

fortrans®

PRESENTATION AND FORM

Powder for oral solution. Box of 4 or 50 sachets. All pack sizes may not be all marketed.

COMPOSITION

For sachets of 73.690 g:

Macrogol (INN) 4000*	64.000 g
Anhydrous sodium sulphate.....	5.700 g
Sodium bicarbonate.....	1.680 g
Sodium chloride.....	1.460 g
Potassium chloride.....	0.750 g
Saccharin sodium.....	0.100 g

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

Excipient with known effect: each sachet contains 2.890 g of sodium.

THERAPEUTIC INDICATIONS

Patients are prepared by colonic lavage for:

- endoscopic and radiological examinations
- colonic surgery

DOSAGE AND ADMINISTRATION

FOR USE IN ADULTS ONLY

Oral administration.

The dosage is approximately one litre of the solution for 15 to 20 kg of body weight, which corresponds to an average dosage of 3 to 4 litres. The contents of each sachet are dissolved in about one litre of drinking water.

Method of administration

It is possible to ingest the preparation as a single dose or as divided doses, providing that the total amount of the reconstituted solution is always fully ingested (average of 3 to 4 litres of solution according to the patient's body weight):

- In divided doses: either 2 litres ingested in the evening before the procedure and 1 to 2 litres in the morning of the procedure, the last glass being ingested 3 to 4 hours before the procedure, or 3 litres ingested the night before and 1 litre on the morning of the procedure, the last glass being ingested at the latest 3 to 4 hours before the procedure.
- In a single dose: 3 to 4 litres in the evening before the procedure, possibly with a break of one hour after the first 2 litres.

The recommended ingestion rate is 1 to 1.5 litres an hour (i.e. 250 ml every 10 to 15 minutes). The doctor may adjust the recommended rate according to the patient clinical condition and to potential comorbidities.

- *Patients with renal impairment*
Insufficient data are available for this population.
- *Paediatric population*

The safety and efficacy of Fortrans in children aged <18 years has not been established.

CONTRAINDICATIONS

FORTTRANS is contraindicated:

- Hypersensitivity to the active substances or to any of the excipients
- Severe heart failure
- Serious deteriorations in general health such as dehydration
- Advanced carcinoma or any other colonic pathology causing excessive mucosal fragility
- Acute phases of intestinal tract inflammation including Crohn's disease and ulcerative colitis
- Gastrointestinal perforation or risk of perforation
- Toxic colitis or toxic megacolon
- Patients likely to have or who already have an ileus
- Patients likely to have or who already have a gastrointestinal obstruction or stenosis
- Gastric emptying disorders (e.g.: gastroparesis, gastric stasis)
- Children and teenagers under 18 years of age

SPECIAL PRECAUTION / SPECIAL WARNINGS FOR USE

This product should be administered to elderly patients in a frail general condition only under medical supervision. Diarrhoea provoked by administration of FORTTRANS® is likely to result in considerable disturbance of the absorption of simultaneously administered drugs. This medicine contains macrogol (polyethylene glycol or PEG). Allergic type reactions have been reported with preparations based upon macrogol : anaphylactic shock, rash, urticarial, angio-oedema.

Electrolytes disturbances are not expected with this product due to its isotonic composition; however, water electrolytes disturbances have been exceptionally reported in at risk patients. Patients with electrolyte abnormalities should have them corrected before administration of the bowel cleansing preparation. This product should be used with caution in patients with these conditions or in patients using concomitant medications that increase the risk of fluid and electrolytes disturbances including hyponatremia and hypokalemia, or may increase the risk of potential complications (such as patients with renal function altered, cardiac insufficiency or treated concomitantly with diuretics). In this case, patients should be appropriately monitored.

The product should be administered carefully and only under medical supervision in patients with tendency to regurgitations or bedridden patients or patients with altered neurological function and/or motor disorders due to the risk of aspiration pneumonia. The product should be administered to these patients in sitting position and eventually through a naso-gastric probe. In patients with cardiac or renal insufficiency, there is a risk of acute pulmonary oedema due to water overload.

This medicine contains sodium. This medicine contains 2.890 g of sodium per sachet. To be taken into account in patients with strict low-salt diet.

Approval
Signature

Date

Warning! We cannot accept responsibility for any errors in this proof after approval. Whilst we take extreme care at all times to ensure accuracy to our client's brief, the final responsibility must be taken by our client.
IF YOU SIGN THIS PROOF YOU ARE SIGNIFYING FULL APPROVAL OF DESIGN AND TEXT.

Customer	Mayoly Spindler Laboratories			Colours Used	Fonts Used	Notes
SAP Code	7N00500ID			Black	Helvetica Neue 6 pt	
SAP Description	NOT M FORTTRANS 4SACH MY			Keyline (Non-Printing)		
Proof / Iteration	2			Text Free Area (Non-Printing)		
Artwork Type	Leaflet			Cirrus_Info_Box		
Profile Ref	N/A					
Size	150mm x 210mm					
Specification Ref	N/A					
Barcode Type		Reel Direction	N/A			
Pharmacode	67000500	Copy Position	N/A			
Proof By	ECA	Date	20/08/2025			

Ischaemic colitis
 Post-marketing cases of ischaemic colitis, including serious, have been reported in patients treated with macrogol for bowel preparation. Macrogol should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate). Patients with sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis should be evaluated promptly.

DRUG INTERACTIONS AND OTHER INTERACTIONS

Prescriber should be informed of any other medicines taken simultaneously by the patient by oral route. Due to the stomach draining provoked by FORTRANS, the other oral treatments may not be absorbed and should be administered more than 2 hours before the draining solution. Avoid intake of oral treatments before and after laxative ingestion until medical examination is completed. For medicines with small therapeutic range or with short half-life such as digoxin, antiepileptics, coumarins, and immunosuppressants, efficacy can be particularly affected.

ADVERSE EFFECTS

Diarrhoea is an expected effect resulting from the use of FORTRANS. Nausea and vomiting have been reported at the start of administration, usually disappearing with continued administration. The table below lists adverse reactions collected from clinical trial data, and adverse events reported from post-marketing sources. The frequencies are defined according to the following convention: Very common (>1/10), Common (>1/100 to <1/10), Uncommon (>1/1,000 to <1/100), Rare (>1/10,000 to <1/1,000), Very rare (< 1/10,000), Unknown (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Gastrointestinal disorders	Very common	Nausea Abdominal pain Abdominal distension
	Common	Vomiting
Immune system disorders	Unknown	Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus)

PREGNANCY AND LACTATION

Pregnancy

There are no or limited amount of data from the use of FORTRANS in pregnant women. Studies in animals are insufficient to conclude on toxicity to reproductive functions. FORTRANS should only be used when necessary.

Lactation

There are no or limited amount of data from the use of FORTRANS during breastfeeding. It is unknown whether macrogol 4000 is excreted in human milk. A risk to the newborns/infants cannot be excluded. Studies in animals are insufficient to conclude on toxicity to reproductive functions. FORTRANS should only be used when necessary.

Fertility

There are no data documenting the effects on fertility with the use of FORTRANS.

OVERDOSE

Intentional or accidental ingestion of more than the recommended dose of FORTRANS powder for oral solution can result in severe diarrhoea and electrolyte imbalance, including hyponatremia and hypokalaemia, as well as dehydration and hypovolaemia with the signs and related symptoms.

In this case, the patient should be monitored and copious amounts of fluids, especially fruit juices, should be given. In rare cases of overdose resulting in severe metabolic imbalance, intravenous rehydration may be performed.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic class: OSMOTIC LAXATIVE

ATC code A06AD65

(A : digestive system and metabolism).

High molecular weight (4000) macrogols are long linear polymers on which water molecules are retained by hydrogen bonds. Following oral administration, they increase the volume of the intestinal fluids. The volume of non absorbed intestinal fluid is responsible for the laxative properties of the solution.

PHARMACOKINETIC PROPERTIES

The electrolyte content of the powder is such that the reconstituted solution does not give rise to intestine/plasma electrolyte exchange. Pharmacokinetic findings confirm the absence of digestive absorption and bioconversion of macrogol 4000 after oral ingestion.

Preclinical safety data

Preclinical data from acute and repeated dose toxicity studies and genotoxicity studies performed with macrogol 4000 have not revealed any particular risk for humans. Due to the short duration of use of the product, no carcinogenicity studies have been performed.

STORAGE CONDITIONS AND SHELF LIFE

Do not store FORTRANS above 30°C.

Do not exceed the expiry date plainly indicated on the packaging.

Keep out of reach of children.

Further Information can be obtained from your doctor or pharmacist.

Revision date: **August 2025**

Country of origin: France

Product Registration Holder: **Zuellig Pharma Sdn Bhd**
 No. 15, Persiaran Pasak Bumi, Sek. U8,
 Perindustrian Bukit Jelutong
 40150, Shah Alam
 Malaysia

Manufacturer: **Mayoly Industrie**
 20 Rue Ethe Virton – 28100 Dreux – France

7N00500



Approval Signature

Date

Warning! We cannot accept responsibility for any errors in this proof after approval. Whilst we take extreme care at all times to ensure accuracy to our client's brief, the final responsibility must be taken by our client.

IF YOU SIGN THIS PROOF YOU ARE SIGNIFYING FULL APPROVAL OF DESIGN AND TEXT.

Customer	Mayoly Spindler Laboratories			Colours Used		Fonts Used		Notes
SAP Code	7N00500ID				Black	Helvetica Neue	6 pt	
SAP Description	NOT M FORTRANS 4SACH MY				Keyline (Non-Printing)			
Proof / Iteration	2				Text Free Area (Non-Printing)			
Artwork Type	Leaflet				Cirrus_Info_Box			
Profile Ref	N/A							
Size	150mm x 210mm							
Specification Ref	N/A							
Barcode Type		Reel Direction	N/A					
Pharmacode	67000500	Copy Position	N/A					
Proof By	ECA	Date	20/08/2025					