BRAND NAME:	**WORMTAC TABLETS**
GENERIC NAME:	**ALBENDAZOLE TABLETS 400 MG**

1.3 PRODUCT INFORMATION

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

Enclosed

MAXHEAL For Maximum Healing	
BRAND NAME:	**WORMTAC TABLETS**
GENERIC NAME:	**ALBENDAZOLE TABLETS 400 MG**

1. Name of drug product:

WORMTAC TABLETS

1.1 (Trade) name of product:

Wormtac Tablets (Albendazole Tablets 400 mg)

1.2 Strength

Each chewable tablets contains:

Albendazole USP…… 400 mg

Excipients…….q.s.

Colour: Sunset Yellow FCF

1.3 Pharmaceutical Dosage Form

Solid Oral Dosage (Tablets).

2. QUALITATIVE & QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

Each Chewable tablets contains:

Albendazole USP…… 400 mg

Excipients…….q.s.

Colour: Sunset Yellow FCF

2.2 Quantitative Declaration Batch Formula:

Batch Size: 5,00,000 Tablets (410.00 kg)

Sr. No.	Name of Raw Material	Reference	Quantity/Batch In kg	Quantity/tablet In mg
Dry Mixing				
1	Albendazole	USP	200.000*	400.000*
2	Lactose	IH	75.150	150.300
3	Maize Starch	BP	104.500	190.00
4	Colour Sunset Yellow (Supra)	IH	0.200	0.400
5	Colloidal anhydrous silica (Aerosil)	BP	2.500	5.000
Binder				
6	Maize Starch	BP	20.000	40.000
7	PVPK-30	BP	1.650	3.300
8	Sodium Benzoate	BP	0.200	0.400
9	Purified Water	IH	43.000	q.s.
Lubricants				
10	Talcum	BP	4.000	8.000
11	Aspartame	IH	2.500	5.000
12	Sodium Starch Glycolate	BP	4.000	8.000
13	Raspberry Flavor	IH	0.800	1.600
14	Magnesium Stearate	BP	4.000	8.000
		Total	410.00 kg	820.0 mg

*Quantity of Albendazole USP is taken after calculation based on assay and Maize Starch

**Quantity changes according to change in quantity of Albendazole USP.

*** 10% Extra Maize Starch used to compensate the loss on drying.

3. PHARMACEUTICAL DOSAGE FORM

Orange Caplet shaped, uncoated Chewable tablets, having embossed with 400 on one side & plain on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

Wormtac Tablets is an antiparasitic medicine, used for the treatment of parasitic worm infections. It works by killing the worms that cause infections and stops the infection from spreading. Wormtac Tablets should be used in the dose and duration as advised by your doctor. Take it with or without food, preferably at a fixed time.

4.2 Posology and Method of Administration

Oral

Echinococcosis

Adult: <60 kg: 15 mg/kg daily in 2 divided doses. Max: 800 mg daily. ≥60 kg: 400 mg bid. Administer doses for 28-day cycle followed by a 14-day drug-free interval for a total of 3 cycles.

Child: Same as adult dose.

Oral

Neurocysticercosis

Adult: <60 kg: 15 mg/kg daily in 2 divided doses. Max: 800 mg daily. ≥60 kg 400 mg bid. Duration of treatment: 8-30 days.

Child: Same as adult dose.

Oral

Ascariasis, Enterobiasis, Hookworm infections, Trichuriasis

Adult: 400 mg as a single dose.

Child: 1-2 years 200 mg as a single dose. >2 years Same as adult dose. Max: 200 mg.

Oral

Clonorchiasis, Opisthorchiasis

Adult: 400 mg bid for 3 days. Max: 800 mg daily; 1,200 mg for 3 days. Confirm with your doctor after 1 month if worms have been eradicated.

Child: >2 years Same as adult dose.

Oral

Tapeworm infections

Adult: 400 mg daily for 3 consecutive days. Max: 400 mg daily; 1,200 mg for 3 days. If patient is not cured after 3 weeks, a second course of treatment is needed. In cases of Hymenolepis nana infestations, retreatment in 10-21 days is recommended. Administration information may vary between countries and individual products.

Child: >2 years Same as adult dose.

Oral

Cutaneous larva migrans

Adult: 400 mg once daily for 1-3 days. Max: 400 mg daily; 1,200 mg for 3 days.

Child: >2 years Same as adult dose.

Oral

Giardiasis

Child: 1-12 years 400 mg once daily for 5 days. Max: 400 mg daily; 2,000 mg for 5 days. Administration information may vary between countries and individual products.

Administration

Should be taken with food. For systemic infections, administer w/ high-fat meal to increase absorption. For patients w/ swallowing difficulty, tab may be crushed/chewed.

Should be taken on an empty stomach. For intraluminal infections w/o systemic involvement, take on an empty stomach. For patients w/ swallowing difficulty, tab may be crushed/chewed.

4.3 Contraindication

Wormtac Tablets are contraindicated in patients with known hypersensitivity to benzimidazole class of compounds or any components of Albendazole Tablets.

4.4 Special warnings and special precautions for use

Patient with neurocysticercosis, retinal lesions. May cause inflammatory reaction within the brain. Increased risk of bone marrow suppression in patient with liver disease. Hepatic impairment. Lactation.

4.5 Interaction with other medicinal products and other forms of interaction

Blood and lymphatic system disorders: Leukopenia, neutropenia. Eye disorders: Blurred vision.

Gastrointestinal disorders: Abdominal pain, nausea, vomiting, diarrhoea.

General disorders and administration site conditions: Fever, asthenia.

Hepatobiliary disorders: Mild to moderate hepatic enzyme elevation, hepatitis, acute liver failure.

Musculoskeletal and connective tissue disorders: Rhabdomyolysis.

Nervous system disorders: Headache, dizziness, somnolence, convulsion.

Renal and urinary disorders: Acute renal failure.

Skin and subcutaneous tissue disorders: Itchiness, rash, alopecia, erythema multiforme, Stevens-Johnson syndrome.

Potentially Fatal: Hypersensitivity reactions e.g. rash, pruritus, urticaria; bone marrow suppression, granulocytopenia, pancytopenia, aplastic anaemia, agranulocytosis.

4.6 Pregnancy and lactation

Pregnancy: Do not use in pregnancy

Lactation: safety is not established, so it should be used with caution. Elderly patient: may be used.

4.7 Effects on ability to drive and use machines

Dizziness is reported as a common reaction. Patients should be advised that if affected they should not drive, operate machinery or take part in activities where this could put them or others at risk.

4.8 Undesirable effects

Data from large clinical studies were used to determine the frequency of very common to rare undesirable reactions. The frequencies assigned to all other undesirable reactions (i.e. those occurring at < 1/1000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

The following convention has been used for the classification of frequency:

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

Blood and the lymphatic system disorders

Uncommon: Leucopenia

Very rare: Pancytopenia, aplastic anaemia, agranulocytosis
Patients with liver disease, including hepatic echinococcosis, appear to be more susceptible to bone marrow suppression (see „Posology and Method of Administration" and „Special Warnings and Precautions for Use").

Immune system disorders
Uncommon: Hypersensitivity reactions including rash, pruritus and urticaria
Nervous system disorders
Very common: Headache
Common: Dizziness

Gastrointestinal disorders
Common: Gastrointestinal disturbances (abdominal pain, nausea, vomiting)
Gastrointestinal disturbances have been associated with albendazole when treating patients with echinococcosis.

Hepato-biliary disorders
Very common: Mild to moderate elevations of hepatic enzymes
Uncommon: Hepatitis

Skin and subcutaneous tissue disorders
Common: Reversible alopecia (thinning of hair, and moderate hair loss)
Very rare: Erythema multiforme, Stevens-Johnson syndrome

General disorders and administrative site conditions
Common: Fever

4.9 Overdose

In case of overdosage, symptomatic therapy (gastric lavage) and general supportive measures should be undertaken.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: anthelmintic

ATC code: P02CA03

Albendazole is a benzimidazole carbamate with anthelmintic effects against tissue parasites. Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and it is thought to exert its anthelmintic effect by inhibiting tubulin polymerisation. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

Albendazole is effective in the treatment of tissue parasites including cystic echinococcosis and alveolar echinococcosis caused by infestation of Echinococcus granulosus and Echinococcus multilocularis, respectively.

In the treatment of cysts due to E. multilocularis, a minority of patients were considered to be cured and a majority had an improvement or stabilisation of disease due to albendazole.

5.2 Pharmacokinetic Properties

Absorption and metabolism

In man, albendazole is poorly absorbed (<5%) following oral administration. Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma. Albendazole sulfoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections. The plasma half-life of albendazole sulfoxide is 8½ hours.

Following oral administration of a single dose of 400 mg albendazole, the pharmacologically active metabolite, albendazole sulfoxide, has been reported to achieve plasma concentrations from 1.6 to 6.0 micromol/litre when taken with breakfast. The systemic pharmacological effect of albendazole is augmented if the dose is administered with a fatty meal, which enhances the absorption by approximately 5-fold.

Excretion

Albendazole sulfoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine. Elimination from cysts has been shown to occur over several weeks following high and prolonged dosing.

Special Patient Populations

Elderly

Although no studies have investigated the effect of age on albendazole sulfoxide pharmacokinetics, data in 26 hydatid cyst patients (up to 79 years) suggest pharmacokinetics similar to those in young healthy subjects. The number of elderly patients treated for either hydatid

disease or neurocysticercosis is limited, but no problems associated with an older population have been observed.

Renal Impairment

The pharmacokinetics of albendazole in patients with impaired renal function have not been studied.

Hepatic Impairment

The pharmacokinetics of albendazole in patients with impaired hepatic function have not been studied.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections.

BRAND NAME:	**WORMTAC TABLETS**
GENERIC NAME:	**ALBENDAZOLE TABLETS 400 MG**

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1. Lactose
2. Maize Starch
3. Colour Sunset Yellow FCF Supra
4. Colloidal anhydrous silica (Aerosil)
5. PVPK-30
6. Sodium Benzoate
7. Talcum
8. Aspartame
9. Sodium Starch Glycolate
10. Raspberry Flavor
11. Magnesium Stearate

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C, in a dry place, protect from light.

6.5 Nature and contents of container

1X1 Alu-PVC Blister Pack

7. Marketing authorization holder

Maxheal Laboratories Pvt. Ltd.
Plot No. -2-7/80-85, Sursez, GIDC
Sachin, Gujrat-394230, INDIA

8. Marketing authorization holder

NA

MAXHEAL For Maximum Healing	
BRAND NAME:	**WORMTAC TABLETS**
GENERIC NAME:	**ALBENDAZOLE TABLETS 400 MG**

9. Date of first authorisation/renewal of the authorization:

NA

10. Date of revision of the text:

NA

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6th December, 2023

The Deputy Director
Drug R&R
NAFDAC
Isolo,
Lagos.

Dear sir/ma,

SUBMISSION OF LAB SAMPLES

We hereby submit the samples of our products below for laboratory analysis.

- **CLONEX A CREAM**
- **DIADON CAPSULES**
- **WORMTAC**
- **DIFLAZON 50MG**
- **FANMET CAPSULES**
- **TENZELTOL 200MG TABLET**

Please find attached all the necessary supporting documents for your perusal

Yours faithfully

Pharm Ayobambo f
Managing Director