Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Cach-e-Worm (Mebendazole Suspension 100mg/5ml)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 5 ml contains:

Mebendazole BP ……100

mg Flavoured syrup Base q.s

3.PHARMACEUTICALFORM

Liquid oral

Description: Light yellow colour homogeneous suspension having sweet taste with peppermint and mango flavours.

4. CLINICALPARTICULARS

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 duodenale (common hookworm)

Necator americanus (American hookworm)

There is no evidence that Cach-e-Worm is effective in the treatment of cysticercosis.

4.2 Posology and method ofadministration

For oral administration

Adults and children over 2 years: 1 x 5ml (1 dosing cup).

Care should be taken to avoid re-infection and it is strongly recommended that all members of the family are treated at the same time.

It is highly recommended that a second dose is taken after two weeks, if re-infection is suspected.

4.3 Contraindications

Cach-e-Worm is contraindicated in pregnancy and in patients who have shown hypersensitivity to the product or any components.

4.4 Special warnings and special precautions foruse

Cach-e worm oral suspension 100mg/5ml contains Sodium benzoate, Methylparaben 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 sucrase-isomaltase insufficiency should not take this medicinal product.

Cach-e-Worm is not recommended in the treatment of children under 2 years. If symptoms do not disappear within a few days, consult your doctor.

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 Mebendazole and Metronidazole should be avoided.

This medicine contains less than 1 mmol sodium (23mg) per <dosage unit><unit volume>, that is to say essentially 'sodium-free'

4.5 Interaction with other FPPs 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 Use in pregnancy

Since Cach-e-Worm is contra-indicated in pregnancy, patients who think they are or may be pregnant should not take this preparation.

Usage in Nursing Mothers:

As it is not known whether Mebendazole is excreted in human milk, it is not advisable to breast feed following administration of Cach-e-Worm.

4.7 Effects on ability to drive and usemachines

None known

4.8 Undesirable effects

At the recommended dose, Cach-e-Worm is generally well tolerated. However, patients with high parasitic burdens when treated with Cach-e-Worm have manifested diarrhea and abdominal pain.

Post-marketing experience

Within each system organ class, the adverse drug reactions are ranked under the headings of reporting frequency, using the following convention:

Very common (>1/10) Common (>1/100, < 1/10) Uncommon (>1/1000, < 1/100) Rare (>1/10000, < 1/1000) Very rare (< 1/10000) including isolated reports.

Immune system disorders

Very rare: hypersensitivity reactions such as anaphylactic and anaphylactoid reactions

Nervous system disorders

Very rare: convulsions in infants

Gastrointestinal disorders

Very rare: abdominal pain, diarrhea (these symptoms can also be the result of the worm infestation itself)

Skin and subcutaneous tissue disorders

Very rare: toxic epidermal necrolysis, Stevens-Johnson syndrome, exanthema, angioedema, urticarial, rash.

Liver function disturbances, hepatitis, glomerulonephritis and neutropenia.

4.9 Overdose

Symptoms

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

Treatment

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

Potential for drug abuse and dependence:

Not applicable

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamic properties

Anthelmintic for oral administration

ATC code: P02CA01

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 appearstoleadtoendogenousdepletionofglycogenstoreswithinthe helminth.Lackofglycogen leads to decreased formation of ATP and ultrastructural changes in thecells.

There is no evidence that Cach-e-Worm is effective in the treatment of cysticercosis

5.2 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 theplasma.

5.3 Preclinical safety data

None.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium Carboxymethyl Cellulose (HVP)
Sodium benzoate
Methyl paraben
Propyl paraben
Sorbitol solution (70%) (Non crystallizing) Saccharin sodium
Aerosil -200 (Colloidal silicon dioxide)
Polysorbate 80 (Tween- 80)
Citric acid monohydrate
Colour Quinoline Yellow
Flavour Peppermint
10211 Flavour Mango
RSV Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4Special precautions for storage

Store below 30°C. Protect from light.
Keep out of the reach ofchildren.

6.5 Nature and contents of container

30ml Amber colored pet bottle with measuring cup, such 1 bottle packed in carton along with Pack insert.

6.6 Instructions for use and handling <and disposal>
Store below 30°C. Shake well before use. Keep out of reach of children.

7. Marketing Authorization Holder

CACHET PHARMACEUTICALS PVT.LTD

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Dr. E. Moses Road, Worli, Mumbai-400

018, Maharashtra, India.

Manufacturer's Name and Address:

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8. Marketing Authorization Numbers

TAN 22 HM 0035

9. Date of First Authorization/ Renewal of the Authorization

10/01/2022

10. Date of Revision of theText

April, 2022