Shalina

TANZOL

(Albendazole Tablets)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TANZOL (Albendazole Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chemical Name	Approved Name (if any)	Quantity per Tablet in mg	Active / Non- active
Active Ingredients			
(3RS)-3-(4-Chlorophenyl)-N,N-dimethyl-3-(pyridin-2- yl) propan-1-amine hydrogen (Z)-butenedioate	Albendazole USP	400.00	Active Ingredient
Excipients			
-------	Lactose BP	220.00	Diluent
-------	Microcrystalline Cellulose BP	81.00	Diluent
-------	Croscarmellose sodium BP	50.00	Disintegrant
-------	Maize Starch BP	176.60	Binder
-------	Povidone (PVP K-30) BP	10.00	Binder
-------	Sunset Yellow Supra IH	2.40	Colouring Agent
-------	Saccharin Sodium BP	8.00	Sweeting Agent
-------	Flavoured Mixed Fruits IH	10.00	Flavouring Agent
-------	Magnesium Stearate BP	6.000	Lubricant

Definitions:

USP: United State Pharmacopoeia

BP: British Pharmacopoeia

IH: In-house Specification

3. PHARMACEUTICAL FORM

Uncoated chewable tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tanzol is indicated for the treatment of parasitic worm infestations (single or mixed) due to: Enterobius vermicularis (Pin worms), Trichuris trichuira (Whipworms), Ascaris lumbricoides (Large Roundworms), Ancylostoma duodenale (Hookworms), Necator americanus (Hookworms), Strongyloides stercoralis (Threadworms), Taenia spp (Tapeworms), Hymenolepis nana (Dwarf tapeworms), Taenia solium (Neurocysticercosis), Echinococcus granulosus (Hydatid cysts).

4.2 Posology and method of administration

The dose of Tanzol for adults and children above 2 years is one tablet or 10ml of suspension (400mg albendazole) as a single dose in suspected or confirmed infestations with Pin worms, Whipworms, Large Roundworms, Hookworms. In case of suspected or confirmed cases of Threadworms, Tapeworms, or Dwarf tapeworms, Tanzol should be used at a dose of one tablet or 10ml suspension once daily for 3 consecutive days. In cases of Dwarf Tapeworms, retreatment in 10-21 days is recommended. Tanzol 400mg twice daily for 3 consecutive days is effective in the treatment of patients with mixed worm infestation including infestation with Opisthorchis viverrini and Opisthorchis sinensis. For hydatid cysts: 10mg / kg of body weight / day for 4-8 weeks. For neurocysticercosis: 400mg twice a day for 30 days.

4.3 Contraindications

Tanzol is contraindicated in pregnancy and in patients with known hypersensitivity to albendazole.

4.4 Special warnings and precautions for use

General: It has been noted that leucopaenia has occurred when used for periods longer than recommended. Patients being treated for neurocysticercosis should receive appropriate steroid and anticonvulsant therapy as required. Cysticercosis may, in rare cases, involve the retina. If retinal lesions are visualized, the need for anticysticeral therapy should be weighed against the possibility of retinal damage caused by albendazole-induced changes to the retinal lesion.

For use in special populations:

Paediatrics: During albendazole therapy, because of the possibility of harm to the liver or bone marrow, routine (every 2 weeks) monitoring of blood counts and liver function tests should take place. Albendazole should be taken with food.

Pregnancy: Tanzol is contraindicated in pregnancy and in patients with known hypersensitivity to albendazole.

Lactation: Because of inadequate data breast feeding should be discontinued during & minimum 5 days after the treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Praziquantel, Cimetidine & Dexamethasone increases the drug level of **Tanzol**.

Theroretical risk of interaction with the theophylline, anticonvulsants, oral contraceptives and oral hypoglycaemics increases.

4.6 Pregnancy and lactation

Pregnancy: Tanzol is contraindicated in pregnancy and in patients with known hypersensitivity to albendazole.

Lactation: Because of inadequate data breast feeding should be discontinued during & minimum 5 days after the treatment.

4.7 Adverse Reactions

Side effects of Tanzol include transient abdominal pain and diarrhea, dizziness, nausea, constipation, dry mouth etc. Use of large doses of Tanzol can cause adverse effects like allergic reactions, raised liver enzyme values, alopecia, bone marrow depression etc.

4.8 Symptoms of Overdosage & Treatment

If poisoning or excessive overdosage is suspected it is recommended, on general principles, that vomiting be induced or gastric lavage be performed, and symptomatic supportive therapy be administered as appears indicated.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological category: Albendazole is a benzimidazole anthelmintic drug

ATC Code: P02CA03.

Tanzol selectively blocks the glucose uptake by adult helminthes in the intestine & their tissue dwelling larvae. Inhibition of glucose uptake leads to endogenous depletion of glycogen stored within the parasite. This in turn causes a decrease in the formation of adenosine triphosphate. By this mechanism, the drug slowly depletes the energy levels of the susceptible parasites.

5.2 Pharmacokinetic properties

Absorption : Oral absorption is low

Plasma half life : 8.5 hrs

Mean plasma peak concentration : 0.46 to 1.58mcg / ml

Elimination : Via bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP, Microcrystalline Cellulose BP, Croscarmellose sodium BP, Maize Starch BP, Povidone (PVP K-30) BP, Sunset Yellow Supra IH, Saccharin Sodium BP, Flavoured Mixed Fruits IH and Magnesium Stearate BP.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight and moisture. Keep out of reach of children.

6.5 Nature and contents of container

TANZOL is available as blister of 1 tablets, packed in inner carton along with pack insert. Such 20 inner cartons are packed in outer carton.

7. MARKETING AUTHORISATION HOLDER

M/s SHALINA HEALTHCARE DMCC

Physical and Postal Address:

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Country: Dubai

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Registered in Democratic Republic of Ghana, Benin, Kenya, Central African Republic.

9. DATE OF FIRST AUTHORISATION

Application for granting new registration certificate

10. DATE OF UPDATE OF TEXT

March 2021