

XOSPATA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using XOSPATA?

XOSPATA contains gilteritinib, a protein kinase inhibitor, which is used to treat adults with acute myeloid leukaemia (AML) who have a defect in a gene called FLT3 when the disease has come back or has not improved after previous treatment(s).

For more information, see Section [1. Why am I using XOSPATA?](#) in the full CMI.

2. What should I know before I use XOSPATA?

Do not use if you have ever had an allergic reaction to XOSPATA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use XOSPATA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XOSPATA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use XOSPATA?

- The usual dose is three 40 mg film-coated tablets (120 mg) taken at the same time once a day.
- Your doctor may decide to increase or lower your dose or temporarily interrupt treatment depending on your medical conditions.

More instructions can be found in Section [4. How do I use XOSPATA?](#) in the full CMI.

5. What should I know while using XOSPATA?

Things you should do	<ul style="list-style-type: none">• If you are about to be started on any new medicine, remind your doctor, dentist and pharmacist that you are taking XOSPATA.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not take XOSPATA to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.• Do not stop taking your medicine or alter the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how XOSPATA affects you.• XOSPATA may have a moderate effect on your ability to drive or use any tools or machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them and keep it where children cannot reach it.• Keep your tablets in the original packaging in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking XOSPATA?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). Some of the serious side effects may include: fever, trouble breathing, rash, dizziness or lightheadedness, rapid weight gain, swelling of your arms or legs; seizure, worsening headache, confusion, blindness or other vision problems; have a change in your heartbeat, or feeling dizzy, lightheaded, or faint.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

XOSPATA®

Active ingredient(s): gilteritinib (as fumarate)

Consumer Medicine Information (CMI)

This leaflet answers some common questions about XOSPATA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking XOSPATA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I using XOSPATA?](#)
- [2. What should I know before I use XOSPATA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use XOSPATA?](#)
- [5. What should I know while taking XOSPATA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using XOSPATA?

XOSPATA contains gilteritinib, a protein kinase inhibitor, which is used to treat adults with acute myeloid leukaemia (AML) who have a defect in a gene called FLT3 when the disease has come back or has not improved after previous treatment(s).

AML is a form of cancer of certain white blood cells (called myeloid cells). This medicine works by blocking the action of certain enzymes (kinases) in the abnormal cells. By blocking kinases, XOSPATA stops the cancer cells from growing and dividing.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

XOSPATA is not for use in children and adolescents.

Safety and effectiveness in children and adolescents have not been established.

2. What should I know before I use XOSPATA?

Warnings

When you must not take it

Do not take XOSPATA if you have an allergy to:

- any medicine containing gilteritinib
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

If you are not sure whether you should start taking this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section

Pregnancy and breastfeeding

XOSPATA is not for use during pregnancy.

This medicine may harm your unborn baby and should not be used during pregnancy. Use an effective method of contraception during treatment with XOSPATA and for at least 6 months after stopping the treatment. Males who have female partners that are able to become pregnant should use an effective method of contraception during treatment of XOSPATA and for at least 4 months after stopping the treatment.

You should not breast-feed during treatment with XOSPATA.

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.

Talk with your doctor if you have questions about birth control. Your doctor can discuss with you the risks and benefits involved.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a heart rhythm disorder, such as an irregular heartbeat or a condition called long QT syndrome
- a history of low levels of 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
- severe pain in the upper abdomen and back, nausea and vomiting. These may be signs of an inflammation of the pancreas (pancreatitis)

Your doctor will perform regular blood tests before and during treatment with XOSPATA. Your doctor will also regularly check your heart function before and during treatment.

If you have not told your doctor about any of the above, tell him/her before you start taking XOSPATA.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and XOSPATA may interfere with each other. These include certain medicines used to:

- treat tuberculosis (e.g. rifampicin)
- treat epilepsy (e.g. phenytoin)
- treat depression (e.g. escitalopram, fluoxetine, sertraline or the herbal medicine St. John's Wort (also known as Hypericum perforatum))
- treat fungal infections (e.g. voriconazole, posaconazole or itraconazole)
- treat bacterial infections (e.g. erythromycin, clarithromycin or azithromycin)
- treat high blood pressure (hypertension) (e.g. captopril or carvedilol)
- treat infections with the human immunodeficiency virus (HIV) (e.g. ritonavir)
- treat heart problems (e.g. digoxin)
- treat blood clots (e.g. dabigatran etexilate)

These medicines may be affected by XOSPATA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How do I use XOSPATA?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is three 40 mg film-coated tablets (120 mg) taken at the same time once a day. Your doctor may decide to increase or lower your dose or temporarily interrupt treatment depending on your medical conditions. Continue treatment at the dose prescribed by your doctor.

How to take it

Swallow the tablets whole with a full glass of water. Do not break or crush the tablets before swallowing.

You can take XOSPATA with or without food.

When to take XOSPATA

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

It is important to keep taking your medicine even if you feel well.

Do not stop treatment with XOSPATA unless your doctor tells you to.

If you forget to take XOSPATA

Take it as soon as you remember, and then go back to taking your medicine as you would normally.

If you forget to take XOSPATA for the whole day, take your usual dose the following day.

If you forget to take XOSPATA for more than one day, talk to your doctor immediately.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much XOSPATA

If you think that you have used too much XOSPATA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or contact your doctor, or go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking XOSPATA?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking XOSPATA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you or your partner becomes pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do

Do not take XOSPATA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or alter the dosage without checking with your doctor.

Driving or using machines

Do not drive or operate machinery until you know how XOSPATA affects you.

XOSPATA may have a moderate effect on your ability to drive or use any tools or machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep your tablets in the pack until it is time to take them.

Keep your tablets in the original packaging in a cool dry place where the temperature stays below 25°C.

Do not store XOSPATA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine (as relevant)

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Do not throw away any medicines via wastewater or household waste.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">diarrhoeanauseaconstipationtirednessswelling due to fluid retention (oedema)loss of energy, weakness (asthenia)abnormal blood test results which can indicate to your doctor how well certain parts of your body are functioning: high levels of blood creatine phosphokinase (indicative	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<p>of muscle or heart function), alanine aminotransferase (ALT), aspartate aminotransferase (AST) and/or blood alkaline phosphatase (indicative of liver function)</p> <ul style="list-style-type: none">pain in limbsjoint pain (arthralgia)muscle pain (myalgia)coughshortness of breath (dyspnoea)dizzinesslow blood pressure (hypotension)a vague feeling of discomfort, feeling unwell (malaise)muscle stiffness	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">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). Differentiation syndrome can happen as early as 1 day after starting XOSPATA treatment and during the first 3 months of treatment. Your doctor may monitor you and give you a medicine to treat your condition. Your doctor may pause XOSPATA treatment until symptoms have been reduced.Posterior Reversible Encephalopathy Syndrome (PRES) There have been uncommon reports of PRES, a rare, reversible condition involving the brain, in patients treated with XOSPATA (may affect up to 1 in 100 people). If you have a seizure, worsening headache, confusion, blindness or other vision problems, please contact your doctor as soon as possible.Heart rhythm problems (QT prolongation) XOSPATA may cause a heart problem called QT prolongation (may affect up to 1 in 10 people). Contact your doctor straight away if you have a change in your heartbeat, or if you feel dizzy, lightheaded, or faint.<ul style="list-style-type: none">collection of fluid around the heart, which, if severe, can decrease the heart's ability to pump blood (pericardial effusion)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul style="list-style-type: none"> • a severe life-threatening allergic reaction, e.g., swelling in the mouth, tongue, face and throat, itching, hives (anaphylactic reaction) • inflammation of the heart (pericarditis) • heart failure (cardiac failure) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What XOSPATA contains

Active ingredient (main ingredient)	XOSPATA contains 40 mg of gilteritinib as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • mannitol • hypromellose • magnesium stearate • hypromellose • purified talc • macrogol 8000 • titanium dioxide • iron oxide yellow

Do not take this medicine if you are allergic to any of these ingredients.

What XOSPATA looks like

XOSPATA 40 mg film-coated tablets (AUST R 321060) are round, light yellow film-coated tablets with the company logo and '235' debossed on one side of the tablet.

XOSPATA is available in packs of 84 tablets (in 4 blisters of 21 tablets each).

Who distributes XOSPATA

XOSPATA is supplied in Australia by:

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park NSW 2113

Tel (Medical Information):

1800 751 755

Website:

www.astellas.com/au

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This leaflet was prepared in September 2022.