PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a physician's prescription only

Tavalisse 100 mg
Tavalisse 150 mg

Film-coated tablets

The active ingredient and its quantity:
Each film-coated tablet of Tavalisse 100 mg and 150 mg contains: 100 mg and 150 mg of **fostamatinib (as disodium hexahydrate) respectively**

For a list of inactive and allergenic ingredients in the preparation, see section 6 "**Further information**". See also "**Important information about some of the medicine's ingredients**" in section 2.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult the physician or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tavalisse is indicated for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.

Therapeutic group -
The medicine belongs to the group of spleen tyrosine kinase (Syk) inhibitors

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (**fostamatinib**) or to any of the additional ingredients that the medicine contains (see section 6 "**Further information**").

Special warnings regarding use of the medicine
Before treatment with Tavalisse, tell the physician if:

- You suffer from:
  - High blood pressure
  - Liver problems
- You are pregnant or are planning to get pregnant. Tavalisse may cause harm to the fetus.
  - The physician will check if you are pregnant before starting treatment
  - If you are of childbearing age, you must use effective means of contraception during treatment with Tavalisse until at least a month after taking the last dose.
- You are breastfeeding or are planning to breastfeed. Do not breastfeed during treatment with Tavalisse until at least a month after taking the last dose.

During treatment with Tavalisse report to the physician, pharmacist or nurse immediately if one of the following symptoms appears:

- **Blood Pressure** - If there is an increase in blood pressure or if you experience high blood pressure which you never had before treatment.
- **Liver problems** - If your eyes or skin become yellow, or if you develop stomach ache or bloating, swelling in the legs and ankles, itchy skin, unusually dark urine, a stool which is light coloured, charcoal coloured or bloody, chronic fatigue, nausea, loss of appetite.
- **Diarrohea** - This is a common side effect during treatment with Tavalisse and it may be severe. The physician will recommend an appropriate diet, drinking copious amounts of water or pharmacologic treatment in order to limit the symptoms.
- **A drop in the white blood cell count (neutropenia) which may increase the risk of infections, including severe infections.**

Children and adolescents:
Tavalisse is not intended for treating children and adolescents under the age of 18. The preparation has not been tested in these age groups.

Tests and follow-up:
During the course of treatment with the preparation the physician may refer you for testing **blood pressure, liver function and blood cell count**.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist about it, especially if you are taking one of the following preparations:

- Ketoconazole, usually used to treat fungal infections
- Rifampicin, usually used to treat bacterial infections
- Simvastatin and rosuvastatin, usually used to treat high levels of cholesterol
- Digoxin, usually used to treat certain types of heart diseases
- Verapamil, usually used to treat various heart diseases such as high blood pressure

Use of the medicine and food
Tavalisse may be taken with or without food.

Pregnancy, breastfeeding and fertility:
If you are pregnant, think that you may be pregnant or are planning to get pregnant, ask your physician for advice before starting to take Tavalisse.
Pregnancy: The medicine may harm the fetus or cause defects in it. If you are of childbearing age, you must use effective means of contraception during treatment with Tavalisse until at least a month after taking the last dose.
Consult the physician immediately if you get pregnant during treatment.
Breastfeeding: There is no data regarding the presence of fostamatinib and/or its metabolites in breast milk, nor on effects on the nursing baby or on lactation. Due to the risk of severe side effects to a nursing baby, it is advised not to breastfeed during treatment with Tavalisse and for at least 1 month after the last dose.
Fertility: There is no information available on the effect of Tavalisse on fertility. Tavalisse may compromise fertility in women. Consult the physician for advice.

Driving and operating machinery:
Tavalisse is not expected to affect the ability to drive or to operate machines. If you feel dizziness, avoid operating machines or driving.

Important information about some of the medicine's ingredients:
Tavalisse contains sodium.
Tavalisse 100 mg contains 23 mg of sodium in each tablet.
Tavalisse 150 mg contains 34 mg of sodium in each tablet.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation in accordance with the physician's instructions.
You should check with the physician or pharmacist if you are unsure about the dosage or treatment regimen for the preparation.
The dosage and treatment regimen will be determined by the physician only.
The usual starting dose is generally one 100 mg tablet twice a day.
The physician will monitor the blood platelet count and may change the dosage accordingly.
After starting treatment, the physician may increase the dosage to 150 mg twice a day, depending on the tolerance to the medicine and the platelet level.

Do not exceed the recommended dose

Method of administration
Swallow the tablet whole with water.
Crushing/splitting/chewing:
Take the tablet whole. No information is available regarding crushing, splitting or chewing the tablet.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult the physician.

If you stop taking the medicine
Adhere to the treatment regimen as recommended by the physician. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the physician.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Tavalisse may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects - Tavalisse may cause severe side effects.

Consult a physician immediately if you suffer any of the following side effects, either for the first time or if they worsen:

- A sharp increase in blood pressure
- An increase in liver function tests, especially ALT and AST
- Diarrhoea
- A drop in the white blood cell count (neutropenia)

Additional side effects:

Very common side effects (side effects occurring in more than one in 10 patients)

- Diarrohea
- High blood pressure
- Nausea
- Abnormal blood test results for liver function
- Dizziness
- Respiratory tract infections (infections of either the upper or lower respiratory tract, or viral infections of the upper respiratory tract)

Common side effects (side effects occurring in less than one in 10 patients)

- Low white blood cell count (neutropenia)
- Low neutrophil count
- Abdominal pain
- Chest pain
- Fatigue
- Rash

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects Due to Drug Treatment" on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
Do not use the medicine after the expiry date (Exp. Date) that appears on the package/label.
The expiry date refers to the last day of that month.

Storage conditions:
Store at a temperature below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient the medicine also contains:
Mannitol, sodium bicarbonate, sodium starch glycolate, povidone, magnesium stearate
Tablet coating:
Polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, iron oxide yellow, iron oxide red

What the medicine looks like and what the package contains:
Tavalisse 100 mg - a round, curved on both sides tablet with a dark orange film coating. One side is imprinted with "R" and the other with "100"
Tavalisse 150 mg - an oval, curved on both sides tablet with a light orange film coating. One side is imprinted with "R" and the other with "150"
Tavalisse 100 mg and Tavalisse 150 mg are packaged in a bottle containing 60 film-coated tablets. Each bottle includes 2 desiccants.
Do not remove the desiccants from the package.

Registration Holder: Medison Pharma Ltd.,
10 Hashiloach St., POB 7090, Petach Tikva

Manufacturer: Rigel Pharmaceuticals, Inc.,
1180 Veterans Blvd., South San Francisco,
CA 94080 USA

This leaflet was revised in August 2021 according to Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health
Tavalisse 100 mg: 168-04-36449-99
Tavalisse 150 mg: 168-05-36450-99