

Package leaflet: Information for the user

Telzir 700 mg film-coated tablets

Fosamprenavir

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

What is in this leaflet

1. **What Telzir is and what it is used for**
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1. What Telzir is and what it is used for

Telzir is used to treat HIV (human immunodeficiency virus) infection.

Telzir is a type of medicine known as an anti-retroviral. It is taken with low doses of another medicine, ritonavir, which boosts the level of Telzir in the blood. Telzir belongs to a group of anti-retroviral medicines called *protease inhibitors*. Protease is an enzyme produced by HIV which enables the virus to multiply in white blood cells (*CD4 cells*) in your blood. By stopping protease from working, Telzir stops HIV multiplying and infecting more CD4 cells.

Telzir with low doses of ritonavir is used in combination with other anti-retroviral medicines ('combination therapy') to treat adults, adolescents and children aged over 6 years infected with HIV.

HIV can become resistant to anti-HIV medicines. To avoid this happening, and to stop your illness getting worse, it is very important that you keep taking all your medicines exactly as prescribed.

Telzir will not stop you passing on HIV. HIV infection is spread by sexual contact with someone who's got the infection, or by transfer of infected blood (for example by sharing needles).

2. What you need to know before you take Telzir

Telzir is to be taken in combination with low doses of ritonavir and other antiretroviral medicines. It is therefore important that you carefully read the package leaflet provided with these medicines. If you have any further questions about ritonavir or the other medicines prescribed, please ask your doctor or pharmacist.

Do not take Telzir:

- **if you are allergic** to fosamprenavir, amprenavir or any of the other ingredients of this medicine (listed in section 6), or to ritonavir.
- **if you are taking any of these medicines:**

- alfuzosin (used to treat **a prostate problem**)
- astemizole or terfenadine (commonly used to treat **allergy** symptoms – these medicines may be available without prescription)
- pimozide (used to treat **schizophrenia**)
- quetiapine (used to treat **schizophrenia, bipolar disorder and major depressive disorder**)
- lurasidone (used to treat **schizophrenia and bipolar disorder**)
- cisapride (used to relieve **indigestion**)
- ergot derivatives (used to treat **headaches**)
- rifampicin (used to treat **tuberculosis**)
- amiodarone, quinidine, flecainide and propafenone (**heart medicines**)
- bepridil (used to treat **high blood pressure**)
- oral midazolam or oral triazolam (used to treat **anxiety**)
- products containing St John's wort (*Hypericum perforatum*)
- lovastatin, simvastatin (used to lower **cholesterol**)
- sildenafil if used to treat **pulmonary arterial hypertension**, (a condition affecting the blood vessels to your lungs)
- paritaprevir (used to treat hepatitis C virus infection)

→Tell your doctor if any of these applies to you.

Take special care with Telzir

Talk to your doctor or pharmacist before taking Telzir:

- **If you have a known allergy to medicines containing sulphonamide.** You may also be allergic to Telzir.
- **If you have liver disease.** Your doctor may lower your dose of Telzir and ritonavir depending on the amount of liver damage. You will be monitored while you are taking Telzir. If your liver disease gets worse, you may need to stop taking Telzir for a while, or permanently. People with hepatitis B or C taking combination therapy are at increased risk of getting severe liver problems.
- **If you have haemophilia.** Increased bleeding may occur while taking protease inhibitors (such as Telzir). The reason for this is not known. You may need additional factor VIII to control any bleeding.
- **If you have diabetes.** In some patients taking antiretroviral medicines including protease inhibitors, there have been reports of increased sugar in the blood and diabetes getting worse. Also, some people have become diabetic while taking these medicines.
- If you are taking any other medicines. See section 'Other medicines and Telzir'.

→Tell your doctor if any of these apply to you. You will need extra check-ups, including blood tests, while you're taking your medication.

Your doctor will monitor your blood glucose levels before and during treatment with Telzir.

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:

- Flare up of old infections
- Change in your body shape
- Problems with your bones.

You need to know about important signs and symptoms to look out for while you're taking Telzir.

Please read the information on 'Other side effects of combination therapy for HIV' in section 4 of this leaflet. If you have any questions about this information or the advice given:

→Talk to your doctor.

You may get a skin rash. However you can still continue to take Telzir. It can be treated with antihistamines. Rarely, the skin rash can be severe and serious (*Stevens Johnson syndrome*). If this happens, Telzir must be stopped immediately and you must never take it again.

Other medicines and Telzir

Tell your doctor or pharmacist if you're taking or have recently taken any other medicines – these include herbal medicines or other medicines you bought without a prescription. Your doctor will decide if these medicines are suitable for you to take with Telzir and ritonavir. This is **very important**, as Telzir or ritonavir can strengthen or weaken the effects of other medicines. This can sometimes lead to serious medical conditions.

There are some medicines that must not be taken with Telzir. You must check the list of medicines under 'Don't take Telzir' at the beginning of section 2 of this leaflet.

These medicines are not recommended with Telzir/ritonavir:

- doses of ketoconazole and itraconazole greater than 200 mg per day (used to treat **fungal infections**)
- doses of rifabutin greater than 150 mg every other day (an **antibiotic**)
- lidocaine given by injection
- halofantrine (used to treat **malaria**)
- sildenafil, vardenafil or tadalafil (used to treat **erectile dysfunction**)
- doses of atorvastatin greater than 20 mg per day (used to lower **cholesterol**)
- fluticasone propionate and similar medicines used to treat **asthma**, unless considered essential. In this case close monitoring is required.
- lopinavir/ritonavir combination (used to treat **HIV infection**)
- raltegravir (used to treat **HIV infection**)
- , , simeprevir, daclatasvir (used to treat **hepatitis C virus infection**)
- maraviroc (used to treat **HIV infection**)

You will be closely monitored if you are taking these medicines with Telzir/ritonavir:

- atorvastatin up to 20 mg per day (used to lower **cholesterol**)
- carbamazepine, phenobarbital, phenytoin (used to treat **epilepsy**)
- cyclosporin, rapamycin, tacrolimus (used to suppress the **immune system**)
- dolutegravir (used to treat **HIV infection**)
- desipramine, nortriptyline, paroxetine and similar medicines (used to treat **depression**)
- warfarin and other medicines that **stop blood clotting**
- injectable midazolam (used to treat **anxiety**)
- clarithromycin, erythromycin (an **antibiotic**)
- methadone (a **heroin substitute**)
- dasatinib, nilotinib, ibrutinib, vinblastine and everolimus (used to treat **several types of cancer**)

Your dose of Telzir may need to be changed if you are taking

- etravirine (used to treat **HIV infection**)

Hormonal contraception

Taking Telzir and ritonavir while taking the contraceptive pill may harm your liver and may stop the contraceptive from working properly.

→ **Use an alternative non-hormonal type of contraception such as a condom.**

No studies have been done on the use of Telzir/ritonavir with other hormonal therapies, such as hormone replacement therapy (HRT).

Pregnancy

If you are pregnant, think you may be pregnant, or are planning to have a baby:

→ **Ask your doctor or pharmacist for advice before** taking this medicine.

Breast-feeding

Breast-feeding is **not recommended** in women living with **HIV** because HIV infection can be passed on to the baby in breast milk. It is not known whether the ingredients in Telzir can also pass into your breast milk. If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines

Telzir can make you feel dizzy and have other side effects that make you less alert.

→ **Don't drive or operate machinery** unless you're feeling well.

Stay in regular contact with your doctor

Telzir helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

→ **Keep in touch with your doctor**, and **don't stop taking Telzir** without your doctor's advice.

Telzir contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Telzir

Always take this medicine exactly as your doctor or pharmacist has told you. It is very important that you take the **full** daily dose of Telzir and ritonavir as prescribed by your doctor. **Do not take more** than the recommended dose. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole, with some water or another drink. Telzir tablets can be taken with or without food. Telzir is also available as a liquid (oral suspension) for people who are unable to swallow tablets. (Read the package leaflet of Telzir oral suspension for guidance on whether to take it with or without food.)

Adults

The recommended dose is **one 700 mg Telzir tablet twice daily** with 100 mg ritonavir twice daily.

Children from 6 years of age and weighing at least 39 kg

Children can take the adult tablet dose of **one 700 mg Telzir tablet twice daily** with ritonavir 100 mg twice daily if they can swallow the tablets whole.

Children from 6 years of age and weighing less than 39 kg

Use Telzir oral suspension.

Adults with liver disease

If you have mild liver disease, the dose is **one Telzir tablet (700 mg) twice daily** with 100 mg ritonavir **only once daily**. If you have moderate or severe liver disease the dose of Telzir has to be lowered. This dose adjustment cannot be made with Telzir tablets. You must take Telzir oral suspension.

If you take too much Telzir

If you have taken more than the prescribed dose of Telzir:

→ **Contact your doctor or pharmacist immediately for advice.**

If you forget to take Telzir

If you forget to take a dose of Telzir, take it as soon as you remember and then continue your treatment as before. **Don't take a double dose to make up for a missed dose.**

Don't stop Telzir without advice

Take Telzir for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, but not everyone gets them. When treating HIV, it can be hard to tell whether side effects are caused by Telzir, by other medicines taken at the same time or by the HIV disease itself. For this reason, it is very important to **talk to your doctor about any changes in your health.**

Very common side effects

These may affect **more than 1 in 10 people**:

- Diarrhoea
- Increase in *cholesterol* (a type of blood fat).

Common side effects

These may affect **up to 1 in 10 people**:

- Increases in *triglycerides* (a type of blood fat).
- Feeling sick or being sick (*nausea or vomiting*), pain in the stomach, loose stools
- Skin rashes (red, raised or itchy) – if the skin rash is severe, you may have to stop taking this medicine
- Headache, feeling dizzy
- Feeling tired
- Increases in enzymes produced by the liver called *transaminases*, increases of an enzyme produced by the pancreas called *lipase*.
- Tingling or numbness around the lips and mouth.

Uncommon side effects

These may affect **up to 1 in 100 people**:

- Swelling of the face, lips and tongue (*angioedema*).

Rare side effects

These may affect **up to 1 in 1000 people**:

- A severe or life-threatening skin reaction (*Stevens Johnson syndrome*).

You may experience muscle problems

There have been reports of muscle pain, tenderness or weakness, particularly with antiretroviral therapy including protease inhibitors and nucleoside analogues. On rare occasions, these muscle disorders have been serious (*rhabdomyolysis*). If you notice any muscle problems:

→**Tell your doctor.**

Haemophiliacs may bleed more

In patients with **haemophilia type A and B**, there have been reports of increased bleeding while taking protease inhibitors.

If this happens to you:

→**Talk to your doctor immediately.**

If you get any side effects

→**Talk to your doctor or pharmacist. This includes any possible side effects** not listed in this leaflet.

Other side effects of combination therapy for HIV

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

If you get any symptoms of infection or signs of inflammation while you're taking Telzir:

→**Tell your doctor immediately. Don't take other medicines for the infection** without your doctor's advice.

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the bone.

People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs to look out for include:

- **stiffness in the joints**
- **aches and pains** (especially in the hip, knee or shoulder)
- **difficulty moving.**

If you notice any of these symptoms:

→**Tell your doctor.**

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 via the 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 Telzir

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 bottle.

Telzir does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Telzir contains

- **The active substance is fosamprenavir.** Each tablet contains 700 mg of fosamprenavir as fosamprenavir calcium (equivalent to approximately 600 mg amprenavir).
- The other ingredients are: microcrystalline cellulose, croscarmellose sodium, povidone K30, magnesium stearate, colloidal anhydrous silica, hypromellose, titanium dioxide (E171), glycerol triacetate, iron oxide red (E172).

What Telzir looks like and contents of the pack

Telzir is supplied in plastic bottles containing 60 film-coated tablets. The tablets are capsule shaped, biconvex, pink coloured and marked with ‘GXLL7’ on one side.

Telzir is also available as an oral suspension for those patients unable to swallow the tablets.

Marketing Authorisation Holder and Manufacturer

Manufacturer

Glaxo Wellcome S.A.
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Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Telzir 700 mg film-coated tablets
Reference number 35728/0043

This is a service provided by the Royal National Institute of Blind People.

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