Core Safety Profile

Active substance: Nifuroxazide
Pharmaceutical form(s)/strength: Capsules, 200 mg
P-RMS: CZ/H/PSUR/0015/001
Date of FAR: 17.03.2010
4.3 Contraindications

*applies to all formulations:*

Hypersensitivity to nitrofurane derivatives or any of the excipients

*applies only to 100 mg and 200 mg capsules:*

Children less than the age of 6 years

*applies only to 4% oral suspension:*

Premature and new-born infants (0 to 1 month)

4.4 Special warnings and precautions for use

*applies to all formulations:*

Rehydration is the essential treatment for acute diarrhoea in infants below the age of 2 years. In children over this age, it should always be considered. If diarrhoea persists after two days of treatment, management should be reviewed and the need for oral or intravenous rehydration should be considered. In case of severe prolonged diarrhoea, severe vomiting or refusal to eat, intravenous rehydration should be considered. In the event of infectious diarrhoea, with clinical signs and symptoms suggestive of an invasive phenomenon, antibacterial agents with good systemic diffusion should be employed.

*applies only to 4% oral suspension:*

This product contains alcohol. The alcohol content of the suspension is 1.44% (v/v), i.e. 55 mg alcohol per measuring spoonful.

4.5 Interaction with other medicinal products and other forms of interaction

*applies only to 4% oral suspension:*

Due to the presence of alcohol, CNS depressants should not be used.

4.6 Pregnancy and lactation

No teratogenic effects have been found in animal studies. In the absence of such effects in animals, a malformative effect is not anticipated in humans. To date, substances responsible for malformations in humans have proved to be teratogenic in animals during well-conducted studies in two species. In clinical use, sufficiently relevant data are not available to assess any malformative or fetotoxic effects of nifuroxazide when administered during pregnancy. Therefore, as a precaution, nifuroxazide should not be used during pregnancy. Breast feeding remains possible in the event of a short course of treatment with the product.

4.7 Effects on ability to drive and use machines

This medicine has no effect on the ability to drive and operate machines.
4.8 Undesirable effects

Allergic reactions such as cutaneous rash, urticaria, angioedema, anaphylactic shock.

4.9 Overdose

No specific information is available on overdose with nifuroxazide. The patient should be closely monitored, and treatment should be symptomatic and supportive.