Badorom

100 mg/5ml oral suspension

Broad spectrum gastrointestinal anthelmintic

Composition:

Each 5 ml of oral suspension contains:

Active ingredient :

Mebendazole 100 mg

Inactive ingredient : aerosil, sorbitolsolution, glycerin, potassium sorbate,methylparabensodium, propylparabensodium , saccharine sodium ,carboxymethylcellulose,citricacid anhydrous,sodium meta bisulphide ,polysorbate 80,banana flavor,purified water.

Indications

Broad spectrum gastrointestinal anthelmintic indicated for the treatment of:

Enterobius vermicularis (threadworm/pinworm)

Oxyuris vermicularis

Trichuris trichuria (whipworm)

Ascaris lumbricoides (large roundworm)

Ancylostoma duodenale (common hookworm)

Necator americanus (American hookworm)

There is no evidence that Badorom is effective in the treatment of cysticercosis.

Dosage&Method of administration

Oral use:

Adults and children over 4 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) bd for three days.

Method of administration.

Oral Uses

Overdose

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

Sympotoms

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

Treatment

There is no specific antidote. Within the first hour after ingestion, gastric lavage may be performed. Activated charcoal may be given if considered appropriate.

Contraindications

Badorom is contraindicated in pregnancy and in patients who have shown hypersensitivity to the product or any components and children under 4 years.

Precautions& Warning

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.

Side Effects

Common:

Abdominal pain

Uncommom:

- Abdominal discomfort

-Diarrhoea

-Flatulence

Rare:

- Neutropenia

-Hypersensitivity including anaphylactic reaction and anaphylactoid reaction

-Convulsions

-Dizziness

-Hepatitis

-Abnormal liver function tests

-Rash

-Toxic epidermal necrolysis

-Stevens-Johnson syndrome

-Exanthema

-Angioedema

-Urticaria

-Alopecia

PHARMACOLOGICAL PROPERTIES:

.1 Pharmacodynamic properties

Pharmacotherapeutic classification: Anthelmintic for oral administration, benzimidazole derivatives

In vitro and *in vivo* work suggests that 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.

There is no evidence that Badorom is effective in the treatment of cysticercosis**.**

2 Pharmacokinetic properties

Using a tracer dose of ^{3}H- mebendazole, the pharmacokinetics and bioavailability of a solution and IV drug have been examined. After oral administration, the half life was 0.93 hours. Absorption of this tracer dose was almost complete but low availability indicated a high first pass effect. At normal therapeutic doses, it is very hard to measure levels in the plasma.

Pregnancy and lactation

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

As it is not known whether mebendazole is excreted in human milk, it is not advisable to breast feed following administration of Badorom.

Drug Interactions

-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

Physical characters:

White to off white suspension free from foreign particles with characteristic odour.

Packing:

Carton box containing 30 ml (type II) amber glass bottle with Aluminium screw cap and inner leaflet .

Storage:

Shake well before use.

Keep out of reach and sight of children

Manufactured by: Badr pharma for pharmaceutical industries