

NEW ZEALAND CONSUMER MEDICINE INFORMATION

VALGANCICLOVIR MYLAN

Valganciclovir film coated tablet 450 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Valganciclovir Mylan.

This leaflet answers some common questions about Valganciclovir Mylan.

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 Valganciclovir Mylan 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.

What Valganciclovir Mylan is used for

Valganciclovir Mylan is used to treat CMV eye infections (known as CMV retinitis) in AIDS patients, which, if left untreated can cause blindness. It is not a cure for CMV eye infections.

Valganciclovir Mylan is not effective against any underlying HIV infection.

Valganciclovir Mylan is also used to prevent CMV infection in patients following organ transplantation.

Valganciclovir Mylan contains the active ingredient valganciclovir. It belongs to a group of medicines used to prevent the growth of viruses.

Valganciclovir Mylan acts against a virus called cytomegalovirus or CMV (a type of herpes virus). It prevents this virus from growing and multiplying in the body. CMV causes infections, mainly in people with poor immunity. Poor immunity can be caused by HIV/ AIDS or by medications taken after an organ transplant.

Your doctor may have prescribed this medicine for another reason.

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

Valganciclovir Mylan is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Valganciclovir Mylan

Animal and other laboratory studies have shown valganciclovir causes infertility, birth defects and cancer. It is possible that these effects may also occur in humans.

When you must not take it

Do not take Valganciclovir Mylan if you have an allergy to:

- any medicine containing valganciclovir
- any other similar medicine such as ganciclovir, valaciclovir, aciclovir
- 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 Valganciclovir Mylan if you have very low blood counts or platelets (which help with clotting), neutrophils (a type of white blood cell which defends against infection) or low haemoglobin (oxygen carrying substance in the blood).

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Use in children

There is limited information on the safe and effective use of valganciclovir in children. Your doctor will advise you whether Valganciclovir Mylan is suitable for your child.

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 history of low blood counts for platelets (thrombocytopenia), neutrophils (neutropenia) or anaemia
- poor kidney function
- poor liver function.

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

Valganciclovir Mylan is not recommended for use during pregnancy. It may affect your developing baby if you take it during pregnancy. Your doctor will discuss

the risks and benefits of using Valganciclovir Mylan if you are pregnant.

Tell your doctor if you are breast-feeding or intend to breast-feed.

It is not known whether valganciclovir passes into breast milk. Breast feeding is not recommended during treatment with Valganciclovir Mylan.

Tell your doctor if you are a woman who could become pregnant and you are not using contraception.

You must use a reliable form of contraception during Valganciclovir Mylan therapy, and for at least 30 days after stopping Valganciclovir Mylan, unless you are not sexually active.

Tell your doctor if you are a sexually active man.

You should use condoms while you are taking Valganciclovir Mylan and for a further 90 days after you have stopped taking it. Valganciclovir Mylan may affect the production of sperm. Your doctor will discuss the risks and benefits of using this medicine.

If you have not told your doctor about any of the above, tell them before you start taking Valganciclovir Mylan.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Valganciclovir Mylan.

Some medicines may interfere with Valganciclovir Mylan. These include:

- imipenem/cilastatin (a combination medicine used to treat some infections)
- probenecid, a medicine used to treat gout
- zidovudine, didanosine, stavudine, also known as D4T – medicines used for people with HIV infection

- medicines used to prevent rejection after a transplant, such as mycophenolate mofetil, ciclosporin, tacrolimus
- medicines used for the treatment of cancer such as vincristine, vinblastine, doxorubicin, hydroxyurea
- anti-infective agents such as trimethoprim, sulphonamides, dapsone, pentamidine, flucytosine, pegylated interferons and amphotericin B.

These medicines may be affected by Valganciclovir Mylan or may affect how well it works. You may need different amounts of your medicine, 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.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take Valganciclovir Mylan

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 bottle, ask your doctor or pharmacist for help.

How much to take

Take Valganciclovir Mylan exactly as your doctor has prescribed.

Your doctor will tell you how many Valganciclovir Mylan tablets to take each day.

Treatment of CMV retinitis in AIDS

The usual starting dose (initial treatment) is two 450 mg tablets twice a day with food (a total of 4 tablets per day) for 21 days.

The usual maintenance dose, or dose for people with inactive CMV retinitis is two 450 mg tablets once a day with food.

Prevention of CMV disease in transplantation

The usual dose is 900 mg (two 450 mg tablets) once daily with food, starting within 10 days of your organ transplant and continuing until 100 days after the transplant.

If you have received a kidney transplant, the same daily dose is required and continues until 200 days after the transplant.

Your dose may have to be reduced or stopped if you have or develop low blood counts, have kidney disease, or if you are older than 65 years.

How to take it

Swallow the tablets whole with a full glass of water. Valganciclovir Mylan must be taken with food.

If you are unable to eat for any reason, you should still take the tablets when they are due.

When to take it

Take Valganciclovir Mylan during or immediately after a meal.

If you take this medicine on an empty stomach, it may not work as well.

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 Valganciclovir Mylan until your doctor tells you to stop.

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, and then go back to taking your medicine as you would normally.

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

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.

While you are taking Valganciclovir Mylan

Things you must do

Tell all doctors, dentists, and pharmacists who treat you that you are taking Valganciclovir Mylan.

If either you or your partner becomes pregnant while taking Valganciclovir Mylan, tell your doctor immediately.

It is extremely important that both men and women of child-bearing age use effective contraception during treatment with Valganciclovir Mylan.

If you need advice on contraception, ask your doctor before you start taking Valganciclovir Mylan. Men should use condoms while taking Valganciclovir Mylan and should continue to use condoms for 90 days after treatment has finished. Women should use effective contraception during and for 30 days after treatment has finished.

See your doctor regularly so that your CMV disease, blood counts and any other potential side effects may be monitored carefully.

If blood cell counts are low then this may reduce your ability to fight infection, or for your blood to clot efficiently. If left undetected these effects may contribute to death or serious illness.

If you have an CMV eye infection, you must also see your doctor regularly to monitor the condition of your retina (part of your eye).

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.

Tell your doctor if you feel the tablets are not helping your condition.

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

Things you must not do

Do not take Valganciclovir Mylan 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 Valganciclovir Mylan or change the dosage without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful when handling Valganciclovir Mylan tablets. Do not break or crush them. If you accidentally touch broken or crushed tablets, wash your hands thoroughly with soap and water. If any powder from the tablet gets in your eyes, rinse your eyes thoroughly with water.

Be careful driving or operating machinery until you know how Valganciclovir Mylan affects you. This medicine may cause dizziness, confusion or seizures (fits) in some people and therefore may affect alertness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Valganciclovir Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include abdominal pain, diarrhoea, vomiting, convulsion (fit), swelling ankles and shortness of breath.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Valganciclovir Mylan.

This medicine helps most people with CMV infections, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- looking pale and/or dizziness (anaemia)
- diarrhoea or constipation
- feeling sick (nausea) or vomiting
- fever
- headache
- indigestion
- tingling or numbness of the hands and feet
- shaking or tremors
- runny nose, sore throat or nasal passages
- loss of appetite, weight loss
- painful, swollen joints, muscle pain
- pain when passing urine.

These are the more common side effects of Valganciclovir Mylan.

Tell your doctor immediately if you notice any of the following:

- skin rash (dermatitis)
- abdominal pain
- cough
- tiredness (fatigue)
- sore, creamy yellow raised patches in the mouth (oral thrush)
- unable to sleep (insomnia)
- worsening of your eyesight.

These side effects may be serious. You may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the tongue, lips or throat
- wheezing or difficulty breathing
- any sign of infection such as fever, chills, sore throat or mouth ulcers
- unexplained bruising or bleeding
- abnormal thoughts, confusion, agitation, hallucinations (seeing, hearing or feeling things that are not there)
- convulsions (fits)
- problems with your eyesight such as seeing bright flashes of light.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

After taking Valganciclovir Mylan

Storage

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

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

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

Do not store Valganciclovir Mylan 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.

Disposal

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.

Product description

What it looks like

Valganciclovir Mylan are pink film-coated, oval, biconvex, bevelled edge tablets marked with "M" on one side of the tablet and "V45" on the other side.

Ingredients

Active ingredient(s):

Valganciclovir Mylan contains 450 mg of valganciclovir as the active ingredient.

Inactive ingredient(s):

Valganciclovir Mylan also contains:

- microcrystalline cellulose
- crospovidone
- stearic acid
- hypromellose
- titanium dioxide
- macrogol
- iron oxide red
- polysorbate.

This medicine does not contain lactose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Valganciclovir Mylan is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

5 February 2019
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