

Package leaflet: Information for the patient

Valotix 500mg 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 Valotix is and what it is used for
2. What you need to know before you take Valotix
3. How to take Valotix
4. Possible side effects
5. How to store Valotix
6. Contents of the pack and other information

1. What Valotix is and what it is used for

Valotix 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).

Valotix 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 Valotix

Do not take Valotix

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine listed in section 6
 - if you have ever developed an extended rash associated with fever, enlarged lymph node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.
- ➔ Do not take Valotix if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valotix.

Warnings and precautions

Check with your doctor or pharmacist before taking Valotix 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 Valotix.

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking valaciclovir and contact your doctor or seek medical attention immediately.

Prevent passing genital herpes on to others

If you are taking Valotix 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.

Other medicines and Valotix

Tell your doctor or pharmacist if you are taking or have recently taken 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 Valotix for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valotix is not usually recommended for use during pregnancy. If you are pregnant, or think you could be, or if you are planning to become pregnant, don't take Valotix without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valotix while you are pregnant or breastfeeding.

Driving or using machines

Valotix can 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 Valotix

Always take this medicine exactly as your doctor 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 Valotix for you. Your doctor will discuss this with you.

Treatment of shingles

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

Treatment of cold sores

- The usual 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 Valotix for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The usual dose is 500 mg (one 500 mg tablet or two 250 mg tablets) twice a day.
- For the first infection you should take Valotix 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 usual 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.
- You should take Valotix until your doctor tells you to stop.

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

- The usual 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 Valotix as soon as possible after your surgery.
- You should take Valotix for around 90 days after your surgery, until your doctor tells you to stop.

Your doctor may adjust the dose of Valotix if:

- you are over 65 years of age
 - you have a weak immune system
 - you have kidney problems.
- Talk to your doctor before taking Valotix if any of the above apply.

Taking this medicine

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

People over 65 years of age or with kidney problems

It is very important while you are taking Valotix 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 Valotix than you should

Valotix is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, get kidney problems, may be confused, agitated, feel less aware, see things that are not there, or become unconscious. Talk to your doctor or pharmacist if you take too much Valotix. Take the medicine pack with you.

If you forget to take Valotix

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Conditions you need to look out for

- severe allergic reactions (*anaphylaxis*). These are rare in people taking Valotix. 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.
- If you have an allergic reaction, stop taking Valotix and see a doctor straight away.

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 after exposure to sunlight (*photosensitivity*).
- rash
- itching (*pruritus*).

Uncommon (may affect up to 1 in 100 people)

- feeling confused
- seeing or hearing things that are not 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 Valotix a day. They usually get better when Valotix 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 urine (*haematuria*).

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*)
- fits (convulsions)
- altered brain function (*encephalopathy*)
- unconsciousness (*coma*)
- confused or disturbed thoughts (*delirium*).

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 Valotix a day. They usually get better when Valotix is stopped or the dose reduced.

Other rare side effects:

- kidney problems where you pass little or no urine.

Not known (cannot be estimated from the available data):

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.
- an inflammation of the kidneys (tubulointerstitial nephritis).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRC Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Valotix

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 cartons and blisters after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Valotix contains

- The active substance is valaciclovir.

Each film-coated tablet contains 556.275 mg valaciclovir hydrochloride equivalent to 500 mg of valaciclovir.

- The other ingredients are crospovidone, microcrystalline cellulose, povidone, magnesium stearate, hypromellose, titanium dioxide (E171), macrogol 400 and polysorbate 80.

What Valotix looks like and contents of the pack

White to off-white capsule shaped film coated tablets with “500” debossed on one side and plain on other side.

The tablets are packed in PVC/PE/PVDC/Aluminium-blisters.

Pack sizes:

Carton box with blister(s) containing: 10, 30, 42 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers**Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

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

Denmark:	Valaciclovir “Hexal”
Germany:	Valaciclovir HEXAL 500 mg Filmtabletten Valaciclovir HEXAL 1000 mg Filmtabletten
Ireland:	Valotix 500 mg film-coated tablets

This leaflet was last revised in 12/2022.