Diazox 100mg/5ml Suspension

(Nitazoxanide)

ڈایازوکس ۱۰۰ ملی گرام/۵ ملی لیٹر سسپنشن

(نیٹازوکسانائیڈ)

COMPOSITION

Diazox Suspension 100mg/5ml

Each 5ml after reconstitution contains:

Nitazoxanide (MS).....100mg

Product complies Innovator's specs.

DESCRIPTION

DIAZOX for oral suspension contain the active ingredient, nitazoxanide, a synthetic antiprotozoal for oral administration that is effective in the treatment of gastrointestinal infections.

MECHANISM OF ACTION

Nitazoxanide is an antiprotozoal. The antiprotozoal activity of nitazoxanide is believed to be due to interference with the pyruvate:ferredoxin oxidoreductase (PFOR) enzyme-dependent electron transfer reaction which is essential to anaerobic energy metabolism. Studies have shown that the PFOR enzyme from G. lamblia directly reduces nitazoxanide by transfer of electrons in the absence of ferredoxin. The DNA-derived PFOR protein sequence of C. parvum appears to be similar to that of G. lamblia. Interference with the PFOR enzyme-dependent electron transfer reaction may not be the only pathway by which nitazoxanide exhibits antiprotozoal activity.

INDICATIONS

Diazox for oral suspension (patients 1 year of age and older) are indicated for the treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum.

Limitations of Use

Diazox for oral suspension have not been shown to be effective for the treatment of diarrhea caused by Cryptosporidium parvum in HIV-infected or immunodeficient patients.

DOSAGE AND ADMINISTRATION

Recommended Dosage

Age	Dosage	Duration
1-3 years	5 mL of DIAZOX for oral suspension (100 mg nitazoxanide) taken orally every 12 hours with food	3 Days
4-11 years	10 mL of DIAZOX for oral suspension (200 mg nitazoxanide) taken orally every 12 hours with food	
12 years and older	25 mL of DIAZOX for oral suspension (500 mg nitazoxanide) taken orally every 12 hours with food	

Directions for Mixing DIAZOX for oral suspension:

Reconstitute DIAZOX for oral suspension as follows:

To prepare 30ml suspension, add 20ml freshly boiled and cooled water with the help of a measuring cup and shake the bottle well.

Keep container tightly closed, and shake the suspension well before each administration. Reconstituted suspension is stable for 7 days when stored in a refrigerator (2-8°C), after which any unused portion must be discarded.

PHARMACOKINETICS

Absorption: The relative bioavailability of the suspension compared to the tablet was 70%. When administered with food the AUC and Cmax increased by two-fold and 50%, respectively, for the tablet and 45 to 50% and ≤ 10%, respectively, for the oral suspension

Distribution: In plasma, more than 99% of tizoxanide is bound to proteins.

Metabolisim: Following oral administration in humans, nitazoxanide is rapidly hydrolyzed to an active metabolite, tizoxanide (desacetyl-nitazoxanide). Tizoxanide then undergoes conjugation, primarily by glucuronidation.

Excretion: Tizoxanide is excreted in the urine, bile and feces, and tizoxanide glucuronide is excreted in urine and bile. Approximately two-thirds of the oral dose of nitazoxanide is excreted in the feces and one third in the urine.

WARNINGS AND PRECAUTIONS

Before using this medication, consult your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, a weakened immune system (such as HIV infection).

The liquid form of this medication contains sugar. Caution is advised if you have diabetes. Ask your doctor or pharmacist about using this product safely.

During pregnancy, this medication should be used only when clearly needed.

Geriatric Use

Clinical studies of DIAZOX for oral suspension did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in elderly patients should be considered when prescribing DIAZOX for oral suspension.

Renal and Hepatic Impairment

The pharmacokinetics of nitazoxanide in patients with compromised renal or hepatic function has not been studied.

SIDE EFFECTS

The following adverse reactions have been identified during post approval use of DIAZOX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, such as: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

DRUG INTERACTIONS

Highly Protein Bound Drugs with Narrow Therapeutic Indices

Tizoxanide (the active metabolite of nitazoxanide) is highly bound to plasma protein (>99.9%). Therefore, monitor for adverse reactions when administering nitazoxanide concurrently with other highly plasma protein-bound drugs with narrow therapeutic indices, as competition for binding sites may occur (e.g., warfarin).

FERTILITY, PREGNANCY AND LACTATION

Pregnancy

There are no data with DIAZOX in pregnant women to inform a drug-associated risk. No teratogenicity or fetotoxicity was observed in animal reproduction studies with administration of nitazoxanide to pregnant rats and rabbits during organogenesis at exposures 30 and 2 times, respectively, the exposure at the maximum recommended human dose of 500 mg twice daily based on body surface area (BSA).

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Lactation

No information regarding the presence of nitazoxanide in human milk, the effects on the breastfed infant, or the effects on milk production is available.

OVERDOSE

Limited information on nitazoxanide overdosage is available. Single oral doses of up to 4000 mg nitazoxanide have been administered to healthy adult volunteers without significant adverse effects. In the event of overdose, gastric lavage may be appropriate soon after oral administration. Patients should be observed and given symptomatic and supportive treatment. There is no specific antidote for overdose with DIAZOX. Because tizoxanide is highly protein bound (>99.9%), dialysis is unlikely to significantly reduce plasma concentrations of the drug.

CONTRAINDICATIONS

Diazox for oral suspension are contraindicated in patients with a prior hypersensitivity to nitazoxanide or any other ingredient in the formulations.

STORAGE & INSTRUCTIONS

Store the powder between 15-25°C. Protect from heat, sunlight and moisture. Do not freeze. Keep away from the reach of children.Reconstituted suspension is stable for 7 days when stored in a refrigerator (2-8°C). Discard the remaining suspension after 7 days.

SHAKE WELL BEFORE USE.

Keep the container tightly closed.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED

Diazox Suspension 100mg/5ml

30ml Bottle.

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا بنانے کا طریقہ:

۳۰ ملی لیٹر سسپنشن بنانے کیلئے دیے گئے کپ کی مدد سے تقریباً ۲۰ ملی لیٹر پانی کو پاؤڈر میں ڈال کر حل کریں اور اچھی طرح ہلائیں۔

ہدایات:

پاؤڈر کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی سے محفوظ اور بچوں کی پہنچ سے دور رکھیں۔ تیار کردہ دوا ریفریجریٹر (۲ سے ۸ ڈگری سینٹی گریڈ درجہ حرارت) میں رکھنے کی صورت میں ۷ دن تک قابل استعمال رہتی ہے۔ ۷ دن کے بعد بچ جانے والی دوا ضائع کر دیں۔ استعمال سے پہلے اچھی طرح ہلائیں۔ صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:

PHARMASOL PRIVATE LIMITED

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