

## **1.3 Product Information**

### **1.3.1 Summary of Product Characteristics (SmPC) - Enclosed**

## **TANZOL 200**

(Albendazole Tablets 200 mg)

### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### **1. NAME OF THE MEDICINAL PRODUCT**

**TANZOL 200** (Albendazole Tablets 200 mg)

#### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Chemical Name	Approved Name (if any)	Quantity per Tablet in mg	Active / Non- active
<b>Active Ingredients</b>			
(3RS)-3-(4-Chlorophenyl)-N,N-dimethyl-3-(pyridin-2-yl)propan-1-amine hydrogen (Z)-butenedioate	Albendazole USP	200.00	Active Ingredient
<b>Excipients</b>			
-----	Lactose BP	100.00	Diluent
-----	Sodium starch Glycolate BP	20.000	Disintegrant
-----	Croscarmellose sodium BP	12.500	Disintegrant
-----	Maize Starch BP	142.500	Diluent/ Disintegrant
-----	Sodium Lauryl Sulphate BP	1.000	Surfactant
-----	Povidone (PVP K-30) BP	5.000	Binder
-----	Sunset Yellow Supra IH	1.200	Colouring Agent
-----	Saccharin Sodium BP	4.000	Sweetening Agent
<b>Lubricants</b>			
-----	Flavour Mixed Fruit IH	5.000	Flavoring agent
-----	Sodium starch Glycolate BP	5.000	Disintegrant
-----	Croscarmellose sodium BP	12.500	Disintegrant
-----	Maize Starch BP	11.800	Diluent/ Disintegrant
-----	Sodium Lauryl Sulphate BP	1.500	Surfactant
-----	Magnesium Stearate BP	3.000	Lubricant

#### **Definitions:**

**USP:** United State Pharmacopoeia

**BP:** British Pharmacopoeia

**IH:** In-house Specification

#### **3. PHARMACEUTICAL FORM**

Uncoated chewable tablet

#### **4. CLINICAL PARTICULARS**

## **TANZOL 200**

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### **4.1 Therapeutic indications**

Tanzol is indicated for the treatment of parasitic worm infestations (single or mixed) due to: *Enterobius vermicularis* (Pin worms), *Trichuris trichiura* (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**

Check with the Healthcare Professional about how to take the medicine. Tanzol tablet may be crushed or chewed and swallowed with water.

In suspected or confirmed infections with Pin worms, Whipworms, Large Roundworms, Hookworm.

Adults and children above 2 years: 400mg as a single dose.

Children 1-2 years: 200 mg as a single dose.

In suspected or confirmed cases of Threadworms, Tapeworms, or Dwarf tapeworms.

Adult and children above 2 years: 400 mg once daily for 3 consecutive days.

In cases of Dwarf Tapeworms, retreatment in 10-21 days is recommended.

In the treatment of patients with mixed worm infestation including infestation with *Opisthorchis viverrini* and *Opisthorchis sinensis*: Adult and children above 2 years: 400 mg twice daily for 3 consecutive days.

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 anticysticercal 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.

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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**.

Theoretical 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**

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Lactose BP, Sodium starch Glycolate BP, Croscarmellose sodium BP, Maize Starch BP, Sodium Lauryl Sulphate BP, Povidone (PVP K-30) BP, Sunset Yellow Supra IH, Saccharin Sodium BP, Flavour Mixed Fruit 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 2 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:

30<sup>th</sup> Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Country: Dubai

## **8. MANUFACTURER**

**SHALINA HEALTHCARE NIGERIA LTD.**

Block 3B, Westerner Industrial Avenue,

Off Lagos-Ibadan Expressway, Isheri,

Ifo Local Government Area,

Ogun State, Nigeria.

## **9. DATE OF REVISION OF TEXT**

Every two years.