

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Valaciclovir Viatris 500 mg, film-coated tablets  
valaciclovir

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

### Contents of this leaflet

1. What is Valaciclovir Viatris and what is it used for?
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#### 1. What is Valaciclovir Viatris and what is it used for?

Valaciclovir Viatris contains the active substance valaciclovir hydrochloride hydrate. This medicine belongs to the group of medicines called antivirals. Its action is to kill or stop the growth of viruses called herpes simplex virus (HSV), herpes zoster virus (VZV), and cytomegalovirus (CMV).

This medicine can be used for:

the treatment of shingles (in adults);

the treatment of HSV infections of the skin and genital infections (genital herpes) (in adults and adolescents over 12 years old). It is also used to prevent these infections from recurring;

the treatment of cold sores (in adults and adolescents over 12 years old);

the prevention of CMV-Cytomegalovirus infections (in adults and adolescents over 12 years old) after organ transplants;

the treatment and prevention of recurring HSV infections of the eye (in users over 12 years old).

#### 2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

If you have ever had a widespread rash after taking valaciclovir accompanied by fever, enlarged lymph nodes, elevated liver enzymes, and/or too many white blood cells, also known as eosinophilia (drug reaction with eosinophilia and systemic symptoms).

If you are unsure, consult your doctor or pharmacist before using this medicine.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you have kidney problems;
- if you have liver problems;
- if you are over 65 years old;
- if you have a weakened immune system.

If you are not sure whether any of these apply to you, consult your doctor or pharmacist before using this medicine.

Drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported when using valaciclovir. DRESS initially appears as flu-like symptoms and a rash on the face, followed by a widespread rash with a high body temperature, elevated liver enzymes as observed in blood tests, and an increase in a type of white blood cells (eosinophilia) and enlarged lymph nodes.

If you develop a rash accompanied by fever and enlarged lymph nodes, stop using valaciclovir and contact your doctor or seek medical help immediately.

Prevent transmitting the genital herpes infection to others

When using this medicine to treat or prevent a genital herpes infection, or if you have ever had a genital herpes infection, you must ensure safe sex practices, including using a condom. This is important to prevent the transmission of the virus to others. You should abstain from sexual activities as long as you have sores or blisters.

Children under 12 years

This medicine should not be used in children under 12 years.

Are you using any other medicines?

Are you using any other medicines besides Valaciclovir Viatrix, or have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines that you can obtain without a prescription and to herbal medicines.

Tell your doctor or pharmacist if you are using other medicines that affect the kidneys. These medicines include aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine, and probenecid.

Always tell your doctor or pharmacist if you are using other medicines while using Valaciclovir Viatrix for the treatment of shingles or after an organ transplant.

Pregnancy and breastfeeding

Normally, the use of this medicine during pregnancy is not recommended. Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Your doctor will weigh the benefit for you against the risk to your unborn child when using this medicine during pregnancy or while breastfeeding.

Driving and using machines

Valaciclovir can have side effects that affect your ability to drive. Do not drive a car or other vehicle and do not use tools if you are unsure whether this medicine also affects you.

### 3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The dosage you should use depends on the reason why you are prescribed this medicine. Your doctor will discuss this with you.

#### Treatment of shingles

The recommended dosage is 1,000 mg three times a day (one 1,000 mg tablet or two 500 mg tablets).

You should use this medicine for 7 days.

#### Treatment of a cold sore

The recommended dosage is 2,000 mg twice a day (two 1,000 mg tablets or four 500 mg tablets)

You should take the second dose 12 hours (not earlier than 6 hours) after the first dose.

You should use this medicine for only one day (two doses).

#### Treatment of HSV infections of the skin and genital infections (genital herpes)

The recommended dosage is 500 mg twice a day (one 500 mg tablet)

For the first occurrence of the infection, you should use this medicine for 5 days, or up to 10 days if prescribed by your doctor. For a recurrent infection, the treatment duration is usually 3 to 5 days.

#### Preventing HSV infections from recurring after you have had them

The recommended dosage is one 500 mg tablet once a day.

Some people with frequently recurring infections may benefit from taking one 250 mg tablet twice a day instead of the above. This medicine is not suitable for doses lower than 500 mg. Lower strengths of other valaciclovir medicines are available. Your doctor will advise you on this.

You should continue using this medicine until your doctor tells you to stop.

#### Preventing a CMV (cytomegalovirus) infection

The recommended dosage is 2,000 mg four times a day (two 1,000 mg tablets or four 500 mg tablets).

You should take the doses approximately 6 hours apart.

Usually, you should start taking this medicine as soon as possible after the surgery.

You should use this medicine for about 90 days after the surgery, until your doctor tells you to stop.

#### Use in children under 12 years

Valaciclovir is not recommended for children under 12 years because there is insufficient data on safety and efficacy.

Your doctor may adjust your dosage of this medicine if:  
you are over 65 years old;

you have a weakened immune system;  
you have kidney problems.

If any of these apply to you, consult your doctor or pharmacist before using this medicine.

#### Method of administration

This medicine should be taken orally.

Swallow the tablets whole with a large glass of water.

Take this medicine at the same time every day.

You must take this medicine as instructed by your doctor or pharmacist.

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Elderly (over 65 years) and people with kidney problems

It is very important that you drink enough water regularly throughout the day while using this medicine. This reduces the risk of side effects on the nervous system or kidneys. Your doctor will closely monitor you for possible signs of these side effects. Side effects on the nervous system include feelings of confusion or excitement, or an unusually sleepy or drowsy feeling.

Have you used too much of this medicine?

This medicine is usually not harmful unless you use too much for several consecutive days. If you have taken too many tablets, you may: feel nauseous, vomit, feel confused or excited, feel unusually sleepy, see, feel, or hear things that are not there (hallucinations), have kidney problems where you can hardly or not urinate, or you may lose consciousness (coma). Contact your doctor or pharmacist if you have taken too much of this medicine. Bring the packaging with you.

Have you forgotten to use this medicine?

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Do not stop using this medicine without consulting your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects usually occur at the beginning of the treatment and become milder or stop altogether within a few weeks. Sometimes it is difficult to distinguish between the symptoms of a disease and the side effects.

If you think you have any of the following side effects, stop using this medicine and contact your doctor immediately or go directly to the emergency department of the nearest hospital:

Rare (affect less than 1 in 1000 users)

severe allergic reactions (anaphylaxis) Symptoms can develop quickly such as:

- excessive flushing, itchy skin rash;
- swelling of the lips, face, neck, or throat, causing difficulty in breathing (angioedema);
- drop in blood pressure causing fainting;

seizures (convulsions);

altered brain function (encephalopathy);

unconsciousness (coma);

confused or disturbed thoughts;

severe mental illness (psychosis).

Not known (cannot be estimated from the available data)

drug reaction with eosinophilia and systemic symptoms also known as DRESS or drug hypersensitivity syndrome, characterized by widespread skin rash, high body temperature, elevated liver enzymes, blood abnormalities (eosinophilia), enlarged lymph nodes, and possibly other organ involvement. See also section 2; a kidney inflammation (tubulo-interstitial nephritis).

Other common side effects:

Very common (affect more than 1 in 10 users)  
headache.

Common (occur in less than 1 in 10 users)  
feeling nauseous (nausea);  
dizziness;  
vomiting;  
diarrhea;  
skin reactions, for example after exposure to sunlight (photosensitivity);  
skin rash.

Sometimes (occur in less than 1 in 100 users)  
feeling confused;  
seeing or hearing things that are not there (hallucinations);  
feeling very drowsy;  
trembling;  
feeling agitated.

These nervous system side effects usually occur in people with kidney problems, in the elderly, or in patients who have undergone an organ transplant and are taking high doses of 8 grams or more of this medication per day. Their condition improves when this medication is stopped or if the dosage is reduced.

Other sometimes occurring side effects  
shortness of breath (dyspnea);  
stomach discomfort;  
skin rash, sometimes itchy, and hives-like skin rash (urticaria); • lower back pain (kidney pain);  
blood in the urine.

Sometimes occurring side effects revealed by blood tests  
decrease in the number of white blood cells (leukopenia);  
decrease in the number of platelets (thrombocytopenia). Platelets are cells that help with blood clotting;  
increase in substances produced by the liver.

Rare (occur in less than 1 in 1000 users)  
unsteady gait and coordination problems (ataxia);  
slow/slurred speech (dysarthria).

These nervous system side effects usually occur in individuals with kidney problems, the elderly, or patients who have undergone organ transplantation and are taking high doses of 8 grams or more of this medication per day. Their condition improves when this medication is stopped or the dosage is reduced.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (website: [www.lareb.nl](http://www.lareb.nl)). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the box and blister pack after "Do not use after:" or "EXP:". It includes a month and a year. The last day of that month is the expiry date.

This medicine has no special storage conditions.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

#### 6. Contents of the package and other information

##### What substances are in this medicine?

The active substance in this medicine is valaciclovir hydrochloride hydrate. Each film-coated tablet contains 500 mg valaciclovir (as valaciclovir hydrochloride hydrate).

The other substances in this medicine are: cellulose, microcrystalline; crospovidone; povidone and magnesium stearate. The components of the film coating are: titanium dioxide (E171), macrogol 400, polysorbate 80 (E433) and hypromellose (E464).

##### What does Valaciclovir Viatris look like and what is in the packaging

Valaciclovir Viatris is a white to off-white, capsule-shaped, biconvex film-coated tablet. The tablet has an inscription "VC 500" on one side and "G" on the other side.

Valaciclovir Viatris is available in blister packs of 10, 21, 24, 30, 42, 60, 90, 100, and 112 film-coated tablets.

Not all mentioned pack sizes are marketed.

##### Marketing authorization holder and manufacturer

Registration holder

Viatris Ltd

Damastown Industrial Park

Mulhuddart

Dublin 15

Dublin, Ireland

For information and inquiries:

Mylan B.V.  
Krijgsman 20  
Amstelveen

Manufacturer

Mylan Hungary Kft, H-2900 Komarom, Mylan utca 1, Hungary  
Generics UK, Station Close, Pottersbar, Hertfordshire EN6 1TL, United Kingdom

This medicine is registered in the register under  
RVG 100108.

This medicine is registered in EEA member states under the following names:

Denmark	Valaciclovir Viatris
Italy	Valaciclovir Mylan Generics
Netherlands	Valaciclovir Viatris 500 mg, film-coated tablets
Norway	Valaciclovir Viatris
Austria	Valaciclovir Viatris 500 mg, 1000 mg - Film-coated tablets
Czech Republic	Valaciclovir Viatris
United Kingdom	Valaciclovir 500 mg Film-coated Tablets
Sweden	Valaciclovir Viatris

This leaflet was last approved in December 2024

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