class	**Adverse Drug Reactions**		
	Frequency Category		
	Common (≥ 1/100 to <	**Uncommon** (≥ 1/1000 to <	**Rare** (≥1/10,000 to <1/1000)
Blood and Lymphatic			Neutropenia Agranulocytosis
Immune System Disorders			Hypersensitivity including anaphylactic reaction and anaphylactoid
Nervous System Disorders			Convulsions Dizziness
Gastrointestinal Disorders	Abdominal pain	Abdominal discomfort; Diarrhoea;	

Hepatobiliary Disorders			Hepatitis; Abnormal liver function tests
Skin and Subcutaneous Tissue Disorders			Rash Toxic epidermal necrolysis; Stevens-Johnson syndrome; Exanthema; Angioedema; Urticaria; Alopecia
Renal and Urinary Disorders			Glomerulonephritis

Reporting of suspected adverse reactions

Reporting 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 professionals are asked to report any suspected adverse reactions to **TMDA.**

4.9.Overdose

In patients treated at dosages substantially higher than recommended or for prolonged periods of time, the following adverse reactions have been reported rarely: alopecia, reversible liver function disturbances, hepatitis, agranulocytosis, neutropenia and glomerulonephritis. With the exception of agranulocytosis and glomerulonephritis, these also have been reported in patients who were treated with mebendazole at standard dosages (see section 4.8).

Signs and symptoms

In the event of accidental overdosage, abdominal cramps, nausea, vomiting and diarrhoea may occur.

Treatment

There is no specific antidote. Activated charcoal may be given if considered appropriate.

5.PHARMACOLOGICAL PROPERTIES

5.1.Pharmacodynamics properties

Pharmacotherapeutic classification: anthelmintic for oral administration, benzimidazole derivatives;

ATC code: P02CA01.

Mebendazole blocks the uptake of glucose by adult and larval forms of helminths, in a selective and irreversible manner. Inhibition of glucose uptake appears to lead to endogenous depletion of glycogen stores within the helminth. Lack of glycogen leads to decreased formation of ATP and ultrastructural changes in the cells.

Pharmacokinetic properties

Absorption

Following oral administration, < 10% of the dose reaches the systemic circulation, due to incomplete absorption and pre-systemic metabolism (first-pass effect). The majority of an orally administered dose remains in the gastrointestinal tract. Maximum plasma concentrations are generally seen 2 to 4 hours after administration. Administration with a high fat meal increases the bioavailability of mebendazole, but the overall effect of food on the amount of drug remaining in the gastrointestinal tract is not expected to be substantial.

Distribution

The plasma protein binding of mebendazole is 90 to 95%. The volume of distribution is 1 to 2 L/kg, indicating that mebendazole penetrates areas outside the vascular space. This is supported by data in patients on chronic mebendazole therapy (e.g., 40 mg/kg/day for 3-21 months) that show drug levels in tissue.

Metabolism

Orally administered mebendazole is extensively metabolised primarily by the liver. Plasma concentrations of its major metabolites (hydrolysed and reduced forms of mebendazole) are substantially higher than those of mebendazole. Impaired hepatic function, impaired metabolism, or impaired biliary elimination may lead to higher plasma levels of mebendazole.

Elimination

Mebendazole, the conjugated forms of mebendazole, and its metabolites likely undergo some degree of enterohepatic recirculation and are excreted in the urine and bile. The apparent elimination half-life after an oral dose ranges from 3 to 6 hours in most patients.

5.2.Preclinical safety data

Not Applicable

6.PHARMACEUTICAL PARTICULARS

6.1.List of excipients

Citric Acid Monohydrate BP
Disodium Edetate BP
Sodium Methyl Hydroxy Benzoate BP
Sodium Propyl Hydroxy Benzoate BP
Xanthan Gum USP/NF

Sorbitol 70% Solution BP
Sugar S 30 IH
Banana Flavour IH
Magnesium Aluminum Silicate IC USP/NF
Colloidal Anhydrous Silica BP
Purified Water BP

6.2.Incompatibilities

Not applicable

6.3.Shelf life

36 Months
In-use shelf life: Not more than 30 days after first opening

6.4.Special precautions for storage

Store below 30°C. Protect from sunlight.

6.5.Nature and contents of container

30 ml Amber colour PET Bottle with ROPP Cap and a 10 ml PP measuring cup.

6.6.Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirments.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Name and address of Marketing Authorization Holder:

NEOMEDIC LIMITED
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8. MARKETING AUTHORISATION NUMBER(S)

TAN 22 HM 0506

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05th December, 2022

10. DATE OF REVISION OF THE TEXT