

TELZIR TABLETS and ORAL SUSPENSION PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

TELZIR TABLETS

(700 mg fosamprenavir)

TELZIR ORAL SUSPENSION

(50 mg/ml fosamprenavir)

Read all of this leaflet carefully before you start taking TELZIR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other health care provider.
- TELZIR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

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 antiretroviral. TELZIR belongs to a group of antiretroviral medicines called protease inhibitors. By stopping protease from working, TELZIR stops HIV from multiplying and infecting more CD4 cells.

TELZIR is used in combination with other antiretroviral medicines ('combination therapy') to treat adults, adolescents and children aged at least 2 years, infected with HIV.

2. What you need to know before you take TELZIR:

TELZIR is taken in combination with other antiretroviral medicines. It is important that you carefully read the Patient Information Leaflet that is provided with these medicines. If you have any further questions, please ask your doctor or pharmacist.

Do not take TELZIR:

- **If you are hypersensitive (allergic) to fosamprenavir, amprenavir, ritonavir or to any of the other ingredients in TELZIR.**
- **if you have severe liver disease**
- **If you are taking any of these medicines:**
 - **Ketoconazole** (used to treat fungal infections)
 - **Cisapride** (used to relieve indigestion)
 - **Ergot derivatives** (used to treat headaches)
 - **Triazolam, midazolam, alprazolam, clorazepate, diazepam, flurazepam** (benzodiazepines used to treat anxiety)
 - **Pimozide** (used to treat schizophrenia)
 - **Quetiapine** (used to treat schizophrenia, bipolar disorder and major depressive disorder)
 - **Rifampicin** (used to treat tuberculosis)
 - **Lovastatin, simvastatin** (used to treat high cholesterol)

- **St John's Wort** (*Hypericum perforatum*, a herbal remedy used to treat depression)
 - **Flecainide, propafenone** (heart medicines)
 - **Alfuzosin** (used to treat a prostate problem)
 - **Sildenafil** (when sildenafil is used to treat increased pressure in blood vessels to your lungs).
 - **Lurasidone** (used to treat schizophrenia and bipolar disorder).
- ➔ **Tell your doctor if any of these applies to you.**

Warnings and precautions:

Take special care with TELZIR:

- **if you have mild to moderate liver disease** including hepatitis B or C. Your doctor may lower your dose of TELZIR depending on the amount of liver damage. If your liver disease gets worse, you may need to stop taking TELZIR for a while, or permanently.
 - **If you have haemophilia.** Increased bleeding may occur while taking 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 TELZIR, there have been reports of increased sugar in the blood and diabetes getting worse. Also, some people have become diabetic while taking TELZIR. Your doctor will monitor your blood glucose levels before and during treatment with TELZIR.
 - **If you are allergic to sulpha medicines.**
- ➔ **Tell your doctor if any of these applies to you.**

Conditions to look out for:

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

- **Change in your body shape:**
A change in body shape due to an increase in body fat.
- **Old infections may flare up:**

If you have a weak immune systems when you start anti-HIV treatment, you may find that during the first few weeks or months of treatment, old, hidden infections flare up, or you get signs and symptoms of inflammation (e.g. pain, redness, swelling, high temperature). The symptoms are probably caused by your immune system becoming stronger and starting to fight these infections.

- **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.

- **You may have increased levels of fat in your blood:**

Your doctor will measure your blood fat levels before and during treatment with TELZIR.

- **If you experience joint aches, pains and stiffness or difficulty in movement or get any symptoms of infection or inflammation** while you are taking TELZIR:

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

Protect other people. TELZIR will not stop you passing HIV infection on to other people, by having sex or by blood transfer. To protect other people from becoming infected with HIV:

- **Use a condom** when you have oral or penetrative sex.
- **Don't risk blood transfer** – for example, don't share needles.

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

You will need to take the TELZIR/ritonavir combination every day. These medicines help to control your condition, but they are not a cure for HIV infection. You can still continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor. Do not stop taking your medicines without first talking to your doctor.

TELZIR and ritonavir may interact with other medicines that you are taking, so it is important that you read the section “Taking other medicines with TELZIR” before taking these medicines.

Other medicines and TELZIR:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Your doctor will decide if these medicines are suitable for you to take with TELZIR. This is **very important**, as taking some types of medicines at the same time as the TELZIR/ritonavir combination can strengthen or weaken the effect of the medicines. This can sometimes lead to serious medical conditions.

Some of the medicines that can interact with TELZIR and ritonavir include:

- **flecainide, propafenone, cisapride, pimozide, triazolam, midazolam, ergot derivatives, atorvastatin lovastatin, simvastatin, ketoconazole, itraconazole rifampicin sildenafil, halofantrine, fluticasone propionate and St John’s Wort.**
- telaprevir, boceprevir, simeprevir, paritaprevir and similar medicines.

While taking the TELZIR/ritonavir combination, you must not take any of these medicines. If you are currently taking any of these medicines, ask your doctor about switching to a different medicine.

TELZIR and ritonavir may interact with certain other medicines. The use of the following medicines, together with the TELZIR/ritonavir combination, should only take place on your doctor’s advice:

- antibiotics (i.e. rifabutin, clarithromycin, dapsone and erythromycin)
- antidepressants (i.e. paroxetine)
- antimalarials (i.e. halofantrine)
- calcium channel blockers (i.e. amlodipine, felodipine, isradipine, nisoldipine, verapamil, diltiazem, nifedipine, nimodipine, bepridil)
- cholesterol lowering agents (i.e. atorvastatin)

- PDE5 inhibitors (used to treat erectile dysfunction) (i.e. sildenafil, tadalafil, vardenafil)
- Hepatitis C virus (HCV) protease inhibitors [i.e. telaprevir and boceprevir (used to treat hepatitis C infection)]
- glucocorticoids (i.e. fluticasone propionate, dexamethasone)
- non-nucleoside reverse transcriptase inhibitors (i.e. efavirenz, nevirapine and delavirdine)
- Integrase inhibitors (i.e. raltegravir)
- steroids (i.e. oestrogens and progestogens)
- immunosuppressants (i.e. ciclosporin, rapamycin, tacrolimus)
- maraviroc, dolutegravir (used to treat HIV infection)
- dasatinib, nilotinib, ibrutinib, vinblastine and everolimus (used to treat several types of cancer)
- other substances (i.e. clozapine, carbamazepine, cimetidine and loratadine)

If you are taking certain medicines that can cause serious side effects, such as amiodarone, phenobarbital, phenytoin, lidocaine, tricyclic antidepressants, quinidine and warfarin, at the same time as you are taking the TELZIR/ritonavir combination, your doctor may carry out additional blood tests to minimise any potential safety problems.

The use of TELZIR/ritonavir combination with the contraceptive (birth control) pill may harm your liver and may stop the oral contraceptive from working properly. Use an alternative non-hormonal method of contraception such as a condom.

Taking TELZIR with food and drink:

TELZIR TABLETS can be taken with or without food.

Adults should take the recommended dosage of TELZIR ORAL SUSPENSION without food and on an empty stomach.

Children should take the recommended dosage of TELZIR ORAL SUSPENSION **with food**.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TELZIR.

Pregnancy: Inform your doctor if you are pregnant or planning to become pregnant soon. The safe use of the TELZIR/ritonavir combination in pregnancy has not been established. TELZIR/ritonavir should not be taken during pregnancy.

Breastfeeding: Do not breastfeed your baby while you are taking TELZIR/ritonavir combination. It is recommended that HIV positive women do not breastfeed their infants in order to avoid transmission of HIV.

A small amount of the ingredients in TELZIR may also pass into your breast milk. Talk to your doctor immediately, if you're breastfeeding, or thinking about breastfeeding.

Driving and using machines:

TELZIR/ritonavir combination may affect the ability to drive and use machines. Do not drive or operate machinery if you are feeling unwell.

TELZIR ORAL SUSPENSION contains propyl and methyl parahydroxybenzoate. These products may cause an allergic reaction in some individuals. This reaction may be delayed.

3. How to take TELZIR

Take your medicine exactly as your doctor has instructed you. If you are unsure about how to take your medicine, then ask your doctor or pharmacist.

Do not share medicines prescribed for you with any other person.

It is very important that you take the **full** daily dose of TELZIR and ritonavir prescribed by your doctor. Do not take more than the recommended dose.

In some cases, your doctor may adapt the dose of the TELZIR/ritonavir combination when other medicines are administered together with this combination. Please follow the advice of your

doctor carefully should they recommend a change to how you should take the TELZIR/ritonavir combination.

TELZIR TABLETS:

Swallow TELZIR TABLETS whole with water or another drink. TELZIR TABLETS can be taken with or without food.

Based on your previous experience of using antiretroviral medicines your doctor will decide which dosing regimen is best for you.

An oral suspension of TELZIR is available for patients unable to swallow tablets.

Adults (18 years of age and older):

If you have not been treated for HIV before (therapy naïve patients): The dose of TELZIR tablets is either:

- 1 400 mg (two tablets) once a day with 200 mg ritonavir once daily, or
- 700 mg TELZIR (1 tablet) with 100 mg ritonavir twice daily.

If you have been treated with a protease inhibitor before (protease inhibitor-experienced patients): the recommended dose is 700 mg TELZIR with 100 mg ritonavir twice daily in combination with other antiretroviral agents.

Children (2 to 17 years of age):

TELZIR TABLETS are not suitable for children weighing less than 39 kg. The TELZIR ORAL SUSPENSION is the recommended formulation for the most accurate dosing in children based on body weight.

TELZIR ORAL SUSPENSION:

Shake the bottle for 20 seconds before first use.

Shake the bottle for 5 seconds before subsequent uses.

Adults (18 years of age and older):

Adults should take the recommended dosage of TELZIR ORAL SUSPENSION **without** food and on an empty stomach.

If you have not been treated for HIV before (therapy naïve patients): The dose of TELZIR ORAL SUSPENSION is either:

- 1 400 mg (28 ml) once a day with 200 mg ritonavir once daily, or
- 700 mg TELZIR (14 ml) with 100 mg ritonavir twice daily.

If you have been treated with a protease inhibitor before (protease inhibitor-experienced patients): the recommended dose is 700 mg (14 ml) fosamprenavir with 100 mg ritonavir twice daily in combination with other antiretroviral agents.

Children (2 to 17 years of age):

Your doctor will calculate the correct dosage based on your child's body weight.

Children should take the recommended dosage of TELZIR ORAL SUSPENSION **with food**.

TELZIR ORAL SUSPENSION is the recommended formulation for the most accurate dosing in children based on body weight.

There is not enough information to recommend the use of TELZIR in children less than 2 years of age.

The label on your pack will tell you how much and how often to take your medicine. If the label does not say, or if you are not sure, ask your doctor or pharmacist.

Use the oral dosing syringe supplied with the pack to measure your dose accurately.

1. Shake the bottle vigorously before use.
2. Remove the bottle cap and keep it safely.
3. Push the plastic adapter into the neck of the bottle, while holding the bottle firmly.
4. Insert the syringe firmly into the adapter.
5. Turn the bottle upside down.
6. Pull out the syringe plunger until the correct amount is withdrawn.
7. Turn the bottle the correct way up and remove the syringe from the adapter.

8. Put the syringe into the mouth placing the tip of the syringe against the inside of the cheek.
Slowly push the plunger in, allowing time to swallow. Don't push too hard and squirt the liquid into the back of the throat or you may choke.
9. Repeat steps 4 to 8 in the same way until you have taken the whole dose.
10. Do not leave the syringe in the bottle. Take the syringe and the adapter off and wash them thoroughly in clean water. Let them dry completely before you use them again.
11. Close the bottle tightly with the cap.

If you take more TELZIR than you should:

If you have taken more than the prescribed dose of TELZIR or ritonavir, you should contact your doctor or pharmacist immediately for advice. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take TELZIR:

If you forget to take a dose of TELZIR and ritonavir, take it as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten individual dose.

4. Possible side effects:

TELZIR and ritonavir can have side effects.

Not all side effects reported for TELZIR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TELZIR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking TELZIR and tell your doctor immediately or go to the casualty department of your nearest hospital:

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

- a severe or life-threatening skin reaction which may appear as a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TELZIR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe crushing pain in your chest or angina (heart attack)
- severe pain in lower back where kidneys are (kidney stones).

Conditions you need to look out for:

You may experience muscle problems:

There have been reports of muscle pain, tenderness or weakness with TELZIR. These muscle disorders can be 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 TELZIR.

If this happens to you:

→ Talk to your doctor immediately.

Your body shape may change

If you are taking combination anti-HIV therapy including a protease inhibitor, you may find that your body shape changes, because of an increase in body fat.

It is not yet known what causes these changes, or whether they have any long-term effects on your health. If you notice changes in your body shape:

→ Tell your doctor.

Frequent side effects:

- increase in *cholesterol* (a type of blood fat). Your doctor will monitor your blood fat levels before and during treatment with TELZIR
- increases in *triglycerides* (a type of blood fat). Your doctor will monitor your blood fat levels before and during treatment with TELZIR
- feeling sick or being sick (*nausea or vomiting*), pain in the stomach, loose stools (*diarrhoea*), wind
- skin rashes (red, raised or itchy) – if the skin rash is severe contact your doctor as you may have to stop taking TELZIR
- headache
- feeling tired
- tingling or numbness around the lips and mouth
- increases in some enzymes produced by your liver called transaminases
- increases of an enzyme produced by your pancreas, called lipase.

Other effects may show up in tests

- **increased levels of sugar or fats** in the blood
- **resistance to insulin**

If you are diabetic, you may have to change your insulin dose to control your blood sugar.

Always tell your doctor or pharmacist about any side effects that occur while taking the TELZIR, even those not mentioned in the leaflets.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TELZIR.

5. How to STORE TELZIR:

Do not take the medicine after the expiry date shown on the tablet pack.

Store all medicines out of reach of children.

TELZIR TABLETS: Store at or below 30 °C.

TELZIR ORAL SUSPENSION: Store at or below 30 °C. Do not freeze. Discard 28 days after first opening.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What TELZIR contains:

TELZIR TABLETS contain fosamprenavir as the active substance. Each tablet contains 700 mg of fosamprenavir as fosamprenavir calcium.

The tablets also contain the following other ingredients: hypromellose, titanium dioxide (E171), triacetin, iron oxide red (E172), microcrystalline cellulose, croscarmellose sodium, povidone K30, magnesium stearate and colloidal silicon dioxide.

TELZIR ORAL SUSPENSION contains fosamprenavir as the active substance. Each ml of the oral suspension contains 50 mg of fosamprenavir as fosamprenavir calcium.

The oral suspension also contains the following other ingredients: hypromellose, sucralose, propylene glycol, polysorbate 80, calcium chloride dihydrate, artificial grape bubblegum flavour,

natural_peppermint flavour, purified water. Preservatives: methyl parahydroxybenzoate (0,15 % *m/v*) and propyl parahydroxybenzoate (0,02 % *m/v*).

What TELZIR looks like and contents of the pack:

TELZIR TABLETS are pink film-coated, capsule-shaped, biconvex tablets with GXLL7 on one face.

TELZIR TABLETS are supplied in white plastic bottles with a child-resistant closure and each bottle contains 60 tablets.

TELZIR ORAL SUSPENSION is a white to off-white suspension with a characteristic bubblegum odour.

TELZIR ORAL SUSPENSION is supplied in white plastic bottles with a child-resistant closure and each bottle contains 225 ml of oral suspension. A 10 ml dosing syringe is provided in the pack.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd
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