

## **PACKAGE INSERT TEMPLATE FOR LACTULOSE**

### **Brand or Product Name**

*[Product name]* Oral solution 3.35g/5ml

*[Product name ]* Syrup 6.67g/10ml

### **Name and Strength of Active Substance(s)**

Lactulose ....g/ml

### **Product Description**

*[Visual description of the appearance of the product (eg colour etc)]*

*eg Clear, viscous, colourless to brownish yellow liquid for oral administration containing ...g lactulose per...ml.*

### **Pharmacodynamics**

Bacteria in the colon degrade lactulose into lactic acid, acetic acid and formic acid resulting in an increase in osmotic pressure and acidification of intestinal contents which in turn, softens the stool by promoting stool water content.

In hepatic encephalopathy(HE); hepatic coma, the effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (e.g. lactobacillus), trapping of ammonia in the ionic form by acidification of the colonic contents, catharsis due to the low pH in the colon as well as an osmotic effect, and alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis.

### **Pharmacokinetics**

Lactulose is poorly absorbed after oral administration and reaches the colon unchanged. Only 0.4 - 2% of a lactulose dose is absorbed from the small intestine, and this proportion is excreted unchanged in urine. The acids produced in the colon are absorbed and metabolised only in part.

### **Indication**

Indicated for constipation , conditions requiring facilitated bowel movements and for the treatment of hepatic encephalopathy(HE); hepatic coma.

### **Recommended Dosage**

#### **Constipation**

*Adults and adolescents Dosage*

Starting dose : 10 to 30 grams single daily dose or in two divided dose.

Maintenance dose : 10 to 20 grams single daily dose or in two divided dose.

*Children Dosage (7-14 years)*

Starting dose : 10 grams single daily dose or in two divided dose.  
Maintenance dose : 6.67 to 10 grams single daily dose or in two divided dose.

*Children Dosage (1-6 years)*

Starting dose : 3.33 to 6.67 grams single daily dose or in two divided dose.  
Maintenance dose : 3.33 to 6.67 grams single daily dose or in two divided dose.

*Infants (under 1 year)*

Starting dose : up to 3.33g grams single daily dose or in two divided dose.  
Maintenance dose : up to 3.33g grams single daily dose or in two divided dose.

**Hepatic encephalopathy(HE);hepatic coma**

*Adults*

Starting dose is 20-30gram three to four times daily.  
Maintenance dose should be adjusted by doctor to achieve 2 to 3 soft stools per day.

*Children*

No dosage recommendations for this indication.

**Mode of Administration**

Oral

**Contraindications**

It is contraindicated in patients with hypersensitivity to lactose or to any of the excipients and suffering from Galactosaemia and bowel obstruction

**Warnings and Precautions**

Patients who are intolerant to lactose should take Lactulose with care.

The dose normally used in constipation should not pose a problem for diabetics. However, the dose used in the treatment of hepatic encephalopathy(HE);hepatic coma is usually much higher and should be taken into consideration for diabetics.

Laxatives (of any kind) should be used in children only when deemed absolutely necessary and only under medical supervision.

Faecal retention abilities could be disturbed during treatment with Lactulose oral solution.

**Interactions with Other Medicaments**

Lactulose should not be taken with other laxatives.

## **Statement on Usage During Pregnancy and Lactation**

### *Pregnancy .*

Lactulose can be used during pregnancy.

### *Lactation*

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of lactulose to the breast-feeding woman is negligible. Lactulose oral solution can be used during breastfeeding

## **Adverse Effects / Undesirable Effects**

Flatulence may occur during the first few days of treatment. As a rule it disappears after a couple of days. Nausea and vomiting has been reported. When dosages higher than instructed are used, abdominal pain and diarrhea may occur. In such a case the dosage should be decreased.

If high doses (normally only associated with hepatic encephalopathy (HE); hepatic coma) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhea. Dosage should then be adjusted to obtain two or three formed stools per day. Muscle cramp also were reported due to lactulose intake. In some serious cases Hyponatremia and Hypokalemia will occur.

## **Overdose and Treatment**

Lactulose overdose may produce nausea, vomiting, diarrhea and water and electrolyte loss, which may have to be corrected by appropriate drug therapy.

Treatment: cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances. There is no specific antidote, only symptomatic treatment should be given.

## **Storage Conditions**

*[Store below 30° C , protect from light and moisture]*

## **Dosage Forms and Packaging Available**

*[ Packaging type & pack size]*

## **Name and Address of Manufacturer**

*[ Name & full address of manufacturer ]*

## **Name and Address of Marketing Authorization Holder**

*[ Name & full address of marketing authorization holder ]*

## **Date of Revision of Package Insert**

*[ day/month/year ]*