

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start Zelitrex.

This leaflet answers some common questions about Zelitrex tablets. 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 Zelitrex tablets against the benefits this medicine is expected to 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.

What Zelitrex tablets is used for

Zelitrex tablets belong to a group of medicines called antivirals. Zelitrex tablets are used for the treatment of genital herpes infection.

Zelitrex tablets work by stopping the multiplication of the virus which causes herpes. They can reduce the length and severity of an outbreak of herpes, the duration of pain and shorten the time to healing of crusts associated with herpes. They do not eliminate the herpes virus from the body. The herpes virus is also known as the Herpes Simplex Virus, or HSV.

Zelitrex tablets help the blisters to heal more quickly. If you start taking them as soon as you feel an outbreak starting, you may actually prevent the blisters from developing. Zelitrex tablets can also be taken long term to help prevent the HSV infection coming back.

Zelitrex is more effective in patients 50 years of age and older.

Zelitrex tablets can also reduce the risk of transmitting the virus that causes genital herpes in patients who are taking it continuously to prevent or reduce recurrent outbreaks. It does not cure genital herpes or completely eliminate the risk of transmission. Therefore, in addition to therapy with Zelitrex, it is recommended that patients avoid contact when symptoms are present and always use condoms.

Zelitrex (or any other antiviral) is not a cure for genital herpes. Because genital herpes is a sexually transmitted disease, you should minimise having intercourse when you have an outbreak of herpes or show any symptoms. This will avoid the risk of spreading herpes to your partner.

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

Zelitrex tablets are not addictive.

Before you take it

When you must not take it

Do not take Zelitrex tablets if you have ever had an allergic reaction to valaciclovir, aciclovir or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of

the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

Do not take Zelitrex 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 Zelitrex tablets when pregnant and during breastfeeding.

Do not take Zelitrex tablets after the expiry date (EXP) printed on the pack.

If you take them after the expiry date has passed, they may not work as well.

Do not take Zelitrex tablets if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be taking Zelitrex, 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.
- you have or have ever had blood disorders.
- you have a kidney or liver condition.
- you are pregnant or plan to become pregnant. Your doctor will discuss the risks and benefits of taking Zelitrex when pregnant.

If you have not told your doctor about any of the above, please do so before you take Zelitrex.

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

Use in children

There is not enough information to recommend the use of Zelitrex in children.

How to take it

Take Zelitrex tablets exactly as your doctor has prescribed. Your doctor or pharmacist will tell you:

- how many tablets to take at each dose
- how many doses to take each day
- when to take your doses each day.

The label on the pack will give the same information. If there is something you do not understand, ask your doctor or pharmacist.

How much to take

Your doctor will decide what dose you should take, how often you should take it and what strength Zelitrex tablets you should use. The dosage may vary depending on your medical history.

Acute (short term) treatment of genital herpes:

If you have had a herpes infection before, you should start to take Zelitrex tablets as early as possible if you think you are about to have another recurrence (attack). Dosing

should ideally start just before, or straight after the first signs of HSV infection appear.

If you have been prescribed Zelitrex 500 mg tablets for the treatment of HSV infection, the usual dose to take is one tablet with water twice daily.

Suppressive (long term) treatment of genital herpes:

If you have been prescribed Zelitrex 500 mg tablets to prevent the herpes infection appearing again, the usual dose to take is 500 mg once daily. Your doctor may recommend that you take this as a divided dose (i.e. 250 mg twice daily).

If you previously have had more than 10 recurrences (attacks) in one year, your doctor may recommend that you take 1000 mg of Zelitrex once daily to prevent recurrences.

If you think you have been advised to take a different dose, talk to your doctor or pharmacist.

How to take it

Swallow the tablets with a glass of water.

You should drink plenty of fluids while taking Zelitrex tablets.

When to take it

The usual times to take the tablets are in the morning and evening.

How long to take it

For the treatment of herpes infections, the usual course of treatment is five days. However in some instances your doctor may want you to take your tablets for ten days.

For prevention of herpes infections, you should continue to take this medicine every day as prescribed by your doctor.

Do not stop taking Zelitrex tablets just because you feel better. The herpes outbreak may not be completely over.

If you forget to take it

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 13 11 26) for advice, if you think you or anyone else may have taken too much Zelitrex, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking it

Things you must do

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

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

intend to breastfeed while you are taking Zelitrex tablets.

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.

Be careful driving or operating machinery until you know how Zelitrex tablets affect you.

Things you must not do

Do not stop taking Zelitrex tablets, or alter 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 Zelitrex 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 Zelitrex tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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

The most commonly reported side effects are:

- headache
- gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion).

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry mouth
- fever
- difficulty sleeping
- chills
- back pain
- nervousness
- skin rash which may be itchy
- weakness.

If you think you are having an allergic reaction to Zelitrex tablets, tell your doctor immediately or go to your casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/smooth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting.

Some rare side effects of Zelitrex tablets include:

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light.
- damage to the kidney, which gets better when Zelitrex treatment is stopped.
- unusual bruising or bleeding. Tell your doctor immediately if you notice any

bruising or bleeding, as it may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood are reduced.

- damage to the liver, which gets better when Zelitrex treatment is stopped.

You should contact your doctor if you experience any of the following side effects which are more common in patients with kidney disease or in those taking high doses of Zelitrex:

- Dizziness
- Confusion or imagining sights or sounds (hallucinations)
- Drowsiness.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking it

Storage

Keep this medicine where young children cannot reach it.

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

Keep Zelitrex tablets in a cool, dry place where it stays below 30°C. Do not store them, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines

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

If you take the tablets out of their pack they may not keep well.

Disposal

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

Product description

What it looks like

Zelitrex 500 mg tablets are white biconvex, elongated tablets with a white to off white core, engraved with "GX CF1" on one side. They are available in a pack size of 10 or 30 tablets.

Ingredients

Zelitrex tablets contain the active ingredient valaciclovir. The tablets also contain microcrystalline cellulose, croscopovidone, povidone, colloidal anhydrous silica, carnauba wax, magnesium stearate and white colour concentrate.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Zelitrex 500 mg tablets: AUST R 128739.

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