

# Nitazoxanide 500 mg Tablet & 100 mg/5 ml Powder for Suspension

Nitide is a preparation of Nitazoxanide. It is a synthetic antiprotozoal agent for oral administration. The antiprotozoal activity of Nitazoxanide is believed to be interference with the Pyruvate Ferredoxin Oxido Reductase (PFOR) enzyme-dependant electron transfer reaction. This reaction is essential for anaerobic energy metabolism of the protozoa. Nitazoxanide and its metabolites, tizoxanid are active in vitro in inhibiting the growth of sporozoites and oocyst of Cryptosporidium parvum and trophozoites of Giardia lamblia.

#### COMPOSITION

Nitide 500 Tablet: Each film coated tablet contains Nitazoxanide INN 500 mg.

Nitide Powder for Suspension: After reconstitution, each 5 ml suspension contains Nitazoxanide INN 100 mg.

#### INDICATION

Nitide (Nitazoxanide) is indicated for the treatment of diarrhea caused by *Cryptosporidium* parvum, *Giardia lamblia* and *Entamoeba histolytica*.

#### DOSAGE AND ADMINISTRATION

Age 1-3 years: 1 tea-spoonfull or 5 ml suspension every 12 hours for 3 days. Age 4-11 years: 2 tea-spoonfulls or 10 ml suspension every 12 hours for 3 days. Age 12 years or above: 5 tea-spoonfulls (25 ml) suspension or 1 tablet every 12 hours for 3 days.

It is recommended to be administered with food

## SIDE EFFECT

The most frequent side effects, reported by Nitazoxanide are abdominal pain, vomiting and headache. These side effects are typically mild and transient in nature. Very rare side effects include- nausea, anorexia, flatulence, increased appetite, enlarged salivary glands, increased creatinine & SGPT level, pruritus, rhinitis, sweating, dizziness, discolored urine etc.

#### PRECAUTION

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

## CONTRAINDICATION

It is contraindicated in patients with known hypersensitivity to Nitazoxanide or any components of the preparation.

#### **DRUG INTERACTION**

It is highly bound to plasma protein. Therefore, caution should be exercised when administering Nitazoxanide concurrently with other highly plasma protein-bound drugs with narrow therapeutic index.

#### **USE IN PREGNANCY AND LACTATION**

US FDA pregnancy category of Nitazoxanide is B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Nitazoxanide have been shown to be excreted in human milk. So, caution should be exercised when Nitazoxanide is administered during lactation.

## STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

### **HOW SUPPLIED**

Nitide 500 Tablet: Each box contains 30 tablets in Alu-PVC blister pack.

Nitide 30 ml Powder for Suspension : Each amber glass bottle contains dry powder to reconstitute 30 ml suspension.

Nitide 60 ml Powder for Suspension : Each amber glass bottle contains dry powder to reconstitute 60 ml suspension.



Manufactured by:

NIPRO JMI Pharma Ltd. Comilla, Bangladesh.