

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Constella 290 micrograms hard capsules Linaclotide

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Constella is and what it is used for
2. What you need to know before you take Constella
3. How to take Constella
4. Possible side effects
5. How to store Constella
6. Contents of the pack and other information

1. What Constella is and what it is used for

What Constella is used for

Constella contains the active substance linaclotide. It is used to treat the symptoms of moderate to severe irritable bowel syndrome (often just called “IBS”) with constipation in adult patients.

IBS is a common gut disorder. The main symptoms of IBS with constipation include:

- stomach or abdominal pain,
- feeling bloated,
- infrequent, hard, small or pellet-like stools (faeces).

These symptoms may vary from person to person.

How Constella works

Constella acts locally in your gut, helping you to feel less pain and less bloated, and to restore the normal functioning of your bowels. It is not absorbed into the body, but attaches to receptor called guanylate cyclase C on the surface of your gut . By attaching to this receptor, it blocks the sensation of pain and allows liquid to enter from the body into the gut, thereby loosening the stools and increasing your bowel movements.

2. What you need to know before you take Constella

Do not take Constella

- if you are allergic to linaclotide or any of the other ingredients of this medicine (listed in section 6).
- if you or your doctor know that you have a blockage in your stomach or bowels.

Warnings and precautions

Your doctor has given this medicine to you after excluding other diseases, especially of your bowels and concluding that you suffer from IBS with constipation. Because these other diseases may have the same symptoms as IBS, it is important that you report any change or irregularity in symptoms to your doctor promptly.

If you experience severe or prolonged diarrhoea (passing of frequent watery stools for 7 days or more), please stop taking Constella and contact your doctor (see section 4). Make sure you drink plenty of fluids to replace the water and electrolytes like potassium lost from the diarrhoea.

Take special care if you are older than 65 years, as there is a higher risk you experience diarrhea.

Take also special care if you have severe or prolonged diarrhoea and an additional disease, such as high blood pressure, previous disease of the heart and blood vessels (e.g. such as previous heart attacks) or diabetes.

Talk to your doctor if you suffer from inflammatory diseases of the guts such as Crohn's disease or ulcerative colitis as Constella is not recommended in these patients.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 years because the safety and efficacy of Constella in this age group has not been established.

Other medicines and Constella

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- Some medicines may not work as effectively if you have severe or prolonged diarrhoea, such as:
 - Oral contraceptives. If you have very bad diarrhoea, the contraceptive pill may not work properly and the use of an extra method of contraception is recommended. See the instructions in the patient leaflet of the contraceptive pill you are taking.
 - Medicines that need careful and exact dosing, such as levothyroxine (a hormone to treat reduced function of the thyroid gland).
- Some medicines may increase the risk of diarrhoea when taken with Constella, such as:
 - Medicines to treat stomach ulcers or excessive production of stomach acid called Proton Pump Inhibitors.
 - Medicines to treat pain and inflammation called NSAIDs.
 - Laxatives.

Constella with food

Constella produces more frequent bowel movements and diarrhoea (looser stools) when it is taken with food than when it is taken on an empty stomach (see section 3).

Pregnancy and breast-feeding

Limited information is available on the effects of Constella in pregnant and breast-feeding women.

Do not take this medicine if you are pregnant, think you may be pregnant or are planning to have a baby, unless your doctor advises you to do so.

If you are breast-feeding, do not take Constella unless your doctor advises to do so.

Driving and using machines

Constella will not affect your ability to drive or use machines

3. How to take Constella

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one capsule taken once a day. The capsule should be taken at least 30 minutes before a meal.

If you take more Constella than you should

The most likely effect of taking too much Constella is diarrhoea. Contact your doctor or pharmacist if you have taken too much of this medicine.

If you forget to take Constella

Do not take a double dose to make up for a forgotten dose. Just take the next dose at the scheduled time and continue as normal.

If you stop taking Constella

It is preferable to discuss stopping treatment with your doctor before actually doing so. However, treatment with Constella can be safely stopped at any time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people):

- diarrhoea

Diarrhoea is normally short lived; however, if you experience severe or prolonged diarrhoea (passing frequent or watery stools for 7 days or more) and feel lightheaded, dizzy or faint, stop taking Constella and contact your doctor.

Common side effects (may affect up to 1 in 10 people):

- stomach or abdominal pain
- feeling bloated
- wind
- stomach flu (viral gastroenteritis)
- feeling dizzy

Uncommon side effects (may affect up to 1 in 100 people):

- lack of control over passing stools (faecal incontinence)
- urgency to pass stools
- feeling lightheaded after standing up quickly

- dehydration
- low level of potassium in your blood
- decreased appetite

Rare side effects (may affect up to 1 in 1,000 people):

- bicarbonate decrease in your blood

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

Ireland

Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie

5. How to store Constella

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after **EXP**. The expiry date refers to the last day of that month.

Once the bottle is opened, the capsules should be used within 18-weeks.

Do not store above 30°C. Keep the bottle tightly closed in order to protect from moisture.

Warning: The bottle contains one or more sealed canisters containing silica gel to keep the capsules dry. Keep the canisters in the bottle. Do not swallow them.

Do not use this medicine if you notice any signs of damage to the bottle or any change in the appearance of the capsules.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Constella contains

- The active substance is linaclotide. Each capsule contains 290 micrograms of linaclotide.
- The other ingredients are :

Capsule content: microcrystalline cellulose, hypromellose, calcium chloride dihydrate and leucine.

Capsule shell: red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172) and gelatin.

Capsule ink: shellac, propylene glycol, concentrated ammonia solution, potassium hydroxide, titanium dioxide (E171) and black iron oxide (E172).

What Constella looks like and contents of the pack

Constella capsules are white to off-white-orange opaque hard capsules marked “290” with grey ink.

They are packaged in a white, high density polyethylene (HDPE) bottle with a tamper evident seal and a child-resistant screw cap, together with one or more desiccant canisters containing silica gel.

Each bottle contains 10, 28, 60 or 90 capsules. Not all pack-sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.