**Package leaflet: Information for the patient**

**Doptelet 20 mg film-coated tablets**
avatrombopag

▼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 Doptelet is and what it is used for

Doptelet contains an active substance called avatrombopag. It belongs to a group of medicines called thrombopoietin receptor agonists.

Doptelet is used in adults with chronic liver disease to treat low platelet count (called thrombocytopenia) before having a medical procedure where there is a risk of bleeding.

Doptelet is used to treat 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 you need to know before you take Doptelet

**Do not take Doptelet**
- if you are allergic to avatrombopag or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor or pharmacist before taking Doptelet.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Doptelet if:
- you are at risk of blood clots in your veins or arteries, or members of your family have had blood clots.
- you have another blood condition known as myelodysplastic syndrome (MDS); taking Doptelet may worsen MDS.

You may be at **higher risk of blood clots** as you get older or if:
- you have had to stay in bed for a long time
- you have cancer
- you are taking the contraceptive birth control pill or hormone replacement therapy
- you have recently had surgery or been injured
- you are very overweight
- you smoke
- you have advanced chronic liver disease.

If any of the above applies to you, or you are not sure, talk to your doctor or pharmacist before taking Doptelet.

**Blood tests for platelet count**
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. The platelet count will be monitored, and your doctor will 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.

**Children and adolescents**
Do not give Doptelet to people less than 18 years old. The safety and effectiveness of this medicine in this age group is not known.

**Other medicines and Doptelet**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking other medicines for ITP, you may need to take a lower dose or to stop taking them while you are taking Doptelet.

**Pregnancy and breast-feeding**
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Doptelet is not recommended in pregnancy and in women who are able to have children and are not using contraception.

If you are breast-feeding, ask your doctor or pharmacist for advice before taking Doptelet. This medicine can pass into breast milk. Your doctor will help you decide whether the benefit of breast-feeding outweighs any possible risks to your baby while you are breast-feeding.

**Driving and using machines**
Doptelet is not expected to affect you being able to drive, cycle or use tools or machines.

**Doptelet contains lactose**
Doptelet contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take Doptelet

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 low platelet count you should be scheduled to undergo your procedure 5 to 8 days after the last dose of Doptelet.

If you have chronic immune thrombocytopenia your doctor will tell you how much Doptelet to take and how often to take it.

**How much to take**

<u>If you have chronic liver disease and are scheduled for an invasive procedure</u>
- Doptelet is available in 20 mg tablets. 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.

<u>If you have chronic immune thrombocytopenia</u>
- 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 this medicine**

- Swallow the tablets whole and take with food at the same time each day that you take Doptelet.

<u>If you have chronic liver disease and low platelet count</u>
- Start taking Doptelet 10 to 13 days before your planned medical procedure.
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.

<u>If you have chronic immune thrombocytopenia</u>
- Your doctor or pharmacist will tell you how many tablets to take and when to take them.

**If you take more Doptelet than you should**
- Talk to a doctor or pharmacist straight away.

**If you forget to take Doptelet**
- Take your missed dose as soon as you remember, then take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

**If you stop taking Doptelet**
Take Doptelet for as long as your doctor tells you. Do not stop taking Doptelet unless your doctor tells you to.

If you have any 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.

Tell your doctor or pharmacist if you notice any of the following side effects.

**The following side effects have been reported to be associated with treatment with Doptelet in adult patients with chronic liver disease:**

**Common** (may affect up to 1 in 10 people)
- feeling tired

**Uncommon** (may affect up to 1 in 100 people)
- low red blood cell count (anaemia)
- blood clot in the portal vein (blood vessel that carries blood to the liver from the intestines) which may result in upper abdominal pain or swelling
- bone pain
- muscle aches
- fever

**Not known** (frequency cannot be estimated from the available data)
- allergic reactions including swollen face, swollen tongue, and skin changes such as rash and itching

**The following side effects have been reported to be associated with treatment with Doptelet in adult patients with primary chronic immune thrombocytopenia**:

**Very common** (may affect more than 1 in 10 people)
- feeling tired
- headache

**Common** (may affect up to 1 in 10 people)
- back pain, muscle pain, joint pain, pain in arms or legs
- discomfort or pain of bones, muscles, ligaments, tendons, and nerves
- feeling sick (nausea), diarrhoea, vomiting, abdominal pain, digestive wind/gas
- dizziness, head discomfort, migraine
- decreased appetite
- weakness
- nose bleeds
- skin rash, itching, acne, red spots on skin
- feeling of tingling, prickling or numbness, commonly called “pins and needles”
- enlarged spleen
- shortness of breath
- elevated blood pressure
- tendency to bruise or bleed (low platelets)

**Common side effects that may show up in blood tests**
- increased fats (cholesterol, triglycerides)
- increased or decreased blood sugar (glucose)
- increased liver enzyme (alanine aminotransferase)
- increased lactate dehydrogenase
- increased gastrin

- decreased number of red blood cells (anaemia)
- increased or decreased number of platelets

**Uncommon** (may affect up to 1 in 100 people)
- redness, swelling and pain of a vein caused by a blood clot
- 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)
- blood clots in the veins which carry blood away from the brain
- narrowing of the blood vessels (vasoconstriction)
- 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
- blockage or narrowing of the vein that brings blood to the liver
- stroke or mini-stroke
- heart attack
- irregular heartbeat
- haemorrhoids
- dilation of the rectal veins
- inflammation (swelling) and infection of the nose, sinuses, throat, tonsils, or middle ear (upper respiratory tract infection)
- scarring of the bone marrow
- loss of water or body fluids (dehydration)
- increased appetite, hunger
- mood changes
- abnormal thinking
- changes in sense of taste, smell, hearing, vision
- eye problems including irritation, discomfort, itching, swelling, tearing, sensitivity to light, blurred vision, vision impaired, loss of vision
- ear pain
- increased sensitivity to everyday sounds
- coughing up blood
- nasal congestion
- abdominal pain, discomfort or swelling
- constipation
- belching
- acid reflux
- burning or stinging sensation in mouth
- numbness of the mouth, swollen tongue, tongue problems
- numbness
- hair loss
- boils
- dry skin
- dark purple spots on skin (blood leakage out of blood vessels, bruising)
- excessive sweating
- changes in skin color
- itchy rash
- skin irritation
- abnormality of a joint
- muscle cramps, muscle weakness
- blood in urine
- heavy menstrual period
- nipple pain
- chest pain

- pain
- swelling in legs or arms

**Uncommon side effects that may show up in blood tests**
- bacteria in the blood
- increased white blood cells
- decreased iron in blood
- increased liver enzyme (aspartate aminotransferase), abnormal liver tests

**Not known** (frequency cannot be estimated from the available data)
- allergic reactions including swollen face, swollen tongue, and skin changes such as rash and itching

**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 via:

**United Kingdom**
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Doptelet

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 on each blister after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 to protect the environment.

## 6. Contents of the pack and other information

**What Doptelet contains**
- The active substance is avatrombopag. Each film-coated tablet contains avatrombopag maleate equivalent to 20 mg of avatrombopag.

- The other ingredients are:
  Tablet core: lactose monohydrate (see section 2 "Doptelet contains lactose"); microcrystalline cellulose [E460(i)]; crospovidone type B [E1202]; silica, colloidal anhydrous [E551]; magnesium stearate [E470b].
  Film coating: poly(vinyl alcohol) [E1203]; talc [E553b]; macrogol 3350 [E1521]; titanium dioxide [E171]; iron oxide yellow [E172].

**What Doptelet looks like and contents of the pack**
Doptelet 20 mg film-coated tablets are pale yellow, round, rounded on the upper and lower side, marked with "AVA" imprinted on one side and "20" on the other.

The tablets are supplied in cartons containing one or two aluminium blisters. Each blister contains either 10 or 15 tablets.

**Marketing Authorisation Holder**
Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm
Sweden

**Manufacturer**
Swedish Orphan Biovitrum AB (publ)
Strandbergsgatan 49,
Stockholm,
112 51
Sweden

**This leaflet was last revised in 01/2022.**