FORTRANS®

powder for oral solution in sachet

Read all of this leaflet carefully before you start using this medicine as it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, if you have doubts, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you have any undesirable effect please contact your doctor or pharmacist. This also refer to any undesirable effects which is not mentioned in this leaflet (see section 4)

In this leaflet:

1. What FORTRANS, POWDER FOR ORAL SOLUTION IN SACHET IS AND WHAT IT IS USED FOR ?

OSMOTIC LAXATIVE ATC Code: A06AD65

A : digestive system and metabolism

This medicine is used to cleanse the bowel before a medical procedure or bowel surgery.

FORTRANS belongs to a group of medicines called osmotic laxatives containing macrogol (polyethylen glycol or PEG) with high molecular weight and additional salts. It works by adding water in the bowel which increase the frequency of the bowels which become more and more liquid and lead forward to a cleaning of the bowel.

2. BEFORE YOU USE FORTRANS, POWDER FOR ORAL SOLUTION IN SACHET ?

Do not use FORTRANS
- If you are allergic to macrogol 4000 or to anhydrous sodium sulfate, or to sodium bicarbonate or to sodium chloride, or to potassium chloride or to any of the other ingredients of this medicine which are listed in Section 6.
- If you have severe impaired general condition such as dehydration or severe heart failure (cardiac insufficiency).
- If you have an existing severe disease of intestinal tract such as :
- advanced stage carcinoma or any other serious colon disease leading to excessive mucosal fragility
- known obstruction or suspicion of intestinal obstruction or an ileus.
- perforation of intestinal mucosa
- gastric emptying troubles (such as gastroparesis)
- toxic colitis or toxic megacolon

Special warnings and precautions for use

This product should be administered to elderly patients in a frail general condition only under medical supervision.

Diarrhoea provoked by administration of FORTRANS is likely to result in considerable disturbance of the absorption of simultaneously administered drugs. (Please see section Interaction with other medicinal products).

This medicine contains macrogol. Allergic reactions have been reported with products containing macrogol (cutaneous eruption, urticarial and severe allergic reactions with sudden swelling of face, lips, tongue and with short breath or wheezing).

If your are subject to disturbances of mineral salts blood levels (electrolytic disturbances), your doctor may decide to monitor your electrolytes blood level before and after the intake of the medicine.

Inform your doctor or pharmacist before taking this medicine if
- You have cardiac troubles (e.g cardiac insufficiency)
- You have renal troubles
- You have difficulties in swallowing or you have tendencies to aspiration (move of food or fluid in your lungs),
- You must remain on bed,
- You are taking a diuretics treatment (medicines which increase urine volume)

Children and adolescents

FORTRANS is not for use in children below 18 years old. Its safety and efficacy has not yet been established in this population.

This medicine contains sodium. This medicine contains 1, 967 g of sodium per sachet. To be taken into account in patients with strict low-salt diet.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, especially:
- Oral medication taken regularly: oral medication may be flushed from the gastro-intestinal tract induced by the preparation and not absorbed and must be taken more than 2 hours before enema ingestion. Avoid other treatments take before and after laxative ingestion and until completion of the exam. The efficacy of drugs with a narrow therapeutic index or short half-life may be particularly affected.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Excipient with known effect

FORTRANS contains sodium

3. HOW TO USE FORTRANS, POWDER FOR ORAL SOLUTION IN SACHET ?

Always take this medicine exactly as your doctor or pharmacist has told you to do. Check with your doctor or pharmacist if you are not sure.

FORTRANS must be used by oral route and in adults only.

The recommended dosage is 1 litre of the solution for 15 to 20 kg of body weight, which corresponds to an average dosage of 3 to 4 litres of reconstituted solution.

Each sachet must be dissolved in one litre of water. Shake until the powder is completely dissolved.

Once reconstituted, the solution should be drunk without delay.

Each litre of solution must be absorbed in 1 hour. FORTRANS can be ingested either in a single dose (3 to 4 litres the evening before the procedure) or in divided doses (2 litres ingested in the evening before the procedure, 1 to 2 litres in the morning of the procedure or 3 litres ingested the night before and 1 litre on the morning of the procedure).

According to the prescription of your doctor you must drink one glass of 250 ml of the solution every 10 to 15 minutes.

You have to finish swallowing the solution at least 3 or 4 hours before the beginning of the procedure.

If you take more FORTRANS, powder for oral solution in sachet, than you should :

If you think you have taken too much FORTRANS tell your doctor and drink sufficient water or clear liquids to stop you becoming dehydrated.

4. POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

After taking this medicine you will need to empty bowels frequently. This is normal and shows that the medicine is taking action. Stay near the toilets until the effects of the medicine stop.

Tell your doctor immediately and stop taking FORTRANS if you get the following effects:
- A severe allergic reaction with swelling of the face, lips, tongue or a difficulty in breathing or a severe malaise with decrease of arterial pressure (anaphylactic choc).
- The other undesirable effects include:
- Very common (in more than 1 patient out of 10 : nausea, abdominal pain and abdominal distention (bloating).
- Common (until 1 patient out of 10) : Vomitings
- Unknown frequency (cannot be estimated based on available data) : other allergic reactions : cutaneous eruption.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance – Web site: www.ansm.sante.fr. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FORTRANS, POWDER FOR ORAL SOLUTION IN SACHET ?

Keep out of the reach and sight of children.

Do not use FORTRANS after the expiry date stated on the carton and sachet. Expiry date is the last day of the concerned month.

No special condition for storage.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What FORTRANS, powder for oral solution in sachet contains ?

The active substance is

Macrogol 4000*.....	.....64.000 g
Anhydrous sodium sulfate	..... 5.700 g
Sodium bicarbonate.....	.....1.680 g
Sodium chloride.	.....1.460 g
Potassium chloride.	..... 0.750 g

For one sachet of 73,690 g.

*= P.E.G.4000 = Polyethyleneglycol 4000

The other ingredients is : Saccharine sodium.

What FORTRANS, powder for oral solution in sachet looks like and contents of the pack ?

This medicinal product is a powder for oral solution, white to almost white.

Pack of 4 or 50 sachets. All pack sizes may not be all marketed

Marketing Authorisation Holder / Distributor

IPSEN PHARMA

65 QUAI GEORGES GORSE

92100 BOULOGNE-BILLANCOURT

Manufacturer

BEAUFOUR IPSEN INDUSTRIE

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28100 DREUX-FRANCE

The leaflet was last approved in 20/07/2015.

Detailed information on this medicine is available on the web site of ANSM (France).