1. NAME OF THE MEDICINAL PRODUCT
Flatrolam 220 mg/5ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Nifuroxazide

One 5 ml measuring spoon contains 220 mg of nifuroxazide.

3. PHARMACEUTICAL FORM
Oral suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
In addition to rehydration, treatment of acute diarrhea presumed to be of bacterial origin in the absence of suspicion of invasive phenomena (deterioration of general condition, fever, toxic-infectious signs, etc.).
The extent of rehydration by oral or intravenous rehydration solution must be adapted according to the intensity of the diarrhea, the age and the particularities of the patient (associated diseases, etc.).
Consideration should be given to official recommendations regarding the appropriate use of antibacterials.

4.2. Posology and method of administration
Dosage
Child over 2 years: 660 mg per day, or 3 measuring spoons per day, in 3 doses.
Treatment should not exceed 7 days.
Administration mode
Oral route.

4.3. Contraindications
- Hypersensitivity to nitrofuran derivatives or any of the other components.
- Premature, newborn (0 to 1 month) and infants under 2 years.

4.4. Special warnings and precautions for use

Special warnings
Rehydration can be the mainstay in the treatment of acute diarrhea in children.
It should be systematically considered.
The prevention or treatment of dehydration will be by oral rehydration solution or intravenous.
It is recommended to use the solutions provided for this purpose and to respect the methods of reconstitution and use.
- The Na + concentration should be between 30 and 60 mmol / l, solutes with a lower sodium content (30 mmol / l) being reserved for mild dehydration.
- A supply of chlorine and potassium is necessary in order to correct digestive losses.
- The recommended glucose concentration is between 74 and 110 mmol / l.
- The addition of hydrolyzed proteins or amino acids does not seem to improve rehydration or nutritional status.

It is essential to offer the child to drink very often, every quarter of an hour for example.
As an indication, the proposed volume of oral rehydration solution must be equivalent to the weight lost, ie 50 to 100 ml / kg for a dehydration of 5 to 10% of the body weight.

In the event of severe or prolonged diarrhea, severe vomiting or refusal of food, intravenous rehydration should be considered.
In the event of infectious diarrhea with clinical manifestations suggesting an invasive phenomenon, resort to antibacterials with good systemic distribution.
This medicine contains sucrose. Its use is not recommended in patients with sucrose intolerance.
This medicine contains methyl parahydroxybenzoate (E218) and may cause allergic reactions (possibly delayed).

Precautions for use
- **In children over 2 years:**

○ If rehydration by rehydration solution is prescribed, the methods of use as well as the method of reconstitution must be clearly and precisely explained.

○ In the absence of the need to prescribe such rehydration, it is nevertheless necessary to clearly explain the need for:

▪ rehydrate the child with abundant, salty or sweet drinks, in order to compensate for fluid losses due to diarrhea (the average daily water ration is 2 liters),

▪ maintain the diet during the diarrhea.

○ by excluding certain intakes and particularly raw vegetables, fruits, green vegetables, spicy dishes, as well as frozen foods or drinks.

○ by favoring grilled meats, rice.
- The elimination of milk and dairy products should be considered on a case-by-case basis.
- Faced with diarrhea in children, it is appropriate to consider the possibility of a deficit sucrase before prescribing a drug containing sucrose.
- This drug contains 39 mg of sodium per 100 g, 2.14 mg per measuring spoon of 5 ml. To be taken into account in patients on a strict sodium diet.

4.5. Interactions with other drugs and other forms of interactions

Not recommended associations
This drug is not recommended with drugs causing an antabuse reaction and CNS depressants.

4.6. Fertility, pregnancy and lactation

Pregnancy
This medicine is intended for children. However, when used in exceptional circumstances in women of childbearing age, the following points should be remembered:
Animal studies have not produced any evidence of a teratogenic effect. In the absence of a teratogenic effect in animals, a malformative effect in humans is not expected. Indeed, to date, the substances responsible for malformations in the human species have been shown to be teratogenic in animals during well-conducted studies on two species.
In the clinic, there are currently no sufficiently relevant data to assess a possible malformative or foetotoxic effect of nifuroxazide when it is administered during pregnancy.
Therefore, as a precautionary measure, it is best not to use nifuroxazide during pregnancy.

Feeding with milk
Breast-feeding is still possible if you take this medicine for a short time.

4.7. Effects on ability to drive and use machines
Not applicable.

4.8. Side effects
The frequency terms used below meet the following definitions:
Very common (≥ 1/10)
Common (≥ 1/100, <1/10)
Uncommon (≥ 1/1000, <1/100)
Rare (≥ 1 / 10,000, <1/1000)
Very rare (<1 / 10,000)
Not known (frequency cannot be estimated from the available data).
Immune system disorders :
Not known: Allergic reactions such as rash, urticaria, angioedema, anaphylactic shock.

Reporting of suspected adverse reactions
The reporting of suspected adverse reactions after authorization of the drug is important. It allows continuous monitoring of the benefit / risk ratio of the medicinal product.

4.9. Overdose
No specific information is available regarding the symptoms of nifuroxazide overdose.
If nifuroxazide overdose is suspected, the patient should be monitored and symptomatic treatment should be implemented.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: INTESTINAL ANTI-INFECTIOUS.

5.2. Pharmacokinetic properties
Absorption
Absorption is extremely low when the intestinal mucosa is not altered.

5.3. Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Disodium edetate, methyl paraben, Propyl paraben, tween 80, saccharin sodium, AVICEL RC 591, glycerol, banana flavor, purified water.

6.2. Incompatibilities
Not applicable.

6.3. The duration of the conversation
3 years.

6.4. Special precautions for storage
No special storage conditions.

6.5. Nature and contents of the outer packaging
Carton box contain amber glass(typeIII) bottle of 100 ml suspension with (HDPE)plastic cap+(EPE) foam liner + inner leaflet.
Carton box contain amber glass(typeIII) bottle of 60 ml suspension with (HDPE)plastic cap+(EPE) foam liner + inner leaflet

6.6. Special precautions for disposal and handling
Shake well before use.