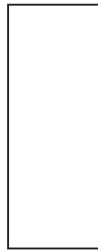


GRIFOLS



Package leaflet: Information for the patient

**TAVLESSE 100 mg
film-coated tablets**

fostamatinib disodium hexahydrate

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▼ 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TAVLESSE is and what it is used for
2. What you need to know before you take TAVLESSE
3. How to take TAVLESSE
4. Possible side effects
5. How to store TAVLESSE
6. Contents of the pack and other information

1. What TAVLESSE is and what it is used for
What TAVLESSE is

TAVLESSE contains the active substance fostamatinib. It specifically targets an enzyme called spleen tyrosine kinase, that plays an important part in the destruction of platelets. In this way TAVLESSE limits platelet destruction by the immune system and increases platelet count in the body. This helps reduce the risk of severe bleeding.

What TAVLESSE is used for

TAVLESSE is used to treat adults with low platelet counts due to chronic immune thrombocytopenia (ITP) when an earlier treatment for ITP has not worked well enough. 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.

2. What you need to know before you take TAVLESSE
Do not take TAVLESSE

- if you are allergic to fostamatinib or any of the other ingredients in this medicine (listed in section 6).
- if you are pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking TAVLESSE, about all of your medical conditions, particularly if you:

- have high blood pressure,
- have liver problems,
- are pregnant or plan to become pregnant,
- are breastfeeding or plan to breastfeed.

Tell your doctor, pharmacist or nurse immediately if you get any of the following symptoms while you are taking this medicine:

- if you have high blood pressure (hypertension). New or worsening high blood pressure is common in people treated with TAVLESSE and can be severe. Your doctor will check your blood pressure regularly during treatment with this medicine. If needed, your doctor may start you on blood pressure medicine or change your current medicine to treat your blood pressure. Tell your doctor or pharmacist if you get headaches, confusion, dizziness, chest pain or shortness of breath.
- if your skin and eyes appear yellowish (jaundice) or if you get abdominal pain and swelling, swelling in your legs and ankles, itchy skin, abnormal dark urine, pale stool colour or bloody or tar-coloured stool, chronic fatigue, feeling or being sick in the stomach, and loss of appetite. Changes in liver function blood tests are common with this medicine. These may be symptoms of liver problems. Liver problems may occur and can be severe. Your doctor will regularly carry out blood tests to check how well your liver is working during treatment with this medicine.
- if you get diarrhoea. This is common in people treated with this medicine and can be severe. Tell your doctor or pharmacist if you get diarrhoea during treatment with this medicine. Your doctor may recommend changes in your diet, drinking more water, or give an anti-diarrhoeal medicine to limit your symptoms.
- if you get a high fever (a sign of serious infection), chills, feel sick, or have a general feeling of being unwell. Your doctor will regularly do blood tests to check your white blood cell counts, and you may be told about a decrease in your white blood cell counts (neutropenia). Decreases in your white blood cell count are common with this medicine and can be severe. This may increase your risk of infection, including serious infections.

Children and adolescents

TAVLESSE should not be used in patients less than 18 years of age. This medicine has not been studied in this age group.

Other medicines and TAVLESSE

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

Taking TAVLESSE with certain other medicines may affect how the other medicines work and other medicines may affect how TAVLESSE works.

In particular, tell your doctor if you are taking anything in this list:

- Ketoconazole, this medicine is typically used to treat fungal infections.
- Rifampicin, this medicine is typically used to treated 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.
- Ranitidine, this medicine is typically used to treat heart burn.
- Ethinylestradiol, this medicine is typically used for birth control.
- Pioglitazone, this medicine is typically used to treat type 2 diabetes.

Pregnancy, breast-feeding and fertility
Pregnancy

TAVLESSE should not be used during pregnancy. It can cause harm or birth defects to your unborn baby.

If you are pregnant, if think you may be pregnant or if you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are a woman who could become pregnant, you must use reliable contraception while you are taking TAVLESSE, and you must continue to use reliable contraception for at least 1 month after taking your last dose.

Contact your doctor straight away if you become pregnant while taking this medicine.

Breast-feeding

TAVLESSE is not recommended while breast-feeding. You should not breastfeed during treatment with TAVLESSE and for at least 1 month after your last dose.

If you are breast-feeding, or are planning to breast-feed, ask your doctor or pharmacist for advice before taking this medicine.

Fertility

TAVLESSE may affect the ability of a woman to get pregnant and have a child. Talk to your doctor if this is a concern for you. There is no impact on males.

TAVLESSE contains sodium

TAVLESSE 100 mg film-coated tablets contains 23 mg sodium (main component of cooking/table salt) per tablet. This is equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take TAVLESSE
How much to take

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment, your doctor will measure your platelet count.

The recommended dose of TAVLESSE is 100 mg twice daily (one tablet of 100 mg).

However, your doctor will check your platelet counts during your treatment with TAVLESSE and may change your dose as needed.

After starting treatment with TAVLESSE, the dose can be increased to 150 mg twice daily (one tablet of 150 mg) based on platelet count and tolerability. A daily dose of 300 mg (two tablets of 150 mg) daily must not be exceeded.

If you do not respond to treatment with fostamatinib, your doctor will stop treatment.

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

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

How to take TAVLESSE

Swallow the tablets whole with water.

TAVLESSE can be taken with food or between meals.

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

If you are sick

If you are sick at any time after taking TAVLESSE, do not take an additional tablet. Take your next dose at its regularly scheduled time.

If you take more TAVLESSE than you should

If you take too much TAVLESSE, call your doctor or pharmacist right away or go to the nearest hospital emergency room.

If you forget to take TAVLESSE

Do not take a double dose to make up for a forgotten tablet. Take your next dose at its regularly scheduled time.

If you stop taking TAVLESSE

It is important to take TAVLESSE for as long as your doctor prescribes it. Do not stop taking this medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

TAVLESSE may cause serious side effects. Tell your doctor immediately if you have any of the following serious side effects, either for the first time or if they get worse (see also section 2):

- high fever. Fever has been associated with low levels of white blood cells (febrile neutropenia) or infection
- diarrhoea
- infection and inflammation of the lungs (pneumonia). Symptoms include feeling short of breath, chest pain and producing discoloured mucus
- jaundice, abdominal pain and swelling, swelling in your legs and ankles, itchy skin, abnormal dark urine, pale stool colour or bloody or tar-coloured stool, chronic fatigue, feeling or being sick in the stomach, loss of appetite. These may be symptoms of liver problems.
- severe increase of blood pressure that can lead to a stroke (hypertensive crisis). Symptoms are headache, confusion, dizziness.

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22/11/2021

Color references



Black

Background

White

Size | Structure (mm)

210 x 480

VIES

layouts & mockups

480 mm

Other side effects

Besides the serious side effects mentioned above, you may also get other side effects.

Very common (may affect more than 1 in 10 people):

- gastrointestinal disorders such as diarrhoea, feeling or being sick in the stomach, and frequent bowel movement
- high blood pressure
- abnormal blood test results showing how your liver is working
- dizziness

Common (may affect up to 1 in 10 people):

- low white blood cell count or neutropenia
- stomach pain
- chest pain
- tiredness (fatigue)
- flu-like symptoms
- infections of the nose and throat, such as sore throat and the common cold
- infection of the windpipe, such as bronchitis
- taste changes
- rash
- headache

Reporting of side effects

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist. You can also report side effects directly via:

Ireland:

HPRA Pharmacovigilance, Website: www.hpra.ie

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 TAVLESSE

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original package to protect from moisture. Keep the bottle tightly closed.

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.

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.

6. Contents of the pack and other information**What TAVLESSE contains**

- The active substance is fostamatinib disodium hexahydrate. TAVLESSE 100 mg film-coated tablets
- The other ingredients are:
 - Mannitol, sodium hydrogen carbonate, sodium starch glycolate (type A), povidone (K30), magnesium stearate
 - Film-coating: poly(vinyl alcohol), titanium dioxide, macrogol (3350), talc, iron oxide yellow, iron oxide red

What TAVLESSE looks like and contents of the packTAVLESSE 100 mg film-coated tablets

The tablet is round, curved on both sides with a dark orange film coat.

The commercial tablets are debossed with "R" on one side and "100" on the reverse side.

Available in bottle of 30 and 60 film-coated tablets. Each bottle has 2 desiccants.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Instituto Grifols, S.A.
Can Guasc, 2 - Parets del Vallès
08150 Barcelona - Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

IE / UK(NI)

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This leaflet was last revised in 08/2021.

Detailed information on this medicine is available on the European Medicines Agency web site:

<https://www.ema.europa.eu/en>