



BRIEF SUMMARY OF PATIENT INFORMATION FOR DOPTELET® (dop-TEL-et) (AVATROMBOPAG) TABLETS

What is DOPTELET?

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.
- chronic immune thrombocytopenia (ITP) when other treatments have not worked well enough.

DOPTELET is not used to make platelet counts normal in adults with chronic liver disease or chronic immune thrombocytopenia.

It is not known if DOPTELET is safe and effective in children.

Before you take DOPTELET, 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 may affect the way other medicines work, and other medicines may affect the way DOPTELET works.

How should I take DOPTELET?

- 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 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 prior to a scheduled medical procedure and you miss a dose, contact your healthcare provider for further dosing instructions.
- If you are taking DOPTELET for chronic immune thrombocytopenia and you miss a dose of DOPTELET, 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 go to the nearest hospital emergency room right away.

What are the possible side effects of DOPTELET? DOPTELET may cause serious side effects, including:

Blood clots. People with chronic liver disease 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 have 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 tract infection
- joint pain
- bleeding gums
- purple or red spots on your skin
- runny nose

The following side effects are reported by an unknown number of volunteers taking DOPTELET, who were not in a clinical trial. It may not be possible to know how often side effects will happen, or if the side effects are from DOPTELET alone.

Immune System Disorders: Allergic reactions including itch, rash, choking sensation, redness of the skin, swelling throat, swelling face, and swollen tongue.

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

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?

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

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

General information about the safe and effective use of DOPTELET.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DOPTELET for a condition for which it was not prescribed. Do not give DOPTELET 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 that is written for health professionals.

This information is not comprehensive.

How to get more information:

- Talk to your healthcare provider or pharmacist about DOPTELET.
- Visit www.DOPTELET.com to obtain the FDA-approved product labeling.

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For more information, go to www.DOPTELET.com or call 1-844-506-3682.

