

## Patient information

# Fostamatinib for Refractory Chronic Immune Thrombocytopenic Purpura

## Clinical Haematology

### What is Refractory Chronic Immune Thrombocytopenic Purpura (ITP)?

Immune thrombocytopenic purpura (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. ITP is called chronic when it persists for more than 12 months. Refractory chronic ITP is where alternative treatments such as steroids, TPO-RAs and other immunosuppressants have been unable to control the disease.

### What is fostamatinib?

Fostamatinib is a medication that is taken orally. It specifically targets an enzyme called spleen tyrosine kinase, that plays an important part in the destruction of platelets. In this way fostamatinib limits platelet destruction by the immune system and increases platelet count in the body. This helps reduce the risk of severe bleeding. This is a novel mode of action.

### Who should not take fostamatinib?

- If you are allergic to fostamatinib or any of the other ingredients in this medicine.
- If you are pregnant.

### Warnings and precautions

Talk to your doctor or pharmacist before taking fostamatinib, 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.

### Side effects

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

## Serious side effects

Fostamatinib may cause serious side effects. Tell your doctor, nurse or pharmacist immediately if you have any of the following serious side effects, either for the first time or if they get worse:

- If you have high blood pressure (hypertension). New or worsening high blood pressure is common in people treated with fostamatinib 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 antidiarrhoeal 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.

## Other side effects

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

<b>Very common (may affect more than 1 in 10 people):</b>	<b>Common (may affect up to 1 in 10 people):</b>
Gastrointestinal disorders such as diarrhoea, feeling or being sick in the stomach, and frequent bowel movements	Low white blood cell count or neutropenia
	Stomach pain
	Chest pain
	Tiredness (fatigue)
High blood pressure	Flu-like symptoms
	Infections of the nose and throat, such as sore throat and the common cold
Abnormal blood test results showing how your liver is working	Infection of the windpipe, such as bronchitis
	Taste changes
Dizziness	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](http://www.hpra.ie) United Kingdom: Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://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.

## **Other medicines and fostamatinib**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking fostamatinib with certain other medicines may affect how the other medicines work and other medicines may affect how fostamatinib 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**

Fostamatinib 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 fostamatinib, and you must continue to use reliable contraception for at least one month after taking your last dose. Contact your doctor straight away if you become pregnant while taking this medicine.

## **Breast-feeding**

Fostamatinib is not recommended while breast-feeding. You should not breastfeed during treatment with fostamatinib and for at least one 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**

Fostamatinib 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.

## **How to take fostamatinib**

### **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 fostamatinib is 100 mg twice daily (one tablet of 100 mg). However, your doctor will check your platelet counts during your treatment with fostamatinib and may change your dose as needed.

After starting treatment with fostamatinib, 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 fostamatinib**

Swallow the tablets whole with water. Fostamatinib can be taken with food or between meals. In case of stomach upset, take the tablets with food.

### **Missed doses**

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

If you are sick at any time after taking fostamatinib, do not take an additional tablet. Take your next dose at its regularly scheduled time. If you take more fostamatinib than you should If you take too much fostamatinib, call your doctor or pharmacist right away or go to the nearest hospital emergency room.

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.

## Feedback

Your feedback is important to us and helps us influence care in the future.

Following your discharge from hospital or attendance at your Outpatient appointment you will receive a text asking if you would recommend our service to others. Please take the time to text back, you will not be charged for the text and can opt out at any point. Your co-operation is greatly appreciated.

## Further information

**If you have any questions or queries please contact Haematology  
Liverpool on Tel: 0151 706 3397**

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