

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrTAVALISSE®
Fostamatinib Tablets
(as fostamatinib disodium hexahydrate)

Read this carefully before you start taking **TAVALISSE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TAVALISSE**.

What is TAVALISSE used for?

TAVALISSE is used to treat **adults** with a bleeding disorder known as immune thrombocytopenia (ITP) when other treatments have not worked well enough.

How does TAVALISSE work?

TAVALISSE targets an enzyme called spleen tyrosine kinase. This enzyme plays an important part in destroying platelets. Platelets are needed to stop bleeding. By limiting platelet destruction, TAVALISSE increases the number of platelets in your body.

What are the ingredients in TAVALISSE?

Medicinal ingredients: fostamatinib disodium hexahydrate

Non-medicinal ingredients: magnesium stearate; mannitol; polyethylene glycol 3350; polyvinyl alcohol; povidone; red iron oxide; sodium bicarbonate; sodium starch glycolate; talc; titanium dioxide; and yellow iron oxide.

TAVALISSE comes in the following dosage forms:

Tablets for oral administration; 100 mg, 150 mg

Do not use TAVALISSE if:

- You are allergic to
 - fostamatinib disodium hexahydrate (medicinal ingredients of TAVALISSE) or
 - any of the other ingredients in TAVALISSE
- You are pregnant or become pregnant

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TAVALISSE. Talk about any health conditions or problems you may have, including if you:

- have high blood pressure
 - are pregnant or plan to become pregnant
 - are breast-feeding or plan to breast-feed
 - you have liver problems
 - are taking any medicine that may have an effect on the way your heart beats
 - have osteoporosis
 - have a fracture
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Other warnings you should know about:

High Blood Pressure (hypertension): New, worsening or severe high blood pressure is common in people treated with TAVALISSE. Your health care professional will check your blood pressure regularly during treatment with TAVALISSE. Your health care professional may start you on blood pressure medicine or change your current medicine to treat your blood pressure. Tell your health care professional if you get:

- headaches,
- confusion,
- dizziness,
- chest pain,
- shortness of breath.

Liver problems. Changes in liver function blood tests are common with TAVALISSE. Liver problems may occur and can be severe. Your health care professional will regularly do blood tests to check how well your liver is working during treatment with TAVALISSE. Tell your health care professional if:

- your skin and eyes appear yellowish (jaundice),
- you have abdominal pain and swelling,
- you have swelling in your legs and ankles,
- you have itchy skin,
- you have dark urine,
- you have pale stool colour,
- you have bloody or tar-coloured stool,
- you have chronic fatigue,
- you have a feeling or being sick in the stomach,
- you have a loss of appetite,
- you have an increase in liver enzymes in your blood tests.

Diarrhea. This is common and can be severe in people treated with TAVALISSE. Tell your health care professional if you get diarrhea during treatment with TAVALISSE. Your health care professional may recommend:

- changes in your diet,
- drinking more water,
- medicine to limit your symptoms.

Decrease in white blood cell counts (neutropenia). Decreases in your white blood cell count are common and can be severe with TAVALISSE. This may increase your risk of infection, including serious infections. Your health care professional will regularly do blood tests to check your white blood cell counts.

Pregnancy: You should avoid becoming pregnant while taking TAVALISSE and for at least 4 weeks after you stop taking it before planning a pregnancy.

Talk to your health care professional right away if you are pregnant or plan on becoming pregnant. TAVALISSE may cause harm to your unborn baby. Female patients must use an effective birth control method while taking TAVALISSE and for at least **4 weeks** after the last dose.

Fertility: TAVALISSE may affect the ability of a woman to get pregnant once treatment is stopped.

Breast-feeding: TAVALISSE is not recommended while breast-feeding. You should not breast-feed during treatment with TAVALISSE and for at least **4 weeks** after your last dose.

Osteoporosis or a fracture: Close monitoring of patients with osteoporosis and fractures is recommended.

Driving and Operating Machinery: Do not drive or operate machinery while taking TAVALISSE if you

- feel tired
- are dizzy
- experience any change in vision

Children (<18 years of age): TAVALISSE is not to be used in children and young adults where epiphyseal fusion (growth plate closure) has not yet occurred.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TAVALISSE:

- Ketoconazole, this medicine is typically used to treat fungal infections.
- Rifampicin (rifampin), this medicine is typically used to treat bacterial infections.
- Simvastatin and rosuvastatin, these medicines are typically used to treat high cholesterol.
- Digoxin, this medicine is typically used to treat various heart conditions such as atrial fibrillation, atrial flutter and heart failure.
- Midazolam, this medicine is typically used for sedation or to treat anxiety.
- Anticoagulants, this medicine is typically used to prevent blood clotting.
- Nelfinavir, this medicine is typically used to treat HIV infection.
- Verapamil, this medicine it typically used to treat various heart conditions such as high blood pressure.
- Ethinylestradiol, this medicine is typically used for birth control.
- Drugs that are known to strongly decrease the activity of a class of enzymes (known as CYP3A4) responsible for breaking down many drugs and toxins.

How to take TAVALISSE:

Always take this medicine exactly as your health care professional has told you. Check with your health care professional if you are not sure.

Swallow the tablets whole with water.

TAVALISSE can be taken with food or between meals.

In case of stomach upset, take the tablets with food.

Usual dose:

The recommended dose of TAVALISSE is 100 mg twice daily.

However, your health care professional will check your platelet counts during your treatment with TAVALISSE and may change your dose of TAVALISSE as needed.

After starting treatment with TAVALISSE, the dose can be increased to 150 mg twice daily based on platelet count and tolerability. A daily dose of 300 mg daily must not be exceeded.

If you have liver problems or high blood pressure, your health care professional may start you on a lower dose.

If you get serious side effects (such as high blood pressure, liver problems, diarrhea or a decrease in white blood cell counts), your health care professional may lower your dose or stop your treatment temporarily or permanently.

Overdose:

If you think you have taken too much TAVALISSE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of TAVALISSE, do not take a double dose to make up for a forgotten tablet. Take your next dose at its regularly scheduled time.

What are possible side effects from using TAVALISSE?

These are not all the possible side effects you may feel when taking TAVALISSE. If you experience any side effects not listed here, contact your healthcare professional.

Other side effects

- Nose Bleeds
- Shortness of breath
- Feeling sick in the stomach
- Excess gas
- Stomach pain
- Dizziness
- Tiredness (fatigue)
- Taste changes
- Rash

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
COMMON	Low white blood cell count		✓	
RARE	Severe Diarrhea	✓		
	Severe high blood pressure	✓		
	Pneumonia		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15 to 30°C). Protect from Moisture.

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 bottle after EXP. The expiry date refers to the last day of that month.

Store in the original container. Keep the bottle tightly closed.

Do not remove desiccants which are the small canisters inside the bottle which help absorb moisture.

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 protect the environment.

If you want more information about TAVALISSE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.medison.ca, or by calling 1-800-696-1341.

This leaflet was prepared by Medison Pharma Canada Inc.

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