Evacusoft™

Lactulose Solution 200 ml

Evacuate Toxins, Soften Stool

Product Description:

Evacusoft 200 ml: Each 5 ml contains Lactulose Concentrate U.S.P.

eq. to Lactulose 3.350 gm

General Information

During the progress of CKD, most unwanted products that used to be excreted or metabolizedby the kidney are accumulated in the body. Theseproducts may have harmful effects and areknown as uremic toxins.Low molecular weightproducts soluble in the water like creatinine and ureacould be excreted during the dialysis, but middlemolecular weight products (β2-microglobulin)protein bond toxins (p-cresol) have low clearanceand are not properly excreted.

Using lactulose and pre-probiotics, may reduce protein-bound uremic toxins, including p-cresylsulphate and indoxyl sulphate (that are not properly filtered from kidney), in CKD patients.In chronic kidney failure, lactulose can promote fecal excretion of water, sodium, potassium, ammonium, urea&creatinine.

Lactulose strengthens the growth of the health-promoting bacteria of the genus *Bifidobacterium* and may suppress potentially pathogenic bacteria like *Clostridium* and *Escherichia coli*. Consequently, it is often described as a prebiotic substance. Its effects on the balance of the intestinal flora may contribute to its action in hepatic encephalopathy

Indication & Usage

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

Dosage and Administration

In constipation

Adults and adolescents Dosage
Starting dose: 10 to 30 grams single daily dose or in two divided doses.
Maintenance dose: 10 to 20 grams single daily dose or in two divided doses.

Children Dosage (7-14 years)
Starting dose: 10 grams single daily dose or in two divided doses.
Maintenance dose: 6.67 to 10 grams single daily dose or in two divided doses.

Children Dosage (1-6 years)
Starting dose: 3.33 to 6.67 grams single daily dose or in two divided doses.
Maintenance dose: 3.33 to 6.67 grams single daily dose or in two divided doses.

In 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.

Mechanism of action

Bacteria present in the colon degrade lactulose into lactic acid, acetic acid and formic acid due to which there is 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.

Pharmacokinetic

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.

Use in Specific Population

Pregnancy: Lactulose has been shown to be effective for the treatment of constipation associated with pregnancy when administered to women at different stages of pregnancy.

Nursing Mother: 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

Pediatric Use: It is recommended that lactulose solution is to be given to infants and children under medical supervision.

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

Warning & Precaution:

- 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.

Drug Interaction:

Lactulose should not be taken with other laxatives.

Adverse Reactions:

- Initial dosing may produce gaseous distension with flatulence and intestinal cramps. These effects are usually mild and transient.
- Excessive dosage can lead to diarrhoea. If untreated potential complications of diarrhoea may include fluid loss, and electrolyte disturbances such as hypokalaemia and hypernatraemia.
- Less frequently, nausea, vomiting, anorexia and increased thirst have been reported.