

bedelix[®]

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Montmorillonite beidellitic

3 g

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

NAME:

BEDELIX, powder for oral suspension.

COMPOSITION:

Montmorillonite beidellitic (Monmectite) 3 g

Excipients: aluminium hydroxide-magnesium carbonate co-dried gel, licorice extract, vanillin, saccharin sodium, glucose monohydrate.

For one sachet

PHARMACEUTICAL FORM:

Powder for oral suspension. Box of 30 or 60 sachets

PHARMACO-THERAPEUTIC GROUP:

GASTRO-OESOPHAGEAL AND GASTRO-INTESTINAL MUCOSAL PROTECTION AGENT

(A : gastro-intestinal apparatus 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 recommended in the symptomatic treatment of functional colonic disturbances.

3. WARNING !

WHEN YOU SHOULD NOT TAKE THIS MEDICINE:

This medicine **MUST NOT BE USED** in the following case :

– Stenosis (narrowing) of the gastro-intestinal tract.

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

PRECAUTIONS FOR USE:

Patients undergoing chronic dialysis should avoid long-term use without medical advice, due to the presence of aluminium hydroxide.

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:

To avoid all risk of interference with the gastro-intestinal absorption of any other medicines, allow at least 2 hours between taking this product and taking another medicine.

IN ORDER TO AVOID INTERACTIONS BETWEEN SEVERAL MEDICINAL PRODUCTS, YOU SHOULD INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING ANY OTHER TREATMENT. ②

USE DURING PREGNANCY AND BREAST-FEEDING:

AS A GENERAL RULE, IF YOU ARE PREGNANT OR BREAST-FEEDING, ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE STARTING A TREATMENT.

4. HOW TO USE THIS MEDICINAL PRODUCT

DOSAGE:

Oral route

Adults: the usual dose is 3 sachets per day.

Children : under 2 years : 1/2 sachet 1 to 2 times per day;
 2 to 5 years : 1/2 sachet 2 to 3 times per day;
 5 to 10 years : 1 sachet twice per day.

Rectal route

Retention enema : 1 to 3 enemas per day of 1 to 3 sachets mixed with 100 ml of water.

METHOD AND ROUTE OF ADMINISTRATION:

Oral route

The contents of one sachet may be stirred into half a glass of water or mixed with a semi-liquid food such as porridge, stewed fruit, mashed potato, etc.

Rectal route

The contents of one or more sachets may be mixed with 100 ml of warm water.

FREQUENCY AND TIME AT WHICH THIS MEDICINAL PRODUCT SHOULD BE ADMINISTERED:

Preferably take between meals or just before a meal.

DURATION OF TREATMENT:

Take as directed by your doctor.

5. UNEXPECTED AND BOTHERSOME EFFECTS

INFORM YOUR DOCTOR OR PHARMACIST OF ANY UNEXPECTED AND BOTHERSOME EFFECT NOT MENTIONED ON THAT LEAFLET.

6. STORAGE

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

7. REVISION DATE OF THE PACKAGE LEAFLET

May 1999.

