

# Imodium™

## plus caplets

### PATIENT INFORMATION LEAFLET

**PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE.**

Keep this leaflet; you may want to read it again.

#### **WHAT IS IN THE CAPLETS?**

Each caplet contains loperamide hydrochloride 2mg and simeticone equivalent to 125mg polydimethylsiloxane.

Other ingredients are calcium hydrogen phosphate anhydrous, microcrystalline cellulose, acesulfame K, artificial vanilla flavour (includes propylene glycol), sodium starch glycolate, and stearic acid.

#### **HOW DO THE CAPLETS WORK?**

Loperamide treats short-lived episodes of diarrhoea by returning the overactive pace of the digestive system to normal and improving reabsorption of water and minerals from the intestinal contents. Simeticone is an anti-foaming agent and disperses trapped gas in the stomach and intestines to relieve abdominal discomfort, cramps and bloating that it causes.

#### **PACK SIZES**

Imodium™ Plus Caplets are supplied as packs of 12 caplets.

#### **PRODUCT LICENCE HOLDER:**

McNeil Ltd, Saunderton, High Wycombe, Buckinghamshire HP14 4HJ.

Product Licence Number: PL 13249/0025.

#### **MANUFACTURED BY:**

Johnson & Johnson•Merck Consumer Pharmaceuticals Company, 1838 Colonial Village Lane, Lancaster, PA 17601, USA.

#### **RELEASED BY:**

Janssen-Cilag SpA, Via C. Janssen, Borgo San Michele, Latina, Italy.

#### **WHAT ARE IMODIUM™ PLUS CAPLETS USED FOR?**

Imodium™ Plus Caplets are used to control short-lived episodes of diarrhoea and calm additional abdominal discomfort such as cramps, wind and bloating.

#### **DO NOT USE IMODIUM™ PLUS IF:**

- The patient is a child under 12 years old
- You are allergic to any of the ingredients in this product
- You have blood in your bowel motions or a high fever
- You have an inflammation of the lower bowel (for example ulcerative colitis, pseudomembranous colitis caused by some antibiotics, or bacterial enterocolitis)
- Your doctor has told you that your intestinal movements should not be slowed (for example if you have constipation or a bloated tummy).

#### **CHECK WITH YOUR DOCTOR BEFORE YOU USE IMODIUM™ PLUS IF:**

- You are dehydrated by fluid loss caused by diarrhoea - you will need oral rehydration salts (to replace the lost water and minerals)
- You are pregnant or breast-feeding
- You have poor liver function

### **WHILE YOU ARE TAKING IMODIUM™ PLUS**

If you become constipated or your abdomen swells, stop taking Imodium™ Plus. If you have AIDS, this is especially important - see your doctor as well.

If you feel tired, dizzy or drowsy, do not drive or operate machinery.

### **HOW SHOULD YOU TAKE IMODIUM™ PLUS CAPLETS?**

#### **Adults over 18 years of age (including the elderly):**

Swallow two caplets initially followed by one caplet after each loose stool (bowel movement).

#### **Young adults 12 to 18 years:**

Swallow one caplet initially followed by one caplet after each loose stool (bowel movement).

#### **All patients:**

Do not take more than 4 caplets in a day. Do not take Imodium™ Plus for more than 2 days. If your symptoms get worse or are no better in 48 hours, consult your doctor.

#### **Children under 12 years of age:**

Not recommended.

### **WHAT IF SOMEONE TAKES TOO MANY CAPLETS?**

If anyone takes too many caplets, consult a doctor or local hospital for advice.

### **WHAT ABOUT SIDE EFFECTS?**

In clinical trials up to 10% of patients taking Imodium™ Plus felt sick or felt their sense of taste had altered.

In normal use very rarely patients taking Imodium™ Plus, or loperamide only, had skin rashes (including itching, hives or swelling), severe allergic reactions (including shock, collapse or difficulty breathing), abdominal pain or bloating, nausea, constipation – sometimes severe, wind, vomiting, indigestion, difficulty in passing water (urine), dizziness, altered sense of taste, or drowsiness.

If you think you are reacting badly in any way to Imodium™ Plus, stop the tablets and see your doctor or pharmacist.

### **STORING IMODIUM™ PLUS CAPLETS**

"Use by" date: Do not use if the caplets are past the expiry date on the box. Return any unused caplets to the pharmacist. Do not store the caplets above 25°C.

**REMEMBER: Keep all medicines out of the sight and reach of children.**