Package leaflet: Information for the patient

Xospata 40 mg film-coated tablets
gilteritinib

▼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 Xospata is and what it is used for

What Xospata is
Xospata belongs to a class of cancer medicines called protein kinase inhibitors. It contains the active substance gilteritinib.

What Xospata is used for
Xospata is used to treat adults with acute myeloid leukaemia (AML), a cancer of certain white blood cells. Xospata is used if AML is linked to an alteration of a gene called FLT3, and is given to patients whose disease has come back or has not improved after previous treatment.

How Xospata works
In AML, patients develop large numbers of abnormal white blood cells. Gilteritinib blocks the action of certain enzymes (kinases) needed for the abnormal cells to multiply and grow, thus preventing the growth of the cancer.

2. What you need to know before you take Xospata

Do not take Xospata
- if you are allergic to gilteritinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to you doctor, pharmacist or nurse straight away:
- if you have any of the following symptoms: fever, trouble breathing, rash, dizziness or lightheadedness, rapid weight gain, swelling of your arms or legs. These may be signs of a condition called differentiation syndrome (see section 4 – Possible side effects). Differentiation syndrome can happen any time during the first 3 months of Xospata treatment from as early as 1

day after starting treatment. If it occurs, your doctor will monitor you and may give you a medicine to treat your condition. She or he may also pause Xospata treatment until symptoms are reduced. You will also find this information in the Patient Alert Card that is included in the packaging. It is important that you keep this Alert Card with you and show it to any healthcare professional you see.
- if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, blurred vision or other problems with seeing. These may be signs of a condition called PRES (see section 4. – Possible side effects). Your doctor may do a test to check if you have developed PRES and will stop Xospata treatment if it is confirmed that you have PRES.

Talk to your doctor, pharmacist or nurse before taking Xospata:
- if you have a heart rhythm disorder, such as an irregular heartbeat or a condition called QT prolongation (see section 4. – Possible side effects).
- if you have a history of low levels of the salts potassium or magnesium in your blood, as this may increase the risk of an abnormal heart rhythm.
- if you have severe pain in the upper abdomen and back, nausea and vomiting. These may be signs of an inflammation of the pancreas (pancreatitis).

Additional monitoring during treatment with Xospata
Your doctor will carry out regular blood tests before and during treatment with Xospata. Your doctor will also regularly check your heart function before and during treatment.

Children and adolescents
Do not give Xospata to children and adolescents under 18 years because it is not known whether it is safe and effective in this age group.

Other medicines and Xospata
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. Xospata may affect the way these medicines work, or these medicines may affect how Xospata works.

In particular, tell your doctor, pharmacist or nurse if you are taking any of the following medicines:
- medicines used to treat tuberculosis, such as rifampicin;
- medicines used to treat epilepsy, such as phenytoin;
- medicines used to treat fungal infections such as voriconazole, posaconazole or itraconazole;
- medicines used to treat bacterial infections such as erythromycin, clarithromycin or azithromycin;
- medicines used to treat high blood pressure (hypertension) such as captopril or carvedilol;
- medicines used to treat infections with the human immunodeficiency virus (HIV) such as ritonavir;
- medicines used to treat depression such as escitalopram, fluoxetine or sertraline;
- medicines used to treat heart problems, such as digoxin;
- medicines used to prevent blood clots, such as dabigatran etexilate;
- St. John’s wort (also known as Hypericum perforatum), a herbal medicine used to treat depression.

If you normally take any of these medicines, your doctor might change it and prescribe a different medicine for you during your treatment with Xospata.

Pregnancy and breast-feeding
Xospata may harm your unborn baby and should not be used during pregnancy. Women taking Xospata who are able to become pregnant should use an effective method of contraception during treatment with Xospata and for at least 6 months after stopping Xospata. If you use a hormonal contraceptive, you must also use a barrier method, such as a condom or a diaphragm. Men taking Xospata whose partners are able to become pregnant should use an effective method of contraception during treatment with Xospata and for at least 4 months after stopping the treatment.

It is not known if Xospata passes into your breast milk and could harm your baby. You should not breast-feed during treatment with Xospata and for at least 2 months after stopping the treatment.

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

Driving and using machines
You may feel dizzy after taking Xospata. If this happens, do not drive or use machines.

3. How to take Xospata

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

Xospata is taken by mouth as tablets.

Your doctor will tell you what dose of Xospata to take. The recommended dose is 120 mg (three tablets) once a day. Your doctor may decide to increase or lower your dose or temporarily interrupt treatment. Continue treatment at the dose prescribed by your doctor.

Taking Xospata
- Take Xospata once a day at the same time each day.
- Swallow the tablets whole with water.
- Do not break or crush the tablets.
- Xospata can be taken with or without food.
- Continue taking Xospata for as long as your doctor tells you.

If you take more Xospata than you should
If you take more tablets than you should, stop taking Xospata and contact your doctor.

If you forget to take Xospata
If you forget to take Xospata at the usual time, take your usual dose as soon as you remember on the same day and take your next dose at the usual time on the following day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Xospata
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.

4. Possible side effects

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

Some possible side effects may be serious:
- **Differentiation syndrome.** Contact your doctor straight away if you have any of the following symptoms: fever, trouble breathing, rash, dizziness or lightheadedness, rapid weight gain, swelling of your arms or legs. These may be signs of a condition called differentiation syndrome (may affect up to 1 in 10 people).
- **Posterior reversible encephalopathy syndrome (PRES).** Contact your doctor straight away if you have a seizure, quickly worsening headache, confusion, or other vision problems. There have been uncommon reports of a condition involving the brain, in patients treated with Xospata, called PRES (may affect up to 1 in 100 people).
- **Heart rhythm problems (QT prolongation).** Contact your doctor straight away if you have a change in your heartbeat, or if you feel dizzy, lightheaded, or faint. Xospata may cause a heart problem called QT prolongation (may affect up to 1 in 10 people).

Other possible side effects

Very common (may affect more than 1 in 10 people):
- diarrhoea
- nausea
- constipation
- tiredness
- swelling due to fluid retention (oedema)
- loss of energy, weakness (asthenia)
- abnormal blood test results: high levels of blood creatine phosphokinase (indicative of muscle or heart function), alanine aminotransferase (ALT), aspartate aminotransferase (AST) and/or blood alkaline phosphatase (indicative of liver function)
- pain in limbs
- joint pain (arthralgia)
- muscle pain (myalgia)
- cough
- shortness of breath (dyspnoea)
- dizziness
- low blood pressure (hypotension)

Common (may affect up to 1 in 10 people):
- collection of fluid around the heart, which, if severe, can decrease the heart's ability to pump blood (pericardial effusion)
- a vague feeling of discomfort, feeling unwell (malaise)
- a severe life-threatening allergic reaction, e.g., swelling in the mouth, tongue, face and throat, itching, hives (anaphylactic reaction)
- muscle stiffness
- passing less urine, swelling in the legs (signs of sudden kidney injury)
- inflammation of the heart (pericarditis)
- heart failure

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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5. How to store Xospata
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

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 Xospata contains
- The active substance is gilteritinib. Each film-coated tablet contains 40 mg gilteritinib (as fumarate).
- The other ingredients are: mannitol (E421), hydroxypropylcellulose, low-substituted hydroxypropylcellulose, magnesium stearate, hypromellose, talc, macrogol, titanium dioxide, iron oxide yellow (E172).

What Xospata looks like and contents of the pack
Xospata 40 mg film-coated tablets are round, light yellow film-coated tablets with the company logo and '235' debossed on one side of the tablet.

The tablets are provided in blisters and are available in packs containing 84 film-coated tablets (4-blisters of 21 film-coated tablets).

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu