

Medication Guide
IBSRELA® (ibs rel`a)
(tenapanor)
tablets, for oral use

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

- Do not give IBSRELA to children who are less than 6 years of age. It may harm them.
 - You should not give IBSRELA to patients 6 years to less than 18 years of age. It may harm them.
- IBSRELA can cause severe diarrhea and your child could get severe dehydration (loss of a large amount of body water and salt).

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

What is IBSRELA?

IBSRELA is a prescription medicine used in adults to treat:

- Irritable bowel syndrome with constipation (IBS-C).

It is not known if IBSRELA is safe and effective in children less than 18 years of age.

Who should not take IBSRELA?

- **Do not give IBSRELA to children who are less than 6 years of age.** IBSRELA can cause severe diarrhea and your child could get severe dehydration (loss of a large amount of body water and salt).
- Do not take IBSRELA if a doctor has told you that you have a bowel blockage (intestinal obstruction).

Before you take IBSRELA, tell your doctor about all your medical conditions, including if you:

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

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

How should I take IBSRELA?

- Take IBSRELA exactly as your doctor tells you to take it.
- Take 1 IBSRELA tablet by mouth, 2 times each day.
- Take IBSRELA immediately before breakfast or the first meal of the day and immediately before dinner.
- If a dose is missed, skip the missed dose and take the next dose at the regular time. **Do not** take 2 doses at the same time.

What are the possible side effects of IBSRELA?

IBSRELA can cause serious side effects, including:

- See “**What is the most important information I should know about IBSRELA?**”
- **Diarrhea is the most common side effect of IBSRELA, and it can sometimes be severe. Stop taking IBSRELA and call your doctor if you develop severe diarrhea.**

The other most common side effects of IBSRELA include:

- swelling, or a feeling of fullness or pressure in your abdomen (distension).
- gas (flatulence).
- dizziness.

These are not all the possible side effects of IBSRELA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to www.fda.gov/medwatch.

How should I store IBSRELA?

- Store IBSRELA at room temperature, between 68°F and 77°F (20°C and 25°C).
- Keep IBSRELA in the original container and protect from moisture. Keep the container of IBSRELA tightly closed and in a dry place.
- Do not put IBSRELA in another container (repackage).
- The IBSRELA bottle contains a desiccant canister to help keep your medicine dry (protect it from moisture). Do not remove the desiccant from the bottle.

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

General information about the safe and effective use of IBSRELA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use IBSRELA for a condition for which it was not prescribed. Do not give IBSRELA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about IBSRELA that is written for health professionals.

What are the ingredients in IBSRELA?

Active ingredient: tenapanor hydrochloride

Inactive ingredients: colloidal silicon dioxide, hypromellose, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, propyl gallate, stearic acid, tartaric acid, titanium dioxide, and triacetin.

Marketed by Ardelyx, Inc. 34175 Ardenwood Blvd., Suite 100 Fremont, CA 94555

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For more information, go to www.ardelyx.com or call 1-844-427-7352