

Package leaflet: Information for the patient

Myval 500 mg film-coated tablets

valaciclovir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Myval is and what it is used for

Myval contains the active substance valaciclovir hydrochloride, hydrate. Myval belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

Myval can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)
- treat and prevent HSV infections of the eye that continue to come back (in adults and adolescents over 12 years old).

2. What you need to know before you take Myval

Do not take Myval:

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or pharmacist before taking Myval.

Warnings and precautions

Talk to your doctor or pharmacist before taking Myval if:

- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Myval.

Prevent passing genital herpes on to others

If you are taking Myval to treat or prevent genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Children under 12 years of age

This medicine is not recommended for children under 12 years of age.

Other medicines and Myval

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

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

Always tell your doctor or pharmacist about other medicines if you are taking Myval for the treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Myval is not usually recommended for use during pregnancy. If you are pregnant, or think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will weigh up the benefit to you against the risk to your baby of taking Myval while you are pregnant or breast-feeding.

Driving and using machines

Valaciclovir may cause side effects that affect your ability to drive. Do not drive or use machines unless you are sure you are not affected.

3. How to take Myval

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on why your doctor has prescribed Myval for you. Your doctor will discuss this with you.

Treatment of shingles

- The recommended dose is 1000 mg (one 1000 mg tablet or two 500 mg tablets) three times a day.
- You should take Myval for seven days.

Treatment of cold sores

- The recommended dose is 2000 mg (two 1000 mg tablets or four 500 mg tablets) twice a day.
- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose.
- You should take Myval for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The recommended dose is 500 mg (one 500 mg tablet) twice a day.
- For the first infection you should take Myval for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them

- The recommended dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250 mg tablet twice a day. For doses less than 500 mg, Myval is not suitable. Lower strengths of other valaciclovir medicinal products are available. Your doctor will advise you accordingly.
- You should take Myval until your doctor tells you to stop.

To stop you being infected with CMV (*Cytomegalovirus*)

- The recommended dose is 2000 mg (two 1000 mg tablets or four 500 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Myval as soon as possible after your surgery.
- You should take Myval for around 90 days after your surgery, until your doctor tells you to stop.

Use in children under 12 years of age

Valaciclovir is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy.

Your doctor may adjust the dose of Myval if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems.

Talk to your doctor before taking Myval if any of the above apply to you.

Method of administration

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Myval at the same time each day.
- Take Myval according to instructions from your doctor or pharmacist.

Older people over 65 years of age or with kidney problems

It is very important while you are taking Myval that you drink water regularly during the day.

This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you take more Myval than you should

Myval is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, be confused, agitated or unusually sleepy, see, feel or hear things that are not there (hallucinations), have kidney problems where you pass little or no urine or lose consciousness (coma). Talk to your doctor or pharmacist if you take too much Myval. Take the medicine pack with you.

If you forget to take Myval

- If you forget to take Myval, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

If you stop taking Myval

Do not stop taking this medicine without consulting your doctor.

If you have any further questions on the use of this medicine, ask 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 in the beginning of treatment and become milder or stop altogether within a few weeks. Sometimes it is difficult to tell the difference between symptoms of an illness and side effects.

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

Rare (may affect up to 1 in 1,000 people)

- severe allergic reactions (anaphylaxis). Rapid development of symptoms including:
 - flushing, itchy skin rash
 - swelling of the lips, face, neck and throat, causing difficulty in breathing (angiodema)
 - fall in blood pressure leading to collapse
- kidney problems where you pass little or no urine
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma) confused or disturbed thoughts (psychoses).

Other side effects include:

Very common (may affect more than 1 in 10 people)

- headache

Common (may affect up to 1 in 10 people)

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction including after exposure to sunlight (photosensitivity)
- rash.

Uncommon (may affect up to 1 in 100 people)

- feeling confused
- seeing or hearing things that aren't there (hallucinations)
- feeling very drowsy
- tremors
- feeling agitated.

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Myval a day. They usually get better when Myval is stopped or the dose reduced.

Other uncommon side effects:

- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)
- blood in the urine

Uncommon side effects that may show up in blood tests:

- reduction in the number of white blood cells (leucopenia)
- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver.

Rare (may affect up to 1 in 1,000 people)

- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Myval a day. They usually get better when Myval is stopped or the dose reduced.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Myval

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and foil after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Myval contains

- The active substance is valaciclovir hydrochloride, hydrate. Each film-coated tablet contains valaciclovir hydrochloride, hydrate equivalent to 500 mg of valaciclovir.
- The other ingredients in the tablet core are: cellulose, microcrystalline; crospovidone; povidone and magnesium stearate.
- The ingredients in the coating are: titanium dioxide (E171); macrogol 400; polysorbate 80 (E433) and hypromellose (E464).

What Myval looks like and contents of the pack

Myval are white to off-white, capsule-shaped, biconvex film-coated tablets.

500 mg film-coated tablets have “VC 500” on one side and “G” on the other side.

Myval is available in blister strips in packages of 10, 21, 24, 30, 42, 60, 90, 100 and 112 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Generics [UK] Ltd., Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Valaciclovir Arcana 500 mg, 1000 mg - Filmtabletten
Czech Republic	Valacilovir Mylan 500 mg, potahované tablety
Denmark	Valaciclovir Mylan
Finland	Valaciclovir Mylan
Ireland	Myval
Italy	Valaciclovir Mylan Generics
Norway	Valaciclovir Mylan
Sweden	Valaciclovir Mylan
The Netherlands	Valaciclovir Mylan 500 mg, filmomhulde tabletten

This leaflet was last revised in 05/2015