SUMMARY OF PRODUCT CHARACTERISTICS

I.B.1.1. Official name:
Antinal, suspension.

I.B.1.2. Qualitative and quantitative composition of the drug, INN or international non-proprietary name, and name of the active substances:

5 ml of suspension contain:

Substance / active / active substances (*):

Name	Quantity	Unit	Reference / international monographic standard
Nifuroxazide	220	mg	BP 2010

Excipient / excipients (*):

Name	Quantity	Unity	Reference / monographic standard
Citric acid monohydrate	3.5	mg	BP 2010
C.M.C (cekol 1000)	20	mg	BP 2010
Avicel RC 581	70	mg	BP 2010
Sodium saccharin	7.5	mg	BP 2010
Sodium Propylparaben	1	mg	BP 2010
Sodium Methylparaben	5.55	mg	BP 2010
Sodium Benzoate	10	mg	BP 2010
liquid banana	0.0075	ml	Sp. is inclued
Tween 80	7.5	mg	BP 2010
Aerosil 200	15	mg	BP 2010
Purified water q.s.	5	ml	BP 2010

I.B.1.3. Form (including method of administration):

Suspension, oral

I.B.1.4. Clinical data

4.1 Therapeutic indications:

- Acute diarrhea of bacterial origin without symptoms or signs of spread (General malaise, fever, signs of infectious toxicity ...)

- Antinal treatment does not exclude dietary restrictions and / or rehydration (if any).

- Oral or intravenous rehydration should be measured according to the severity of the diarrhea, the age and condition of the patient (associated diseases, etc.)

4.2 Doses and method of administration for adults, and when applicable, for children and / or elderly patients:

Unless otherwise prescribed by the doctor, the usual dose is as follows:

Children over 2 years: 1 teaspoon (5 ml) 3 times / day

The treatment should not exceed 3 days.

4.3 Contraindications:

- Hypersensitivity to nitrofuran derivatives or to any of the constituents of the suspension
- premature infants and new-borns (0-1 months) and children under 2 years of age.

4.4 Special warnings and precautions:

- Acute diarrhea is treated by rehydration in children under 2 years of age and is considered an essential part of antidiarrheal therapy.
- If diarrhea persists for 3 days, the patient's condition is assessed for rehydration (oral or intravenous)
- Broad-spectrum systemic antibiotics should be considered for infectious diarrhea with clinical manifestations of systemic spread.

Precautions:
Patients should be aware of the need to:
- Rehydrate with a lot of liquids (salty or sweet) to make up for the loss of fluid following diarrhea.
- Eat properly during episodes of diarrhea
- Exclude certain foodstuffs, including raw foods, fruits and vegetables, spliced food, food and cold drinks.
- Priority should be given to grilled meat and rice

4.5 Drug Interactions, Other Interactions:

This medicine is not compatible with anti-abuse drugs and CNS depressants

4.6 Pregnancy and lactation:

No clinically relevant data are available to evaluate the potential teratogenic or fetotoxic effects of nifuroxazide during pregnancy. Therefore, as a precaution, nifuroxazide should be avoided during pregnancy. Breastfeeding can continue normally if therapy with Antinal is limited in time.

4.7 Effect on ability to drive and drive machines:

No effect on the ability to drive a vehicle.

4.8 Undesirable effects (frequency and seriousness):

Probability of allergic skin reactions such as rash, Quincke oedema, urticaria or anaphylactic shock.

4.9 Overdose

No clinical data are available on overdose of nifuroxazide.

I.B.J .5. Pharmacological properties

5.1 Pharmacodynamic properties:

• Pharmacotherapeutic group: other intestinal anti-infective agents

5.2 Pharmacokinetic properties

• Absorption of Antinal is extremely low with normal intestinal mucosa

5.3 Preclinical safety data:

no data available

I.B.1.6. Pharmaceutical properties

6.1 List of excipients: Citric acid monohydrate, C.M.C (cekol 1000), Saccharin sodium, Sodium propylparaben, Sodium methylparaben, Sodium benzoate, Liquid banana, Tween 80, Aerosil 200, Purified water.

6.2 Major incompatibilities:

no data available

6.3 Time of expiration (finished product, after dilution or reconstitution, or after opening the package):

4 years

6.4 Special precautions during storage:

keep below 30 ° C

6.5. Packaging and contents of the packaging:

Box containing a bottle of 60 ml.

6.6. Special precautions for disposal and handling

No special requirements.

7. Operator and Manufacturer

HOLDER AND INTERNATIONAL OPERATOR:
FRILAB SA
17 rue des Pierres du Niton
1207 Geneva SWITZERLAND

Manufacturer and holder in the country of origin: AMOUN PHARMACEUTICAL COMPANY

8. DOSIMETRY
Not applicable.

9. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS
Not applicable.