

PATIENT INFORMATION

DOPTELET® (dop-TEL-et)
(avatrombopag) tablets, for oral use

DOPTELET® SPRINKLE (dop-TEL-et SPRINK-el)
(avatrombopag) oral granules

What are DOPTELET and DOPTELET SPRINKLE?

- DOPTELET is a prescription medicine used to treat low blood platelet counts in:
 - adults with long-lasting (chronic) liver disease (CLD) who are scheduled to have a medical or dental procedure.
 - adults with chronic immune thrombocytopenia (ITP) when other treatments have not worked well enough.
 - children 1 year and older with persistent or chronic ITP when other treatments have not worked well enough.

DOPTELET tablets and DOPTELET SPRINKLE are different dosage forms of DOPTELET. DOPTELET SPRINKLE is a capsule that contains granules that are mixed with a soft food or liquid for dosing.

DOPTELET tablets and DOPTELET SPRINKLE are not used to make platelet counts normal.

It is not known if DOPTELET tablets or DOPTELET SPRINKLE are safe and effective in children younger than 1 year of age.

Before you take DOPTELET or DOPTELET SPRINKLE, tell your healthcare provider about all of your medical conditions, including if you:

- have ever had a blood clot.
- are pregnant or plan to become pregnant. DOPTELET may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with DOPTELET.
- are breastfeeding or plan to breastfeed. It is not known if DOPTELET passes into your breast milk. Do not breastfeed during your treatment with DOPTELET and for at least 2 weeks after the last dose. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. DOPTELET or DOPTELET SPRINKLE may affect the way other medicines work, and other medicines may affect the way DOPTELET or DOPTELET SPRINKLE works.

How should I take DOPTELET?

- DOPTELET tablets that come in a blister package are **not** the same dosage form as DOPTELET SPRINKLE that come in a bottle and **cannot** be directly substituted for each other. Contact your or your child's pharmacist or healthcare provider if you did not receive the correct dosage form.
- Take DOPTELET exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much DOPTELET to take and when to start taking it.
- Your healthcare provider may change your dose of DOPTELET depending on your blood platelet counts.
- Take DOPTELET with food.
- If you take DOPTELET to treat your low blood platelet counts due to chronic liver disease before a medical or dental procedure, your healthcare provider will check your platelet count before treatment and on the day of your scheduled procedure.
- If you take DOPTELET to treat your low blood platelet counts due to persistent or chronic immune thrombocytopenia, your healthcare provider will check your platelet count before, during and for at least 4 weeks after stopping your treatment with DOPTELET.
- If you are taking DOPTELET before a scheduled medical procedure and you miss a dose, contact your healthcare provider for further dosing instructions.
- If you are taking DOPTELET for persistent or chronic immune thrombocytopenia and you miss a dose, take it as soon as you remember. Do not take 2 doses at one time to make up for a missed dose. Take your next dose at your usual scheduled time.
- If you take too much DOPTELET, call your healthcare provider or Poison Help Line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

How should I give DOPTELET SPRINKLE?

- DOPTELET SPRINKLE oral granules that come in a bottle are **not** the same dosage form as DOPTELET tablets that come in a blister card and **cannot** be directly substituted for each other. Contact your child's pharmacist or healthcare provider if you did not receive the correct dosage form.
- If your child is prescribed DOPTELET SPRINKLE: **See the Instructions for Use** on how to prepare and give a dose.
- Open the capsules and sprinkle the contents onto a small amount of a soft food or liquid. Mix or stir the granules into the soft food or liquid and take right away.
- **Do not** swallow the capsules whole or the empty capsule shells.
- Do not chew or crush the oral granules.
- Give DOPTELET SPRINKLE exactly as your child's healthcare provider tells you to give it.
- Your child's healthcare provider will tell you how much DOPTELET SPRINKLE to give and when to start taking it.
- Your child's healthcare provider may change the dose of DOPTELET SPRINKLE.
- Give your child DOPTELET SPRINKLE with food.
- If your child is taking DOPTELET SPRINKLE to treat low blood platelet counts due to persistent or chronic immune thrombocytopenia, your child's healthcare provider will check your child's platelet count before, during and for at least 4 weeks after stopping treatment with DOPTELET SPRINKLE.
- If you are giving DOPTELET SPRINKLE for your child's persistent or chronic immune thrombocytopenia and miss a dose, give it as soon as you remember. Do not give 2 doses at one time to make up for a missed dose. Give the next dose at the usual scheduled time.
- If your child takes too much DOPTELET SPRINKLE, call your child's healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of DOPTELET or DOPTELET SPRINKLE?

DOPTELET or DOPTELET SPRINKLE may cause serious side effects, including:

Blood clots. People with chronic liver disease or persistent or chronic immune thrombocytopenia and people with certain blood clotting conditions may have an increased risk of developing blood clots. Tell your healthcare provider right away if you get signs and symptoms of a blood clot, including:

- swelling, pain, or tenderness in your legs
- shortness of breath
- chest pain
- fast heartbeat
- stomach (abdominal) pain or tenderness

The most common side effects of DOPTELET when used to treat low blood platelet counts in adults with chronic liver disease (CLD) who are scheduled to have a medical or dental procedure are:

- fever
- stomach (abdominal) pain
- nausea
- headache
- tiredness
- swelling of hands or feet

The most common side effects of DOPTELET when used to treat low blood platelet counts in adults with chronic immune thrombocytopenia (ITP) are:

- headache
- tiredness
- bruising
- nosebleed
- upper respiratory infection
- joint pain
- bleeding gums
- purple or red spots on your skin
- runny nose

The most common side effects of DOPTELET or DOPTELET SPRINKLE when used to treat low blood platelet counts in children 1 year and older with persistent or chronic immune thrombocytopenia (ITP) are:

- viral infection
- runny nose
- cough
- fever
- pain in the mouth or throat

These are not all of the possible side effects of DOPTELET or DOPTELET SPRINKLE.

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 DOPTELET tablets or DOPTELET SPRINKLE?

- Store DOPTELET tablets or DOPTELET SPRINKLE at room temperature from 68°F to 77°F (20°C to 25°C).
- Store DOPTELET tablets in the original package.

Keep DOPTELET tablets, DOPTELET SPRINKLE and all medicines out of the reach of children.

General information about the safe and effective use of DOPTELET or DOPTELET SPRINKLE.

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

What are the ingredients in DOPTELET tablets or DOPTELET SPRINKLE?

Active ingredient: avatrombopag

Inactive ingredients in DOPTELET tablets: colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate and microcrystalline cellulose. Tablet coating film: ferric oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Inactive ingredients in DOPTELET SPRINKLE: crospovidone Type A, magnesium stearate, mannitol, microcrystalline cellulose, and sodium lauryl sulfate. Capsule shells: Hypromellose.

DOPTELET is a registered trademark of AkaRx, Inc.

Manufactured for AkaRx, Inc., Morrisville, North Carolina 27560

For more information, go to www.DOPTELET.com or call 1-855-454-3887.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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INSTRUCTIONS FOR USE
DOPTELET® SPRINKLE (dop-TEL-et SPRINK-el)
(avatrombopag) oral granules

Read these Instructions for Use to prepare and give a dose of DOPTELET SPRINKLE correctly.

- **Important information that you need to know before giving DOPTELET SPRINKLE:**

The contents of DOPTELET SPRINKLE should be sprinkled onto a soft food or liquid, as described below.

- DOPTELET SPRINKLE that comes in a bottle is **not** the same dosage form as DOPTELET tablets that come in a blister card and these products **cannot** be directly substituted for each other. Contact your child's pharmacist or healthcare provider if your child did not receive the correct dosage form.
- DOPTELET SPRINKLE contains granules inside of a capsule.
 - The capsule must be opened, and the granules inside must be sprinkled onto a soft food or liquid to give a dose of DOPTELET SPRINKLE.
 - Do not swallow the capsule whole or the empty capsule shells.
 - Do not chew or crush the granules.
- Use all of the granules in the capsule. **Do not** use part of a capsule to try to prepare a dose.

Steps to prepare and give a dose of DOPTELET SPRINKLE:

1. Gather supplies to prepare a dose of DOPTELET SPRINKLE: capsule(s), liquid or soft food, cup or spoon, and mixing utensil (e.g., stir stick or small spoon); then wash your hands.
2. Put a small amount of soft food or liquid in a cup or spoon. The following soft foods and liquids can be used:

Soft foods

- applesauce
- strawberry jelly
- yogurt (plain)

Liquids

- milk (whole or skim)
- orange juice
- pediatric electrolyte solution (unflavored)
- water

3. Carefully open the capsule (or 2 capsules if prescribed) by pulling it apart.
 - Sprinkle the entire contents of the capsule onto the soft food or liquid that you put in the spoon or cup. Make sure that all of the granules from the capsule have been completely emptied.
4. Mix or stir the granules into the soft food or liquid. The granules will **not** dissolve.
5. Give the mixture **right away**; **do not** save for later use.
6. Rinse the spoon or cup with additional soft food or liquid to make sure that the entire dose is given.
7. Throw the empty capsule shells away in the trash.

How should I store DOPTELET SPRINKLE?

- Store DOPTELET SPRINKLE at room temperature from 68°F to 77°F (20°C to 25°C).

Keep DOPTELET SPRINKLE and all medicines out of the reach of children.

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