

Medication Guide
TRULANCE™ (troo' lans)
(plecanatide) tablets

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

- **Do not give TRULANCE to children who are less than 6 years of age. It may harm them.**
- **You should not give TRULANCE to children 6 years to less than 18 years of age. It may harm them.**

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

What is TRULANCE?

TRULANCE is a prescription medicine used in adults to treat a type of constipation called chronic idiopathic constipation (CIC). Idiopathic means the cause of the constipation is unknown.

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

Who should not take TRULANCE?

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

Before taking TRULANCE, tell your doctor about all of your medical conditions, including if you:

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

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

How should I take TRULANCE?

- Take TRULANCE exactly as your doctor tells you to take it.
- Take TRULANCE by mouth, 1 time each day with or without food.
- If you miss a dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.
- TRULANCE tablets should be swallowed whole.
 - Adults who cannot swallow TRULANCE tablets whole may crush the TRULANCE tablet and mix with applesauce or dissolve TRULANCE in water before swallowing. TRULANCE tablets may also be taken with water by adults through a nasogastric or gastric feeding tube.

It is not known if TRULANCE is safe and effective when crushed and mixed with other foods or dissolved in other liquids.

Taking TRULANCE in applesauce:

- Crush the TRULANCE tablet in a clean container until it is a powder and mix with 1 teaspoon of room temperature applesauce.
- Swallow all of the TRULANCE and applesauce mixture right away. Do not keep the TRULANCE and applesauce mixture for future use.

Taking TRULANCE in water:

- Place the TRULANCE tablet in a clean cup and pour 1 ounce (30 mL) of room temperature water into the cup.
- Gently swirl the TRULANCE tablet and water for at least 10 seconds. The TRULANCE tablet will fall apart in the water.
- Swallow all of the TRULANCE tablet and water mixture right away. Do not keep the mixture for

future use.

- If you see any part of the tablet left in the cup, add another 1 ounce (30 mL) of water to the cup, swirl for at least 10 seconds, and swallow right away.

Taking TRULANCE through a nasogastric or gastric feeding tube:

Gather the supplies you will need to take your TRULANCE 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 TRULANCE the right way.

- Place the TRULANCE tablet in a clean cup with 1 ounce (30 mL) of room temperature water.
- Gently swirl the TRULANCE tablet and water for at least 15 seconds. The TRULANCE tablet will fall apart in the water.
- Flush the nasogastric or gastric feeding tube with 1 ounce (30 mL) of water.
- Draw up the TRULANCE tablet and water mixture into a catheter tipped syringe and give right away through the nasogastric or gastric feeding tube. Do not keep the mixture for future use.
- If you see any part of the tablet left in the cup, add another 1 ounce (30 mL) of water to the cup, swirl for at least 15 seconds and use the same catheter tipped syringe to give the mixture through the nasogastric or gastric feeding tube.
- Using the same or another catheter tipped syringe, flush the nasogastric or gastric feeding tube with at least 10 mL of water.

What are the possible side effects of TRULANCE?

TRULANCE can cause serious side effects, including:

- See “**What is the most important information I should know about TRULANCE?**”
- **Diarrhea is the most common side effect of TRULANCE, and it can sometimes be severe.**
 - Diarrhea often begins within the first 4 weeks of TRULANCE treatment.

Stop taking TRULANCE and call your doctor if you develop severe diarrhea.

These are not all the possible side effects of TRULANCE.

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 TRULANCE?

- Store TRULANCE at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep TRULANCE in a secure place and in the bottle or blister pack that it comes in.
- The TRULANCE bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). Do not remove the desiccant packet from the bottle.
- The TRULANCE bottle contains a polyester coil to help protect the tablets during shipping. Remove the polyester coil from the bottle and throw it away when you are ready to start taking TRULANCE.
- Keep the container of TRULANCE tightly closed and in a dry place.
- Safely throw away TRULANCE that is out of date or no longer needed.

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

General information about the safe and effective use of TRULANCE.

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

You can ask your doctor or pharmacist for information about TRULANCE that is written for health professionals.

What are the ingredients in TRULANCE?

Active ingredient: plecanatide

Inactive ingredients: magnesium stearate and microcrystalline cellulose

TRULANCE™ is a trademark of Synergy Pharmaceuticals Inc.

Manufactured for:
Synergy Pharmaceuticals Inc.
420 Lexington Avenue, Suite 2012
New York, New York 10170

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For more information, go to www.synergypharma.com or call 1-888-869-8869.

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

Issued: 01/2017