

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCONSTELLA®

Linacotide Capsules

Read this carefully before you start taking CONSTELLA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about CONSTELLA.

Serious Warnings and Precautions

- CONSTELLA must not be used in children under 6 years of age. This is because children can get diarrhea which can be severe. This can seriously harm a child less than 6 years of age.

What is CONSTELLA used for?

CONSTELLA is used to treat the following conditions:

- Irritable bowel syndrome with constipations (IBS-C) in adults.
- Chronic idiopathic constipation (CIC) in adults. “Idiopathic” means the cause of the constipation is unknown.
- Functional constipation (FC) in children and adolescents 6 to 17 years of age.

How does CONSTELLA work?

Constella works by attaching to a receptor in your gut called guanylate cyclase C. This relieves abdominal pain and allows liquid to enter the gut. This in turn helps make bowel movements occur more often and makes them softer. It can also reduce bloating and discomfort. Bowel symptoms may improve in 1 week but pain and discomfort may take longer.

What are the ingredients in CONSTELLA?

Medicinal ingredients: linacotide

Non-medicinal ingredients:

145 mcg and 290 mcg capsules: calcium chloride dihydrate, gelatin, hypromellose, iron oxide black, iron oxide yellow, L-leucine, microcrystalline cellulose, shellac glaze, and titanium dioxide.

72 mcg capsules: calcium chloride dihydrate, gelatin, L-histidine, iron oxide black, iron oxide yellow, microcrystalline cellulose, polyvinyl alcohol, shellac glaze, talc, titanium dioxide.

CONSTELLA comes in the following dosage forms:

Capsules: 72 mcg, 145 mcg and 290 mcg of linaclotide.

Do not use CONSTELLA if:

- You are allergic to linaclotide.
- You are allergic to any of the other ingredients in CONSTELLA or to a component of the container (see **What are the ingredients in CONSTELLA?**).
- You have an intestinal obstruction which is a condition where your bowel is blocked.

Children under 6 years of age must not take CONSTELLA. This is because it may cause severe dehydration in children less than 6 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CONSTELLA. Talk about any health conditions or problems you may have, including if you:

- are pregnant, think you may be pregnant, or plan to become pregnant. It is not known if CONSTELLA will harm your unborn baby.
- are breast-feeding or planning to breastfeed. Although CONSTELLA is not expected to pass into your breast milk, you and your healthcare professional should decide if you will take CONSTELLA and breastfeed.

Other warnings you should know about:

CONSTELLA can cause diarrhea. Mild to moderate diarrhea often begins within the first two weeks of taking CONSTELLA. Stop taking CONSTELLA and call your doctor right away if you get **severe diarrhea** (persistent watery stools) during treatment with CONSTELLA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Your doctor or pharmacist will tell you if it is safe to take CONSTELLA with your other medicines. Do not start any medicine while taking CONSTELLA without talking to your healthcare provider first.

How to take CONSTELLA:

- Take CONSTELLA exactly as your doctor tells you to take it.
- Take CONSTELLA once a day on an empty stomach, at least 30 minutes before a meal.
- Swallow the capsule whole with water. Do not crush or chew the capsule. Patients who are unable to swallow the capsule whole can open the capsules and sprinkle the beads over applesauce or mix the contents with bottled water before swallowing.

It is not known if CONSTELLA can be sprinkled on other foods or mixed with other liquids.

To take with applesauce:

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

To take with water:

- Open the CONSTELLA capsule and pour all of the beads into a clean cup with 30 mL of room temperature bottled water.
- Gently swirl the beads and water for at least 20 seconds.
- Swallow all of the CONSTELLA beads and water mixture right away. Do not keep the mixture for future use.
- Add another 30 mL of water to the cup, swirl for at least 20 seconds and swallow right away.
- The medicine is coated on the beads and dissolves in water so you will get the full dose even if some beads are left in the cup.

To take in a nasogastric or gastric feeding tube:

- Open the CONSTELLA capsule and pour all of the beads into a clean cup with 30 mL of room temperature bottled water.
- Gently swirl the beads and water for at least 20 seconds.
- Draw-up the bead-water mixture into an appropriately sized catheter-tipped syringe. Your doctor should tell you the appropriate size for your dose.
- Remove the cap from the syringe, insert the tip of the syringe into the nasogastric tube or gastric feeding tube and push the plunger all the way in to give the dose.
- Add another 30 mL of water to the cup and repeat the process.
- After giving the CONSTELLA dose, flush the nasogastric or gastric tube with at least 10 mL of water.
- The mixture of beads and water should be used right away. Do not keep for future use.
- It is not necessary to flush all the beads through to get the full dose.

A meal can be consumed 30 minutes after dosing with CONSTELLA.

Usual dose:

IBS-C: Take 290 mcg orally once a day, at least 30 minutes before a meal.

CIC: Take 145 mcg orally, once a day, at least 30 minutes before a meal. Your doctor may prescribe a dose of 72 mcg instead depending on your response.

FC: Take 72 mcg orally, once a day, at least 30 minutes before a meal.

Overdose:

If you think you, or a person you are caring for, have taken too much CONSTELLA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of CONSTELLA, skip that dose. Do not take two capsules to make up the missed dose. Instead, wait until the next time you are supposed to take it and then take your next dose at the normal time.

What are possible side effects from using CONSTELLA?

These are not all the possible side effects you may have when taking CONSTELLA. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects reported with CONSTELLA are:

- Diarrhea
- Passing gas
- Abdominal pain
- Swelling, or a feeling of fullness or pressure in your abdomen (bloating)
- Nausea
- Vomiting
- Fatigue
- Stomach flu
- Indigestion

Serious side effects and what to do about them			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Severe diarrhea (persistent watery stools): watery stools that do not go away			✓
RARE			
New or worsening abdominal pain not typical of your IBS-C, CIC or FC symptoms			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store CONSTELLA at room temperature between 15°C and 25°C.
- Keep CONSTELLA in the bottle that it comes in.
- The CONSTELLA 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 CONSTELLA tightly closed and in a dry place.

Keep out of reach and sight of children.

If you want more information about CONSTELLA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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