

PATIENT INFORMATION
TAVALISSE™ (TAV-a-leese)
(fostamatinib disodium hexahydrate)
tablets

What is the most important information I should know about TAVALISSE?

TAVALISSE can cause serious side effects, including:

- **High blood pressure (hypertension).** New or worsening high blood pressure is common in people treated with TAVALISSE and can be severe. Your healthcare provider will check your blood pressure regularly during treatment with TAVALISSE. If needed, your healthcare provider may start you on blood pressure medicine or change your current medicine to treat your blood pressure. Tell your healthcare provider if you get headaches, confusion, dizziness, chest pain or shortness of breath.
- **Liver problems.** Changes in liver function blood tests are common with TAVALISSE. Liver problems may occur and can be severe. Your healthcare provider will regularly do blood tests to check how well your liver is working during treatment with TAVALISSE.
- **Diarrhea.** Diarrhea is common in people treated with TAVALISSE and can be severe. Tell your healthcare provider if you get diarrhea during treatment with TAVALISSE. Your healthcare provider may recommend changes in your diet, drinking more water, or medicine to limit these symptoms.
- **Decrease in white blood cell counts (neutropenia).** Decreases in your white blood cell count are common with TAVALISSE and can be severe. This may increase your risk for infection, including serious infections. Your healthcare provider will regularly do blood tests to check your white blood cell counts.

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with TAVALISSE if you have side effects.

See “What are the possible side effects of TAVALISSE?” for more information about side effects.

What is TAVALISSE?

TAVALISSE is a prescription medicine that is used to treat adults with low platelet counts due to chronic immune thrombocytopenia (ITP) when a prior treatment for ITP has not worked well enough.

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

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

- have high blood pressure
- have liver problems
- are pregnant or plan to become pregnant. TAVALISSE can harm your unborn baby.
 - Your healthcare provider will check if you are pregnant before starting treatment with TAVALISSE.
 - Females who can become pregnant should use effective birth control during treatment with TAVALISSE and for at least 1 month after the last dose.
- are breastfeeding or plan to breastfeed. You should not breastfeed during treatment with TAVALISSE and for at least 1 month after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking TAVALISSE with certain other medicines may affect how the other medicines work and other medicines may affect how TAVALISSE works.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take TAVALISSE?

- Take TAVALISSE exactly as your healthcare provider tells you to take it.
- Take TAVALISSE with or without food.
- If you miss a dose of TAVALISSE, take your next dose at its regularly scheduled time.
- If you take too much TAVALISSE, call your healthcare provider right away or go to the nearest hospital emergency room right away.
- Your healthcare provider will check your platelet count during your treatment with TAVALISSE and may change your dose of TAVALISSE as needed.

What are the possible side effects of TAVALISSE?**See “What is the most important information I should know about TAVALISSE?”**

The most common side effects of TAVALISSE include:

- nausea
- dizziness
- respiratory infection
- rash
- tiredness
- chest pain
- stomach (abdomen) pain

These are not all the side effects of TAVALISSE. For more information, ask your healthcare provider or pharmacist.

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 TAVALISSE?

- Store TAVALISSE at room temperature between 68°F and 77°F (20°C to 25°C).
- The bottle of TAVALISSE contains 2 desiccant canisters that help keep your medicine dry. Do not remove the desiccant canisters from the bottle.

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

General information about the safe and effective use of TAVALISSE

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

What are the ingredients in TAVALISSE?

Active ingredient: fostamatinib disodium hexahydrate

Inactive ingredients: The tablet core contains mannitol, sodium bicarbonate, sodium starch glycolate, povidone, and magnesium stearate. The film coating contains polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, iron oxide yellow, and iron oxide red.

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

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