TELZIR® TABLETS

fosamprenavir

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start Telzir tablets.

This leaflet answers some common questions about Telzir tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Telzir in combination with ritonavir against the expected benefits it will have for you.

As you will be taking Telzir together with low doses of ritonavir, you should also carefully read the Patient Leaflet for that product before starting treatment with this combination.

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

Keep this leaflet with the tablets.

You may need to read it again.

What Telzir tablets are used for

Telzir tablets contain fosamprenavir which belongs to a group of antiretroviral medicines called protease inhibitors.

The low doses of ritonavir you take together with Telzir are designed to increase the amount of the active ingredient, amprenavir, available to control your HIV infection.

Telzir, taken with ritonavir, are used together with other antiretroviral medicines to slow down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (eg AIDS-related Complex or ARC).

Telzir does not cure AIDS or kill the HIV virus, but prevents further damage to the immune system by stopping production of new viruses.

Telzir does not reduce the risk of passing the infection to others. You will still be able to pass on the HIV virus by sexual activity or by contamination with infected blood. You should still use proper precautions to prevent this.

While taking Telzir and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with the doctor who is looking after you.

Telzir tablets are not addictive.

Ask your doctor if you have any questions about why Telzir tablets have been prescribed for you.

Before you take Telzir tablets

Telzir is to be taken in combination with ritonavir. It is therefore important that you carefully read the Package Leaflet that is provided with that medicine. If you have any further questions about ritonavir please ask your doctor or pharmacist.

When you must not take them

- **Do not take Telzir tablets if you have ever had an allergic or hypersensitivity reaction to fosamprenavir or amprenavir or any of the ingredients listed at the end of this leaflet.**

- **Do not take ritonavir if you have ever had an allergic or hypersensitivity reaction to ritonavir or any of the ingredients found in that medicine.**

  If you develop any of the symptoms of allergy or hypersensitivity, tell your doctor immediately. If an allergy or hypersensitivity is diagnosed then your doctor may stop your Telzir and ritonavir treatment.

- **Do not take Telzir tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

  Your doctor will discuss the risks and benefits of using Telzir with ritonavir if you are pregnant or breastfeeding.

- **There are some medicines that must not be taken with Telzir in combination with ritonavir. These medicines include:**

  - **astemizole and terfenadine, which are used to treat hayfever**
  - **rifampicin which is used to treat tuberculosis**
  - **midazolam and triazolam which are used to induce sedation**
  - **Sildenafil when used to treat increased pressure in blood vessels to your lungs**
  - **dihydroergotamine and ergotamine which are used to treat migraine**
  - **cisapride which is used to treat gastric reflux**
  - **pimozide which is used to treat chronic psychotic disorders**
  - **flecainide which is used to treat heart conditions**
  - **propafenone which is used to treat heart conditions**
  - **Herbal treatments such as St Johns Wort.**

Please refer to the ritonavir Package Leaflet for further details of the medicines that must not be taken with ritonavir.

- **Do not give Telzir to anyone else, even though their symptoms may sound similar to yours.**

- **Do not take Telzir tablets after the expiry or "use by" date (EXP) printed on the bottle.**

  If you're not sure whether you should be taking Telzir oral suspension, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines (eg sulfonamide).**

- **you had a previous allergic reaction to Telzir (fosamprenavir) or amprenavir containing products or to ritonavir.**

- **you have, or have ever had, liver problems, for example jaundice, hepatitis, virus affecting the liver, enlarged liver or liver scarring (cirrhosis).**

  People with liver disease will need to have their dose of Telzir and/or ritonavir adjusted. As it is not possible to reduce the dose of Telzir tablets to less than 700 mg, patients with moderate or severe liver disease must not be treated with Telzir tablets. Your doctor may recommend using Telzir oral suspension to achieve the doses required. If you are unsure about your level of liver disease consult your doctor who may carry out additional testing to see

whether the Telzir/ritonavir combination is suitable for you.

- **you have any other illness, for example diabetes mellitus or haemophilia, including those that you think are not related to HIV infection.**

Taking other medicines

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

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Telzir tablets with other medicines.

Some of the medicines that can interact with Telzir and ritonavir include astemizole, alfuzosin, terfenadine, flecainide, propafenone, cisapride, pimozide, triazolam, midazolam, sildenafil (when sildenafil is used to treat increased pressure in blood vessels to your lungs), ergot derivatives, nevirapine and rifampicin. 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 medications. The use of the following medicines, together with the Telzir /ritonavir combination, should only take place on the basis of medical advice: antibiotics (i.e. rifabutin, clarithromycin, dapsone and erythromycin), antifungals (i.e.

ketoconazole, itraconazole), antimalarials (i.e. halofantrine), benzodiazepines (i.e. alprazolam and clorazepam), calcium channel blockers (i.e. diltiazem, nicardipine, nifedipine, nimodipine, felodipine, verapamil, amlodipine, and isradipine), cholesterol lowering agents (i.e. atorvastatin, lovastatin and simvastatin), erectile dysfunction agents (i.e. sildenafil, tadalafil, vardenafil), non-nucleoside reverse transcriptase inhibitors (i.e. efavirenz, nevirapine and delavirdine), opioids (i.e. methadone), steroids (i.e. oestrogens, progestogens and some glucocorticoids), Immunosuppressants (ie cyclosporin, tacrolimus), Inhaled/ nasal steroid (ie fluticasone), and other substances (i.e. clozapine, carbamazepine, famotidine, nizatidine, ranitidine, cimetidine, paroxetine and loratadine) and ergot derivatives (ie Dihydroergotamine, ergotamine)

If you are taking certain medicines that can cause serious side effects, such as amiodarone, phenobarbitone, 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.

If you are taking the contraceptive pill, it is recommended that you use an alternative method (e.g. a condom) to prevent pregnancy while you are taking Telzir.

How to take Telzir tablets

Your doctor will tell you how many Telzir tablets to take and how often to take them. You will also find this information on the label of your medicine.

Do not take extra tablets. Do not take the tablets more often than you have been told.

How much to take

Adults (greater than or equal to 18 years of age):

Therapy-Naive Patients: the dose of Telzir is 1400 mg (two tablets) once a day with 200 mg ritonavir once daily or 700 mg Telzir (one tablet) twice daily with 100 mg ritonavir twice daily.

Telzir oral suspension is also available for those who cannot swallow tablets.

Protease Inhibitor-Experienced Patients: the recommended dose is 700 mg Telzir with 100 mg ritonavir twice daily in combination with other antiretroviral agents. The once daily administration of fosamprenavir plus ritonavir is not recommended in protease inhibitor experienced patients.

Children and Adolescents (6 to 18 years of age):

The adult tablet regimens (Telzir 700 mg twice daily plus 100 mg ritonavir twice daily for protease inhibitor experienced patients) may be used by children and adolescents if they weigh at least 39 kg and can swallow the tablets whole. Ritonavir 100 mg capsules may be used by children and adolescents if they weigh at least 33 kg and can swallow the capsules whole.

Telzir oral suspension is the recommended option for the most accurate dosing in children based on body weight.

The use of Telzir in combination with ritonavir has not been established for children less than 6 years of age.

How to take them

Telzir tablets should be swallowed whole with a glass of water. Telzir tablets can be taken with or without food.

How long to take them

Because your medicine helps to control your condition, but does not cure it, you will need to take the tablets every day. Do not stop taking your medicine without first talking to your doctor.

If you forget to take them

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126), or go to the Accident and Emergency unit at your nearest hospital, if you think you or anyone else may have taken too many Telzir tablets. Do this even if there are no signs of discomfort or poisoning.

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

While you are taking Telzir tablets

Things you must do

Tell your doctor or pharmacist that you are taking Telzir tablets if you are about to be started on any other medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking Telzir tablets or ritonavir, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Telzir tablets to treat any other complaints unless your doctor says to.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Telzir tablets or ritonavir, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, Telzir and ritonavir can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and may need medical attention.

Common side-effects associated with Telzir and ritonavir treatment include:

- **nausea & vomiting.**
- **diarrhoea.**
- **flatulence.**
- **abdominal pain.**
- **headache.**
- **rash.**
- **fatigue.**
- **altered sensation in your mouth.**
- **dizziness.**

Occasionally the skin rash may be severe and as a result your doctor may decide that you have to stop taking this medicine.

Other side-effects that have been reported, include:

- **muscle pain.**
- **tenderness and weakness**

These have been seen particularly with antiretrovirals therapy including protease inhibitors and nucleoside analogues.

In some individuals, treatment with a combination of antiretroviral medicines that includes a protease inhibitor has caused a change in body shape due to changes in fat distribution. These may include decreased fat under the skin, increased fat in the abdomen (belly), breast enlargement and fatty lumps on the back of the neck.

Your doctor will test your blood regularly for any abnormalities (blood lipids and sugar). Increases in liver enzymes and blood fats have been reported in patients taking Telzir and ritonavir.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (eg pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV. If you become concerned about any new symptoms, or any changes

in your health after starting HIV treatment, please discuss with your doctor immediately.

Some people may get other side-effects while taking Telzir and ritonavir. If you are concerned, talk to your doctor or pharmacist.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking Telzir tablets

Storage

Keep the tablets where children cannot reach them.

Keep Telzir tablets in a cool, dry place where it stays below 30°C.

Disposal

If your doctor tells you to stop taking Telzir tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What Telzir tablets looks like.

Telzir are pink coloured, film-coated, capsule shaped tablets. They are biconvex and marked GXLL7 on one face.

Telzir tablets are supplied in a plastic bottle containing 60 tablets.

Ingredients

Telzir tablets contain 700 mg of fosamprenavir, present as fosamprenavir calcium. Your tablets also contain the following inactive ingredients:

Hypromellose, titanium dioxide (E171), glycerol triacetate, Iron oxide red (E172), microcrystalline cellulose, croscarmellose sodium, Povidone K30, magnesium stearate and colloidal silicon dioxide.

Manufacturer

Your Telzir tablets are supplied by:

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, Victoria, 3067

Licensed from

Vertex Pharmaceuticals Inc.

Cambridge. MA 02139

Further Information

Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your illness and its treatment from other sources, for example from books in public libraries.

Counselling is also available from your local AIDS council.

This leaflet was prepared on

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The information provided applies only to: Telzir® tablets.

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Telzir 700mg tablets:

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