

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 09/2020

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Linzess Tablets 0.25mg

Active ingredient: Linaclotide

Dosage form: pale yellow tablets, diameter: approx. 6.6 mm, thickness: approx. 3.1 mm

Print on wrapping: (Face) リンゼス 0.25mg, 本剤は吸湿するため、服用直前に取り出してください。 , house-mark + 725, (Back) Linzess 0.25mg, リンゼス 0.25mg, 注意 服用直前に取り出す, house-mark, アステラス製薬



Effects of this medicine

This medicine activates the guanylate cyclase C receptor, which is present on the surface of the intestinal epithelium, to promote water secretion in the intestine and thus defecation. It also improves hypersensitivity in the large intestine to alleviate abdominal pain and discomfort.

It is usually used to treat constipation predominant irritable bowel syndrome, or chronic constipation (excluding constipation due to organic diseases).

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines. If you have, or are suspected of having, mechanical intestinal obstruction.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults, take 2 tablets (0.5 mg of the active ingredient) at a time, once a day, before meal. The dosage may be decreased to 1 tablet (0.25 mg) according to the symptoms. Strictly follow the instructions.
- If you miss a dose, skip the missed dose on that day. Take the daily dose again from the next day at the regular time before meal. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- mud-like or water-like stool, severe abdominal pain [severe diarrhea]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- Since this medicine is hygroscopic, take out the tablet from the sheet immediately before taking it. Do not leave naked tablets in an un-wrapped condition or store in a different container.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.