

# TOTALAX

Lactulose Solution USP 667 mg/ml

## What is in this leaflet?

1. What TOTALAX is used for
2. How TOTALAX works
3. Before you use TOTALAX
4. How to use TOTALAX
5. While you are using it
6. Side effects
7. Storage and Disposal of TOTALAX
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

### 1. What TOTALAX is used for

TOTALAX is used to treat constipation (infrequent bowel movements, hard and dry stools) and hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness). Hepatic encephalopathy can lead to a hepatic coma

### 2. How TOTALAX works

TOTALAX contains a laxative called lactulose. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.

### 3. Before you use TOTALAX

#### - When you must not use it

Do not take TOTALAX if:

- You are allergic (hypersensitive) to lactulose or any of the other ingredients of TOTALAX
- You have a rare problem called 'galactosaemia'.
- You have a blockage caused by anything else but normal constipation, digestive perforation (ruptured bowel) or risk of it

Do not use TOTALAX if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking TOTALAX.

#### - Before you start to use it

Talk to your doctor or pharmacist before taking TOTALAX if you suffer from any medical conditions or illnesses, in particular:

- if you suffer from unexplained tummy ache
- if you are unable to digest milk

sugar (lactose intolerant)

- if you have diabetes

#### - Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### 4. How to use TOTALAX

#### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

You may take TOTALAX oral solution diluted or undiluted. Take your dose of lactulose in one swallow; do not hold the solution in your mouth for any length of time.

#### Constipation

**Adults and adolescents:** The starting dose is 15-45ml per day. After this the dose can be adjusted to 15-30ml daily.

**Children 7 to 14 years:** The starting dose is 15ml daily. After this the dose can be adjusted to 10-15ml daily.

**Children 1-6 years:** The usual dose is 5-10ml daily.

**Infants under 1 year:** The usual dose is up to 5ml daily.

#### Hepatic encephalopathy

**Adults:** The usual starting dose is 3 to 4 times a day of 30-45ml

#### - When to use it

Use as directed by your doctor or pharmacist and always take it at the same time of the day.

#### - How long to use it

Continue taking TOTALAX for as long as your doctor or pharmacist recommends.

#### - If you forget to use it

Do not take a double dose to make up for the forgotten dose. Take the next dose at

your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist.

#### - If you use too much (overdose)

If you take more TOTALAX than recommended dose, you should stop taking TOTALAX and talk to a doctor or pharmacist.

You may have diarrhoea, loss of electrolytes and abdominal pain.

### 5. While you are using it

#### - Things you must do

Take your medicine exactly as your doctor has told you.

During therapy with laxatives it is important for you to drink sufficient amounts of fluids (1.5-2 litres, equal to 6-8 glasses) during the day.

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. TOTALAX can be used during pregnancy and when breast-feeding if necessary.

#### - Things to be careful of

TOTALAX contains sugars, such as lactose, galactose and fructose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

If TOTALAX is used for small child, you may want to take protective measures, such as using diapers.

### 6. Side effects

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

- Very common (may affect more than 1 in 10 people):  
Diarrhoea
- Common (may affect up to 1 in 10 people)  
Flatulence (wind), nausea (feeling sick), vomiting, abdominal pain
- Uncommon (may affect up to 1 in 100 people)

# TOTALAX

Lactulose Solution USP 667 mg/ml

Electrolyte imbalance due to diarrhoea

- Hypersensitivity reactions mainly limited to the skin have been observed and identified as potential adverse reactions during postapproval use. Because these reactions were reported spontaneously from a population of uncertain size, it is not possible to reliably estimate their frequency.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## 7. Storage and Disposal of TOTALAX

### - Storage

Do not store above 30°C. Protect from light.

Keep medicine out of reach of children.

Do not use **TOTALAX** after the expiry date printed on the Bottle label and carton.

### - Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 8. Product Description

### - What it looks like

Colourless to amber syrupy liquid filled in 200ml white PET bottle.

### - Ingredients

#### - *Active ingredient*

Lactulose

#### - *Inactive ingredients*

Purified water

**TOTALAX** contains Lactose.

### - MAL number:

MAL\*\*\*\*\*

## 9. Manufacturer

Mankind Pharma Ltd.

Unit-II, Village-Kishanpura, P.O. Jamniwala, Tehsil- Paonta Sahib, District Sirmour- 173025, Himachal Pradesh (India)

### Product Registration Holder

Pahang Pharmacy Sdn. Bhd.

Lot 5979, Jalan Teratai,

5 1/2 Miles off Jalan Meru, 41050

Klang, Selangor, Malaysia

## 10. Date of revision

19/09/2023

### Serial number

NPRA (R2) 23/151