

DOPTELET

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using DOPTELET?

DOPTELET contains the active ingredient avatrombopag maleate. DOPTELET is used to treat low platelet count (called thrombocytopenia) in adults with chronic liver disease before having an invasive medical procedure where there is a risk of bleeding and adults with low platelet counts due to primary chronic immune thrombocytopenia (ITP) when a prior treatment for ITP has not worked well enough.

For more information, see Section [1. Why am I using DOPTELET?](#) in the full CMI.

2. What should I know before I use DOPTELET?

Do not use if you have ever had an allergic reaction to avatrombopag or to any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use DOPTELET?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DOPTELET and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use DOPTELET?

- Take DOPTELET exactly as your doctor has told you. Your dose will depend on your platelet counts.
- If you have chronic liver disease and are scheduled for an invasive medical procedure, the usual dose is either 40 mg (2 tablets) or 60 mg (3 tablets) every day for 5 days in a row.
- If you have chronic immune thrombocytopenia, the usual starting dose is 20 mg (1 tablet) a day.
- DOPTELET tablets should be swallowed whole and taken with food.

More instructions can be found in Section [4. How do I use DOPTELET?](#) in the full CMI.

5. What should I know while using DOPTELET?

Things you should do	<ul style="list-style-type: none">• Attend your scheduled appointments so that your doctor can monitor your platelet count and discuss appropriate precautions with you.• Remind any doctor, dentist or pharmacist you visit that you are taking DOPTELET.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly or change the dose unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• DOPTELET is not expected to affect your ability to drive or operate machines.
Looking after your medicine	<ul style="list-style-type: none">• Follow the instructions in the carton on how to take care of your medicine properly.• Store below 25°C.

For more information, see Section [5. What should I know while using DOPTELET?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of DOPTELET are feeling tired and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

DOPTELET

Active ingredient(s): *avatrombopag (as maleate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DOPTELET. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DOPTELET.**

Where to find information in this leaflet:

- [1. Why am I using DOPTELET?](#)
- [2. What should I know before I use DOPTELET?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DOPTELET?](#)
- [5. What should I know while using DOPTELET?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DOPTELET?

DOPTELET contains the active ingredient **avatrombopag**. DOPTELET belongs to a group of medicines called thrombopoietin receptor agonists.

DOPTELET is used to treat:

- low platelet count (called **thrombocytopenia**) in adults with chronic liver disease before having a medical procedure where there is a risk of bleeding.
- adults with low platelet counts due to **primary chronic immune thrombocytopenia (ITP)** when a prior treatment for ITP (such as corticosteroids or immunoglobulins) has not worked well enough.

DOPTELET works by helping to increase the number of platelets in the blood. Platelets are blood cells that help the blood to clot and so reduce or prevent bleeding.

2. What should I know before I use DOPTELET?

Warnings

Do not use DOPTELET if:

- you are allergic to avatrombopag, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- are at risk of blood clots in your veins or arteries, or members of your family have had blood clots.

- have another blood condition known as myelodysplastic syndrome (MDS). Taking DOPTELET may worsen MDS.
- take any medicines for any other condition.
- have severe liver disease.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Doptelet is not recommended in pregnancy and in women who are able to have children and are not using contraception.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding is not recommended during treatment with DOPTELET and for at least 2 weeks after the last dose.

Use in children and adolescents

DOPTELET should not be used in children and adolescents under the age of 18 years. The safety of DOPTELET and how well it works has not been studied in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with DOPTELET and affect how it works.

- Some medicines (e.g. fluconazole) may increase the effect of DOPTELET.
- Some medicines (e.g. rifampicin) may reduce the effects of DOPTELET.

You may need to take a different dose of DOPTELET than usual if you are taking medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DOPTELET.

4. How do I use DOPTELET?

How much to take

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

If you have chronic liver disease and are scheduled for an invasive procedure:

- The usual recommended dose is either 40 mg (2 tablets) or 60 mg (3 tablets) every day for 5 days in a row.
- Your dose will depend on your platelet counts.
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.

If you have chronic immune thrombocytopenia:

- The usual recommended starting dose is 20 mg (1 tablet) a day. If you are taking certain other medicines, you may need a different starting dose.
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.
- Your doctor will monitor your platelet count regularly and will adjust your dose as needed.

Taking DOPTELET

- Swallow the tablets whole and take with food at the same time each day that you take DOPTELET.
- If you have chronic liver disease and are scheduled for an invasive medical procedure, start taking DOPTELET 10 to 13 days before your planned procedure. You should be scheduled to undergo your procedure 5 to 8 days after the last dose of DOPTELET.
- Take DOPTELET for as long as your doctor tells you. Do not stop taking DOPTELET unless your doctor tells you to.

If you forget to take DOPTELET

If you miss your dose at the usual time, take your missed dose as soon as you remember, then take your next dose at the usual time.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much DOPTELET

If you think that you have taken too much DOPTELET, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using DOPTELET?

Things you should do

- Attend your scheduled appointments so that your doctor can check on your progress.
Blood tests for platelet count: Your doctor will carry out tests to monitor your platelet count and discuss appropriate precautions with you.
Tests to check your bone marrow: In people who have problems with their bone marrow, medicines like DOPTELET could make the problems worse. Signs of bone marrow changes may show up as abnormal results in your blood tests. Your doctor may also carry out a test to directly check your bone marrow during treatment with DOPTELET.
- Remind any doctor, dentist or pharmacist you visit that you are using DOPTELET.

Things you should not do

- Do not stop taking this medicine suddenly or change the dose unless your doctor tells you to. If you stop taking DOPTELET, your platelet count is likely to become low as before treatment or even lower, with a risk of bleeding. This may happen within days.

Driving or using machines

DOPTELET is not expected to affect your ability to drive, cycle or use tools or machines.

Looking after your medicine

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: <ul style="list-style-type: none">• feeling sick (nausea)• abdominal pain Infections: <ul style="list-style-type: none">• cold or cough• inflammation of throat and nose Muscle and joints related: <ul style="list-style-type: none">• joint pain or painful swollen joints Skin related: <ul style="list-style-type: none">• red or purple, flat, pinhead spots under the skin Other: <ul style="list-style-type: none">• feeling tired• headache• fever or high temperature• nose bleeds• gums bleeding easily• tendency to bruise easily• swelling of hands, ankles or feet	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Hypersensitivity/allergy related: <ul style="list-style-type: none">• shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin. Blood clot related <ul style="list-style-type: none">• pain, swelling and tenderness in one of your legs (usually the calf) with warm skin in the affected area (signs of a blood clot in a deep vein)• sudden shortness of breath, especially when accompanied with sharp pain in the chest and/or rapid breathing, which could be signs of a blood clot in the lungs	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DOPTELET contains

Active ingredient (main ingredient)	avatrombopag maleate (equivalent to 20 mg avatrombopag)
Other ingredients (inactive ingredients)	Core tablet: lactose monohydrate, colloidal anhydrous silica, crospovidone, magnesium stearate and microcrystalline cellulose. Film coating: OPADRY II Complete Film Coating System 85F42244 Yellow.
Potential allergens	sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What DOPTELET looks like

DOPTELET 20 mg film-coated tablets are pale yellow, round biconvex tablets, debossed with "AVA" on one side and "20" on the other side.

DOPTELET is supplied in PA/Al/PVC/Al blister packs of 10, 15 or 30 tablets.

Not all pack sizes may be available.

Who distributes DOPTELET

Swedish Orphan Biovitrum Pty Ltd
Floor 22 (Business Sweden Office)
44 Market Street, Sydney NSW 2000
Australia
<https://au.sobi.com>

This leaflet was prepared in January 2023.