

A.C DRUGS LIMITED
PLOT C5/C6 OLD AIRPORT ROAD EMENE ENUGU,
ENUGU STATE

SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)

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AC MEBEZOLE (Mebendazole 100 mg Tablets)

AC DRUGS LIMITED

Plot C5/C6 Old Airport Road, Emene, Enugu, Nigeria

1. NAME OF THE MEDICINAL PRODUCT

AC MEBEZOLE

Mebendazole 100 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

- **Mebendazole BP** – 100 mg

Excipients with known effect:

None listed above safety threshold.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

White to off-white, flat, round tablets with a break-line on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

AC MEBEZOLE is indicated for the treatment of gastrointestinal helminth infections caused by:

- **Enterobius vermicularis** (pinworm/threadworm)
- **Ascaris lumbricoides** (roundworm)
- **Trichuris trichiura** (whipworm)
- **Ancylostoma duodenale** and **Necator americanus** (hookworms)

- Mixed helminth infections

4.2 Posology and Method of Administration

Adults and children ≥ 2 years:

- **Pinworm (Enterobiasis):** 100 mg single dose
- **Roundworm, whipworm, hookworm:** 100 mg twice daily for 3 days
- **Mixed infections:** 100 mg twice daily for 3 days

Children < 2 years:

Not recommended unless under physician supervision.

Method of administration:

For oral use. Tablets may be chewed, swallowed whole, or crushed and mixed with food.

4.3 Contraindications

- Hypersensitivity to mebendazole or any component of the product
- Children under 1 year (risk of convulsions has been reported)
- Pregnancy (especially first trimester, unless essential)

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with hepatic impairment
- Periodic blood counts and liver function tests are recommended with prolonged therapy
- Treatment may not eradicate eggs completely; hygiene measures should be followed to prevent reinfection

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- **Cimetidine:** May increase plasma levels of mebendazole
- **Metronidazole:** Concomitant use may increase risk of Stevens-Johnson Syndrome (rare)
- **Carbamazepine/phenytoin:** May reduce efficacy due to enzyme induction

4.6 Fertility, Pregnancy and Lactation

- **Pregnancy:** Contraindicated in the first trimester. Use only if clearly needed thereafter
- **Breastfeeding:** Caution advised; small amounts may pass into breast milk
- **Fertility:** No known adverse effect at therapeutic doses

4.7 Effects on Ability to Drive and Use Machines

AC MEBEZOLE has no known effects on the ability to drive or operate machinery.

4.8 Undesirable Effects

Common:

- Abdominal pain
- Diarrhoea
- Flatulence

Uncommon/Rare:

- Hypersensitivity reactions (rash, urticaria)
- Elevated liver enzymes
- Alopecia (reversible)
- Convulsions in infants <1 year (rare)
- Neutropenia with prolonged use (rare)

4.9 Overdose

Symptoms: Gastrointestinal upset, reversible liver function changes, alopecia

Management: Symptomatic and supportive. Activated charcoal may be given if ingestion is recent.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Anthelmintic

ATC Code: P02CA01

Mebendazole inhibits the polymerisation of tubulin into microtubules in intestinal helminths, leading to glucose depletion and parasite death.

5.2 Pharmacokinetic Properties

- **Absorption:** Poorly absorbed orally (~5–10% bioavailability)
- **Distribution:** Mostly confined to the gastrointestinal tract
- **Metabolism:** Extensive first-pass hepatic metabolism
- **Elimination:** Primarily via bile and faeces; minor renal elimination

5.3 Preclinical Safety Data

High doses in animal studies have shown embryotoxicity. No evidence of genotoxicity at therapeutic human doses. No carcinogenicity observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Lactose monohydrate
- Corn starch
- Microcrystalline cellulose
- Sodium starch glycolate
- Magnesium stearate
- Povidone

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years

6.4 Special Precautions for Storage

Store below 30°C. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and Contents of Container

- Blister packs of 6 tablets

6.6 Special Precautions for Disposal

No special requirements. Dispose of according to local regulations.

7. MARKETING AUTHORISATION HOLDER

AC Drugs Limited

Plot C5/C6 Old Airport Road, Emene, Enugu, Nigeria

Email: Acdrugslimited@yahoo.com

8. MARKETING AUTHORISATION NUMBER

A11-0762

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

Oct 2018-oct 2023

10. DATE OF REVISION OF THE TEXT

May 2025
