fortrans®

macrogol 4000 64 g

powder for oral solution in sachet

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

COMPOSITION

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

Excipient : saccharin sodique.

For one sachet

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

PHARMACEUTICAL FORM

Powder for oral solution.
Box of 4 and 50 sachets.

PHARMACO-THERAPEUTIC GROUP

OSMOTIC LAXATIVE ATC Code : A06AD65
A : digestive system and metabolism

MARKETING AUTHORISATION HOLDER / DISTRIBUTOR

IPSEN Pharma
65, quai Georges Gorse
92100 Boulogne-Billancourt - FRANCE
Manufacturer : BEAUFOUR IPSEN Industrie
rue Ethe Virton - 28100 Dreux - FRANCE

2. WHAT IS YOUR MEDICINE USED FOR ?

This medicine is used for colon lavage to prepare patients prior to :
– endoscopic or radiological investigations,
– colon surgery.

3. WARNING !

WHEN SHOULD THIS MEDICINE NOT BE TAKEN

This medicine SHOULD NOT BE TAKEN in the following cases :
– severely impaired general condition such as dehydration or severe heart failure ;
– serious colon disease leading to excessive mucosal fragility ;
– patients likely to develop intestinal obstruction ;
– children under 15 years.

IF YOU HAVE ANY DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

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.
This medicine contains polyethyleneglycol. Very rare allergic reactions (skin rash, urticaria, œdema) have been reported with products containing polyethyleneglycol.

IF YOU HAVE ANY DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

IN ORDER TO AVOID INTERACTIONS BETWEEN SEVERAL MEDICINAL PRODUCTS, YOU SHOULD ALWAYS TELL YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING ANY OTHER TREATMENT.

USE DURING PREGNANCY AND BREAST-FEEDING

This medicine should be taken during pregnancy only on medical advice.
This medicine may be taken during breast-feeding.

AS A GENERAL RULE IF YOU ARE PREGNANT OR BREAST FEEDING, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINES.

4. HOW TO USE THIS MEDICINAL PRODUCT ?

DOSAGE

FOR USE IN ADULTS ONLY.
The dosage is approximately one litre of the solution for 15 to 20 kg of body weight, that corresponds to an average dosage of 3 to 4 litres.

METHOD AND ROUTE OF ADMINISTRATION

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

FREQUENCY AND TIME AT WHICH THIS MEDICINAL PRODUCT SHOULD BE ADMINISTERED

This medicine can be ingested either as a single dose (4 litres in the evening before) or divided dose (2 litres in the evening before and 2 litres the next morning ; it is usually recommended that last intake is completed 3 to 4 hours before the procedure).

5. POSSIBLE SIDE EFFECTS

LIKE ALL MEDICINES ; THIS MEDICINAL PRODUCT CAN HAVE SIDE EFFECTS :
– Nausea and vomiting have been reported at the start of administration, usually disappearing with continued administration.
– Feelings of intestinal distension have also been described.
– Very rare cases of allergic skin reactions in the form of skin rash, urticaria (hives) and œdema.

IF YOU NOTICE ANY SIDE EFFECTS NOT MENTIONED IN THIS LEAFLET, PLEASE INFORM YOUR DOCTOR OR PHARMACIST.

6. STORAGE

DO NOT STORE ABOVE 30°C

DO NOT USE AFTER THE EXPIRY DATE STATED ON THE PACKAGING

7. LAST REVISION DATE OF THE PACKAGE LEAFLET

JANUARY 2004

IPSEN