1.3.1
Summary Of Product Characteristics (SPC)

1.3.1 Summary of Product Characteristics

1.3.1.1 Invented Name of the Medicinal Product

ALBEROL TABLETS

Albendazole 400 mg Tablets

1.3.1.2 Strength

Albendazole 400 mg

1.3.1.3 Dosage Form

Solid Dosage Form

1.3.1.4 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Uncoated Chewable Tablet Contains:

Albendazole USP……400mg

Excipients……Q.S.

Colour .....Permitted colour

1.3.1.5 PHARMACEUTICAL FORM

Almost white coloured capsule shaped biconvex uncoated tablets, plain on one side and embossed ALBEROL on other side.

1.3.1.6. CLINICAL PARTICULARS

1.3.1.6.1 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 Albendazole Tablets are effective in the treatment of cysticercosis.

1.3.1.6.2 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.

Method of Administration

Oral use.

1.3.1.6.3 CONTRAINDICATIONS

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

1.3.1.6.4 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.

1.3.1.6.5 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.

1.3.1.6.6 PREGNANCY AND LACTATION

Since Albendazole 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 Albendazole.

1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Albendazole has no influence on the ability to drive and use machines.

1.3.1.6.8 UNDESIRABLE EFFECTS

Throughout this section adverse reactions are reported. Adverse reactions are adverse events that were considered to be reasonably associated with the use of Albendazole based on the comprehensive assessment of the available adverse event information. A causal relationship with Albendazole 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 Albendazole 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 Albendazole-treated subjects.

ADRs identified from clinical trials and post-marketing experience with Albendazole 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 Albendazole

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 including anaphylactic reaction and anaphylactic reaction
Nervous system disorders			Convulsions Dizziness
Gastrointestinal disorders	Abdominal pain	Abdominal discomfort Diarrhea Flatulence	
Hepatobiliary disorders			Hepatitis Abnormal liver function tests
Skin and subcutaneous tissue disorders			Rash Toxic epidermal necrolysis Stevens-Johnson syndrome Exanthema Angioedema Urticaria Alopecia

1.3.1.6.9 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.

1.3.1.7 PHARMACOLOGICAL PROPERTIES

1.3.1.7.1 Pharmacodynamic 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 Albendazole is effective in the treatment of cysticercosis.

1.3.1.7.2 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.

1.3.1.7.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the Summary of Product Characteristics.

1.3.1.8. PHARMACEUTICAL PARTICULARS

1.3.1.8.1 List of excipients

Maize Starch BP
Cross carmellose Sodium BP
Microcrystalline cellulose BP
Sugar BP
Colour titanium dioxide IH
Polyvinyl pyrolidone BP
Sodium Methyl Paraben BP
Sodium Propyl Paraben BP
Sodium lauryl sulphate BP
Talcum BP
Magnesium Stearate BP
flavour pineapple STR DM IH
Menthol BP
Aspartame
Sodium starch Glycolate BP

1.3.1.8.2 Incompatibilities: Not applicable.

1.3.1.8.3 Shelf life: Three years.

1.3.1.8.4 Special precautions for storage: Store below 30°C. Protected from light.

1.3.1.8.5 Nature and contents of container

Available as blister pack of 01 tablet. Such 01 blister packed in an inner carton along with pack insert. Such 20 inner cartons are packed in outer carton.

1.3.1.8.6 Special precautions for disposal and other Special handling

None

1.3.1.9 Marketed by:

M/S. AQUATIX PHARMACEUTICALS LIMITED,
NO. 14, PRINCE BODE, OLUWO STREET,
MENDE, MARYLAND, LAGOS, NIGERIA.

1.3.1.10 Manufactured by:

McW Healthcare (P) LTD.
286, 287-A, 287-B, Sector-E,
Industrial Area, Sanwer Road,
Indore (M.P.) India