

MEDICATION GUIDE
LINZESS[®] (lin-ZESS)
(linaclotide) capsules

Read this Medication Guide before you start taking LINZESS and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about LINZESS?

- **Do not give LINZESS to children who are under 6 years of age. It may harm them.**
- **You should not give LINZESS to children 6 to 17 years of age. It may harm them.**

See the section “**What are the possible side effects of LINZESS?**” for more information about side effects.

What is LINZESS?

LINZESS is a prescription medication used in adults to treat

- irritable bowel syndrome with constipation (IBS-C)
- a type of constipation called chronic idiopathic constipation (CIC). “Idiopathic” means the cause of the constipation is unknown.

It is not known if LINZESS is safe and effective in children.

Who should not take LINZESS?

- **Do not give LINZESS to children who are under 6 years of age.**
- Do not take LINZESS if a doctor has told you that you have a bowel blockage (intestinal obstruction).

What should I tell my doctor before taking LINZESS?

Before you take LINZESS, tell your doctor if you:

- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if LINZESS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LINZESS passes into your breast milk. Talk with your doctor about the best way to feed your baby, if you take LINZESS.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

How should I take LINZESS?

- Take LINZESS exactly as your doctor tells you to take it.
- Take LINZESS 1 time each day on an empty stomach, at least 30 minutes before your first meal of the day. You should also wait 30 minutes before eating a meal if you take LINZESS with applesauce or mixed with water.
- If you miss a dose, skip the missed dose. Just take the next dose at your regular time. Do not take 2 doses at the same time.
- LINZESS capsule should be swallowed whole. Do not crush or chew LINZESS.
 - Adults who cannot swallow LINZESS capsules whole may open the LINZESS capsule and sprinkle over applesauce or mix LINZESS with bottled water before swallowing.

It is not known if LINZESS is safe and effective when sprinkled on other foods or mixed with other liquids.

Taking LINZESS in applesauce:

- Open the LINZESS capsule and sprinkle all of the LINZESS beads onto 1 teaspoon of room temperature applesauce.
- Swallow all of the LINZESS beads and applesauce right away. Do not keep the applesauce for future use.
- Do not chew the LINZESS beads.

Taking LINZESS in water:

- Open the LINZESS capsule and pour all of the LINZESS beads into a cup with 1 ounce (30 mL) of room temperature bottled water.
- Gently swirl the beads and water for at least 10 seconds.
- Swallow all of the LINZESS beads and water mixture right away. Do not keep the mixture for future use.
- If you see any LINZESS beads left in the cup, add another 1 ounce (30mL) of water to the beads in the cup, swirl for at least 10 seconds, and swallow right away.

Taking LINZESS in a nasogastric or gastric feeding tube:

Gather the supplies you will need to take your LINZESS dose. Your doctor should tell you what size catheter tipped syringe you will need for your dose. Ask your doctor if you have any questions about how to give LINZESS the right way.

- Open the LINZESS capsule and pour all the LINZESS beads into a cup with 1 ounce (30 mL) room temperature bottled water.
- Gently swirl the beads and water for at least 10 seconds.
- Remove the plunger from the catheter tipped syringe, and then pour the LINZESS bead and water mixture into the syringe and replace the plunger.
- Remove the cap from the syringe, insert the tip of the syringe into the nasogastric or gastric feeding tube and push the plunger all the way in to give the dose.

After giving the LINZESS dose, flush the nasogastric or gastric tube with at least 10 mL of water.

What are the possible side effects of LINZESS?

LINZESS can cause serious side effects, including:

- **See “What is the most important information I should know about LINZESS?”**
- **Diarrhea is the most common side effect of LINZESS, and it can sometimes be severe.**
 - Diarrhea often begins within the first 2 weeks of LINZESS treatment.
 - **Stop taking LINZESS and call your doctor right away if you get severe diarrhea during treatment with LINZESS.**

Other common side effects of LINZESS include:

- gas

- stomach-area (abdomen) pain
- swelling, or a feeling of fullness or pressure in your abdomen (distention)

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of LINZESS. For more information, ask your doctor or pharmacist.

In addition, call your doctor or go to the nearest hospital emergency room right away, if you develop unusual or severe stomach-area (abdomen) pain, especially if you also have bright red, bloody stools or black stools that look like tar.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LINZESS?

- Store LINZESS at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep LINZESS in the bottle that it comes in.
- The LINZESS bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). Do not remove the desiccant packet from the bottle.
- Keep the container of LINZESS tightly closed and in a dry place.

Keep LINZESS and all medicines out of the reach of children.

General information about LINZESS

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LINZESS for a condition for which it was not prescribed. Do not give LINZESS to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about LINZESS. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about LINZESS that is written for health professionals. For more information, go to www.LINZESS.com or call 1-800-678-1605.

What are the ingredients in LINZESS?

Active ingredient: linaclotide

Inactive ingredients: calcium chloride dihydrate, L-leucine, hypromellose, microcrystalline cellulose, gelatin, and titanium dioxide

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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