SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

CACH-E-WORM TABLETS

2. Qualitative and quantitative composition

Each Uncoated tablet Contains:

Mebendazole USP 100 mg

Excipients Q.S.

3. Pharmaceutical form

Solid Oral tablets

Description: Pale Orange colour plain circular un- coated tablets having bisecting line on one side.

4. Clinical particulars:

4.1 Therapeutic indications:

For the treatment of Trichuris trichuria (whipworm), Enterobius vermicularis (pinworm or threadworm), Ascaris lumbricoides (roundworm), Ancylostoma duodenale (common hookworm), Necator americanus (American hookworm) in single or mixed gastrointestinal infestations.

There is no evidence that Cacheworm Tablets are effective in the treatment of cysticercosis.

4.2 Posology and method of administration:

Adults and children over 2 years:

For the control of trichuriasis, ascariasis and hookworm infections, one tablet twice a day for three consecutive days.

For the control of enterobiasis a single tablet is administered. It is highly recommended that a second tablet is taken after two weeks, if re-infection is suspected.

Tablets may be chewed or swallowed whole. Crush the tablet before giving it to a young child. Always supervise a child while they are taking this medicine.

The scoreline is not intended for the division of the tablet. The tablet should be chewed or swallowed whole.

Method of Administration

Oral use.

The scoreline is not intended for the division of the tablet. The tablet should be chewed or swallowed whole.

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 warning and precautions:

Not recommended in the treatment of children under 2 years.

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.

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

Lactation

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 use machines

Cach-e-worm has no influence on the ability to drive and use machines.

4.8 Undesirable effects:

"The tablet contains Sunset yellow which may cause allergic reactions to some patients".

Adverse reactions are adverse events that were considered to be reasonably associated with the use of Cach-e-worm based on the comprehensive assessment of the available adverse event information. A causal relationship with Cach-e-worm cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of Cach-e-worm was evaluated in 6276 subjects who participated in 39 clinical trials for the treatment of single or mixed parasitic infestations of the gastrointestinal tract. In these 39 clinical trials, no adverse drug reactions (ADRs) occurred in ≥1% of Cach-e-worm treated subjects.

ADRs identified from clinical trials and post-marketing experience with Cach-e-worm are included in Table 1. 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).

Table 1: Adverse Drug Reactions Reported in Clinical Trials and Post-marketing Experience for Cach-e-worm

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Common (≥ 1/100 to < 1/10)	**Uncommon** (≥ 1/1000 to < 1/100)	**Rare** (≥1/10,000 to <1/1000)
Blood and lymphatic system disorders			Neutropenia
Immune system disorders			Hypersensitivity includ anaphylactic reaction anaphylactoid reaction
Nervous system disorders			Convulsions Dizziness
Gastrointestinal disorders	Abdominal pain	Abdominal discomfort Diarrhoea Flatulence	
Hepatobiliary disorders			Hepatitis Abnormal liver function te
Skin and subcutaneous tissue disorders			Rash Toxic epidermal necrolysi
			Stevens-Johnson Syndrome Exanthema Angioedema Urticaria Alopecia

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.

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

5.1Pharmacodynamic properties

Pharmacotherapeutic group: Anthelmintic for oral administration, benzimidazole derivatives;
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 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 Cacheworm is effective in the treatment of cysticercosis.

5.2 Pharmacokinetic properties Absorption

Following oral administration, < 10% of the dose reaches the systemic circulation, due to incomplete absorption and to extensive pre-systemic metabolism (first-pass effect). Maximum plasma concentrations are generally seen 2 to 4 hours after administration. Dosing with a high fat meal leads to a modest increase in the bioavailability of mebendazole.
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 (amino and hydroxylated amino 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.

Steady-state pharmacokinetics

During chronic dosing (e.g., 40 mg/kg/day for 3-21 months), plasma concentrations of mebendazole and its major metabolites increase, resulting in approximately 3-fold higher exposure at steady-state compared to single dosing.

5.3 Preclinical safety data

There are no pre-clinical data of relevance

6. Pharmaceutical particulars

List of excipients: Polyvinyl Pyrolidone K 30, Sodium starch glycolate , Microcrystalline cellulose, Starch , Talcum Powder, Magnesium stearate, Colour sunset yellow FCF, Purified water

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store in a dry place below 30° C. Protect from Light. Keep out of reach of Children.

6.5 Nature and contents of container

10 tablets packed in ALU/PVC Blister and such 10 Blister packed in monocarton with pack insert

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

Cachet Pharmaceuticals Pvt. Ltd
415, Shah Nahar, Worli,
Mumbai 400 018. India.

8. Marketing authorization number(s)

TAN 22 HM 0034

9. Date of first authorization

10/01/2022

10. Date of revision of the text

April, 2022