Toza®

Nitazoxanide powder for suspension / film coated tablet

DESCRIPTION

Toza® is a preparation of nitazoxanide, a synthetic antiprotozoal agent for oral administration. The antiprotozoal activity of nitazoxanide is believed to be due to interference with the pyruvate: ferredoxin oxidoreductase (PFOR) enzyme - dependant electron transfer reaction that is essential to anaerobic energy metabolism. Studies have shown that the PFOR enzyme from *Giardia lamblia* directly reduces nitazoxanide by transfer of electrons in the absence of ferredoxin. Nitazoxanide and its metabolites, tizoxanide are active in vitro in inhibiting the growth of sporozoites and oocysts of *Cryptosporidium parvum and trophozoites of Giardia lamblia.*

INDICATIONS

Toza® is indicated for the treatment of diarrhoea caused by *Cryptosporidium parvum, Giardia lamblia and Entamoeba histolytica.*

DOSAGE AND ADMINISTRATION

Toza® is recommended to be administered with food.

Age 12-47 months: One teaspoonful (5 ml) oral suspension (100 mg nitazoxanide) every 12 hours for 3 days.

Age 4-11 years: Two teaspoonful (10 ml) oral suspension (200 mg nitazoxanide) every 12 hours for 3 days.

Age 12 years or above: 500 mg tablet or five teaspoonful (25 ml) oral suspension every 12 hours for 3 days.

CONTRAINDICATIONS

It is contraindicated in patients with prior hypersensitivity to nitazoxanide.

USE IN PREGNANCY AND LACTATION

Nitazoxanide is used in pregnancy category-B. There are no adequate studies for the use of nitazoxanide in pregnancy or lactating mothers. Therefore use of nitazoxanide is indicated only in absolute indication.

PRECAUTIONS

Nitazoxanide must be administered with caution to patients with hepatic and biliary disease, with renal disease and with combined renal and hepatic disease.

SIDE-EFFECTS

The most frequent adverse events of nitazoxanide are abdominal pain, vomiting and headache. These are typically mild and transient in nature. Very rarely the side-effects includes nausea, anorexia, flatulence, fever, infection, increased appetite, enlarged salivary glands, malaise, increased creatinine, increased SGPT, pruritis, rhinitis, sweating, dizziness, discolored urine and in special sense eye discoloration etc.

DRUG INTERACTIONS

Tizoxanide is highly bound to plasma protein. Therefore, caution should be taken when administering nitazoxanide concurrently with other highly plasma protein-bound drugs with narrow therapeutic indices, as competition for binding sites may occur. Patients using nitazoxanide have reported no interactions with other medicinal products. However, no clinical studies have been conducted to specifically exclude the possibility of interactions between nitazoxanide and other medicinal products.

PHARMACEUTICAL PRECAUTION

Unsuspended powder and the reconstituted oral suspension should be stored below 25°C, in a dry place and away from light. The container should be kept tightly closed and the suspension should be shaken well before each administration. The suspension may be stored for 7 days, after which any unused portion must be discarded.

Tablet : Store in a dry place and away from light.
Keep out of reach of children.

PACKAGING

Toza® powder for suspension : Bottle containing powder for reconstitution of 30 ml / 60 ml suspension. Each 5 ml reconstituted suspension contains nitazoxanide INN 100 mg.

Toza® 500 tablet : Box containing 2 alu-alu blisters of 6 tablets each. Each film coated tablet contains nitazoxanide INN 500 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LTD.

DHAKA, BANGLADESH

® REGD. TRADEMARK

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