

Lactulose

【ODUPS6】 Lactul[®] Syrup 666mg/mL, 60mL/Bot *ATC Code : A06AD11*

【ODUPS3】 Lactul[®] Syrup 666mg/mL, 300mL/Bot *ATC Code : A06AD11*

中文名： 樂多糖漿（拉特樂斯） «杏輝»

適應症： 患病期慢性便秘、門系肝腦病變、肝昏迷前期、肝昏迷。

成分： Each mL contains: Lactulose 666 mg

藥理分類： **Ammonium Detoxicant; Laxative, Osmotic.**

用法用量： **Administration:**

1. **Orally**, may minimize sweet taste by diluting with water, fruit juice, milk or by adding to food (e.g. desserts). When administering via gastric tube, dilute well to prevent induction of vomiting and possible aspiration pneumonia.
2. **Rectal:** Dilute with 700 mL of water or NS; administer as retention enema using a rectal balloon catheter; retain for 30 to 60 minutes. May repeat enema immediately if inadvertently evacuated too promptly. Cleansing enemas containing soapsuds or other alkaline agents should not be used.

Indications and dosage regimens:

Chronic constipation:

Administer as a single daily dose, preferably following breakfast. Following oral administration, 24-48 hours may be required to produce a normal bowel movement.

— Adults:

Initial dosage is 15-30 mL/day. Dosage may be increased to 60 mL/day.

— Children:

Safety and efficacy for the treatment of chronic constipation in children not established.

Treatment and prevention of portal-systemic encephalopathy (PSE):

— Adults:

Chronic PSE:

30-45 mL 3-4 times daily. Adjust dosage every 1-2 days as necessary to produce 2 or 3 soft stools daily. Usually dosage is 90-150 mL daily.

Some clinicians recommend dosage adjustment according to acidity of colonic contents by measuring stool pH at initiation of therapy and adjusting dosage until stool pH is about 5. This pH is usually achieved when the patient has 2 or 3 soft stools daily during therapy.

During treatment, improvement in patient's clinical condition usually occurs within 1-3 days.

Continuous long-term therapy with lactulose may decrease severity and prevent recurrence of PSE.

Acute PSE episodes:

30-45 ml at 1- to 2- hour intervals to induce rapid laxation. When the laxative effect has been achieved, reduce dosage to the amount required to produce 2 or 3 soft stools daily.

— Children:

Adjust dosage every 1-2 days as necessary to produce 2-3 soft stools daily. If the initial dose produces diarrhea, reduce dose immediately; if diarrhea persists,

discontinue drug.

Infants (limited data):

Initially, 2.5-10 mL/day in divided doses.

Older children and adolescents:

Initially, 40-90 mL/day in divided doses.

不良反應： 脹氣、腹痛、腹瀉、噁心、嘔吐；長期使用高劑量，則可能因腹瀉而造成電解質不平衡。

注意事項： 1.本品含少量的 galactose 及 lactose，糖尿病患及半乳糖血症病患須謹慎使用。
2.本品因會降低結腸的酸鹼度，因此對藥物釋放會受結腸酸鹼度影響者(如 mesalazine 製劑)，可能無效。
3.直腸灌腸時，需加水或生理食鹽水稀釋。

懷 孕 期： 1.Adverse events have not been observed in animal reproduction studies.
2.Lactulose is poorly absorbed following oral administration.
3.Short-term use of lactulose is also considered to be safe/low risk when therapy is needed; however, side effects may limit its use (*Cullen, 2007; Mahadevan, 2006; Prather, 2004; Wald, 2003*).

授 乳 期： 1.It is not known if lactulose is excreted in breast milk; however, lactulose is poorly absorbed following oral administration.
2.The manufacturer recommends that caution be exercised when administering lactulose to nursing women.

安 定 性： 1.在室溫良好條件儲存下，顏色變深並不影響療效。
2.長期置於 30 °C 以上或光直射時，易變成極深色及混濁，當此現象發生時，請勿使用。
3.長期置於冷凍溫度時，呈半固體狀、變稠、不易倒出，但恢復至室溫時，即可恢復原狀，不影響療效。

儲 存： 15-30 °C 避光儲存。