TAVALISSE is an oral medicine that can help you manage chronic immune thrombocytopenia (ITP) by protecting platelets from the immune system.

What is TAVALISSE?

TAVALISSE is a prescription medication used to treat adults with low platelet counts due to chronic ITP when a prior treatment for ITP has not worked well enough. It is not known if TAVALISSE is safe and effective in children.

Please see the Important Safety Information on pages 16–17 and accompanying full Prescribing Information.
I find myself more reluctant about meeting new people because I have so many bruises so often.

— Patient living with chronic ITP

The goal of chronic ITP treatment is to reduce the risk of bleeding.

Chronic ITP can be a serious condition

If not managed properly, chronic ITP can lead to excessive bleeding and other complications.

What is chronic ITP?

Chronic ITP is an autoimmune disease, in which the body’s own immune system attacks and destroys platelets in the blood. Platelets are needed to help create clots and stop bleeding. People with chronic ITP have low platelet counts, which can cause excessive bleeding and other complications.

What happens when you have low platelet counts?

When platelet counts are low, the body is not able to create a clot to stop bleeding. This can lead to bruising, bleeding, and the potential for serious bleeding events. Every person’s body is unique, so your symptoms of chronic ITP may be different.

In general, healthcare providers consider treatment when platelet counts are less than 30,000 per microliter or when patients have low platelet counts and experience symptoms.

A novel approach to treating chronic ITP

TAVALISSE works in a different way than other chronic ITP treatments you may be familiar with.

How is chronic ITP treated?

Current chronic ITP therapies raise platelet counts and reduce the risk of excessive bleeding in one of two ways:

- Some therapies stimulate the bone marrow to make more platelets.
- Some therapies suppress the immune system to slow down platelet destruction, which is the underlying cause of the disease.

SELECTED IMPORTANT SAFETY INFORMATION

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.

Please see the Important Safety Information on pages 16–17 and accompanying full Prescribing Information.

How does TAVALISSE work to treat chronic ITP?

Some therapies stimulate the bone marrow to make more platelets. Some therapies suppress the immune system to slow down platelet destruction, which is the underlying cause of the disease.

TAVALISSE specifically targets spleen tyrosine kinase (SYK), an important part of the pathway that leads to platelet destruction. TAVALISSE works differently than other treatments.

TAVALISSE is the first and only oral treatment to work this way to treat adult chronic ITP.

TAVALISSE limits platelet destruction by the immune system to raise platelet counts in the body and to help reduce the risk of severe bleeding.

TAVALISSE targets a part of the immune pathway that leads to platelet destruction.

Talk to your doctor to see if it’s right for you.

Please see the Important Safety Information on pages 16–17 and accompanying full Prescribing Information.
In a study of 150 adults with chronic ITP, TAVALISSE was compared to placebo (a sugar pill) to see how effective it was in raising platelet counts over 6 months. All study patients had at least one prior treatment, such as steroids, immunoglobulins, rituximab, a thrombopoietin receptor agonist, and/or splenectomy. Patients who benefited from TAVALISSE responded to the drug regardless of prior treatment.

Many patients who had a positive response with TAVALISSE saw an increase in their platelet counts at their first check-in (approximately 2 weeks). Your healthcare provider will monitor your platelet counts and make any necessary adjustments that are right for you.

In an ongoing clinical trial, the duration of response was maintained for over 2 years in more than half of responders.†

A subset of patients, those with a stable response to TAVALISSE, achieved a median platelet count of approximately 97,000 per microliter at the end of the 6-month study. The median starting platelet count for these patients was 16,000 per microliter.

In an ongoing clinical trial, the duration of response was maintained for over 2 years in more than half of responders.†

* Stable response in the clinical trial was defined as a platelet count greater than or equal to 50,000 per microliter for 4 (or more) doctor visits during the last 3 months of the 6-month study.

† Estimate of the median duration of response.

How long should I be taking TAVALISSE?

TAVALISSE is a medicine that you take daily, as prescribed. Your healthcare provider will advise you to keep taking TAVALISSE for as long as it maintains your platelet counts and you respond well to therapy.

ITP is a chronic condition, so it’s important to take TAVALISSE every day to manage your platelet counts, even if you start to feel better. If changes to your dose or medicine are needed, your healthcare provider will discuss this with you.

SELECTED IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TAVALISSE? (cont’d)

TAVALISSE can cause serious side effects including:

- 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.

- Decreases in white blood cell count (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.

Please see the Important Safety Information on pages 16–17 and accompanying full Prescribing Information.
The benefit of an oral medicine
TAVALISSE has no dietary restrictions.

How should I take TAVALISSE?
Available in two dose strengths, 100 mg and 150 mg
Twice-daily oral medicine
Can be taken with or without food

Based on your response to therapy, your healthcare provider will find the right treatment schedule for you. You should take TAVALISSE exactly as your healthcare provider tells you to take it.

How will my healthcare provider monitor my response?
Your healthcare provider will check your platelet count, complete blood count including white blood cell count, liver function tests, and blood pressure during your treatment with TAVALISSE and may change your dose of TAVALISSE as needed.

What else should I know about taking TAVALISSE?
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.

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 store TAVALISSE tablets?
• 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.

Available in two dose strengths, 100 mg and 150 mg
Twice-daily oral medicine
Can be taken with or without food

Please see the Important Safety Information on pages 16-17 and accompanying full Prescribing Information.
What are some ways to help me remember to take my medicine?

It’s important that you take TAVALISSE every day as prescribed by your healthcare provider. Creating a daily routine will help make TAVALISSE a regular part of your lifestyle. Here are some tips to get you started. Find a method that works best for you.

- **Take advantage of technology.** You can set a daily alarm on your cell phone. Or you can use a smartphone to alert you when it’s time to take your medication. Smartphones and other handheld devices can also provide texts, emails, or other reminders to help you keep track of your dosing schedule.

- **Combine with a daily activity.** You can tie taking your medication with a daily routine like brushing your teeth or getting ready for bed.

- **Engage other family members or friends.** There may be others in your circle of support who would be willing to help remind you to take your medication. Identify individuals you know and work out a plan that will work for you.

Please see the Important Safety Information on pages 16–17 and accompanying full Prescribing Information.

SELECTED IMPORTANT SAFETY INFORMATION

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.

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 or how TAVALISSE works.
Understanding potential side effects

Your doctor will explain the potential common and serious side effects associated with TAVALISSE, and provide tips on what to do should you experience them.

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.

• 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.

What are the possible side effects of TAVALISSE?

The most common side effects of TAVALISSE include:

• Nausea
• Rash
• Dizziness
• Tiredness
• Respiratory infection
• 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.

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

Please see the Important Safety Information on pages 16–17 and accompanying full Prescribing Information.

Managing diarrhea

Your healthcare provider may recommend the following:

Stay hydrated. To prevent dehydration, drink fluids throughout the day, such as water, electrolytes, decaffeinated tea, and clear broth. You can even consider popsicles, gelatin, and ice chips to mix things up.

Make changes to your diet. Eat small meals often, and limit high fiber foods (such as nuts or seeds) or spicy or greasy foods.

Take medicine. Some over-the-counter antidiarrheal medicines can help provide relief. Your healthcare provider can help with specific recommendations.

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A dedicated TAVALISSE support team

RIGEL ONECARE can help you start and stay on track with your treatment.

RIGEL ONECARE can help you get off to a smooth start with TAVALISSE by:
- Coordinating with your insurance plan and your healthcare providers to determine coverage
- Determining eligibility and facilitating enrollment in copay and financial assistance programs
- Contacting you to answer questions to prepare you to start taking TAVALISSE
- Working with you through the first several weeks of your treatment to provide any additional support
- Being available Monday–Friday from 8 AM – 8 PM EST to answer your questions

To enroll:
- Visit TAVALISSEcopay.com
- Fill out and submit your information to determine if you are eligible
- Print out the copay card and have it available when speaking with the specialty pharmacy

Enroll in RIGEL ONECARE.

RIGEL ONECARE can help you stay on track with your healthcare provider’s plan by:
- Nursing Navigators
- Reimbursement Specialists
- Financial and Copay Assistance
- Educational Materials

Pay as little as $15 per prescription with TAVALISSE copay assistance

Eligibility and limitations:
Eligible patients may receive TAVALISSE at a $15 copay for each prescription, if they pay through commercial insurance.
- Patients must have a valid prescription for TAVALISSE and commercial insurance
- Patients must be 18 years of age or older
- This offer is not valid for prescriptions reimbursed under Medicare, Medicaid, TriCare or any other federal or state program, or where prohibited by law
- The patient will be responsible for any out-of-pocket expenses after the $15,000 annual cap
- This offer is not insurance and offer is valid only for prescriptions filled in the United States and Puerto Rico
- Not valid for cash-paying patients
- Rigel reserves the right to rescind, revoke, or amend this program without notice
- Other restrictions may apply

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- **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.

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IMPORTANT SAFETY INFORMATION

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A different way to treat adult chronic ITP

Raising platelet counts and keeping them there can be challenging. For adults living with chronic ITP, TAVALISSE might be the treatment that’s right for you.

EARLY RESULTS
Increased platelet counts seen in as early as 2 weeks in many patients

FITS YOUR LIFESTYLE
The benefit of an oral medicine that can be taken with or without food

TARGETED TREATMENT
Works in a different way to limit platelet destruction and raise platelet counts over time

Start managing your chronic ITP today.
Talk to your doctor about starting TAVALISSE.

SELECTED IMPORTANT SAFETY INFORMATION

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