Package Leaflet: Information for the User

Valtrex® 500mg film-coated tablets

(valaciclovir hydrochloride)

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. 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.

The name of your medicine is Valtrex 500mg film-coated tablets but will be referred to as Valtrex throughout this leaflet. Please note that this leaflet also contains information about other strength Valtrex 250mg film-coated tablets.

What is in this leaflet:

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

1. What Valtrex is and what it is used for

Valtrex 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).
Valtrex 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 Valtrex

Do not take Valtrex

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

→ Don't take Valtrex if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valtrex.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valtrex if:

- **you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking valaciclovir or aciclovir**
- **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 Valtrex.

Take special care with Valtrex – Important Information:

Valtrex can cause severe skin reactions. Stop using Valtrex and seek medical attention immediately if you notice any of the symptoms of severe skin reactions described in section 4.

Prevent passing genital herpes on to others

If you are taking Valtrex 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 Valtrex

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 Valtrex for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valtrex 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 Valtrex without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valtrex while you're pregnant or breastfeeding.

Driving and using machines

Valtrex can cause side effects that affect your ability to drive.

→ Don't drive or use machines unless you are sure you're not affected.

3. How to take Valtrex

Always take this medicine exactly as your doctor has told you. You should 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 Valtrex for you. Your doctor will discuss this with you.

Treatment of shingles

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

Treatment of cold sores

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

Treatment of HSV infections of the skin and genital herpes

- The usual dose is 500mg (one 500mg tablet or two 250mg tablets) twice a day.
- For the first infection you should take Valtrex 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 500mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250mg tablet twice a day.
- You should take Valtrex until your doctor tells you to stop.

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

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

Your doctor may adjust the dose of Valtrex if:

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

➔ Talk to your doctor before taking Valtrex if any of the above apply.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valtrex at the same time each day.
- Take Valtrex 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 Valtrex 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 Valtrex than you should
Valtrex 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 aren't there, or become unconscious. Talk to your doctor or pharmacist if you take too much Valtrex. Take the medicine pack with you.

If you forget to take Valtrex
- If you forget to take Valtrex, 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.

Conditions you need to look out for:

→ **Stop using Valtrex and seek medical attention immediately if you notice any of the following symptoms:**

Severe allergic reactions (*anaphylaxis*). These are rare in people taking Valtrex. 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.

Serious skin reactions.

These are very rare in people taking Valtrex. Signs include:
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment [acute generalised exanthematous pustulosis (AGEP)].

These frequencies are not known, signs include:
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN)].

The following side effects may also happen with this medicine:

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

Other rare side effects:
- kidney problems where you pass little or no urine.

Frequency Not Known (cannot be estimated from the available data)
- 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 possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Valtrex

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.
If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

The active ingredient in the Valtrex is valaciclovir.
Each tablet contains 500mg valaciclovir (as hydrochloride).
The other ingredients are:
Tablet core: microcrystalline cellulose, crospovidone, povidone, magnesium stearate, silica colloidal anhydrous
Film coat: hypromellose, titanium dioxide, macrogol 400, polysorbate 80, carnauba wax.

What Valtrex looks like and contents of the pack
Valtrex is white, biconvex, elongated, film-coated tablet with a white to off-white core, engraved 'GX CF1' on one side and plain on other side.
It is available in blister packs of 10 or 42 film-coated tablets.

Manufacturered by:
Delpharm Poznan Spolka Akcyjna, ul. Grunwaldzka 189, Poznan, 60-322, Poland.
OR
GlaxoSmithKline Pharmaceuticals S.A., ul. Grunwaldzka 189, Poznan, 60-322, Poland.
OR
Glaxo Wellcome, S.A., Avda. Extremadura, 3, Pol. Ind. Allendeduero, Aranda de Duero, Burgos, 09400, Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Valtrex® 500mg film-coated tablets; PL 18799/4010
Leaflet date: 28.07.2026 **POM**
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Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

Package Leaflet: Information for the User

Valaciclovir 500mg film-coated tablets

(valaciclovir hydrochloride)

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- 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. 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.

The name of your medicine is Valaciclovir 500mg film-coated tablets but will be referred to as Valaciclovir throughout this leaflet. Please note that this leaflet also contains information about other strength Valaciclovir 250mg tablets.

What is in this leaflet:

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

1. What Valaciclovir is and what it is used for

Valaciclovir 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).
Valaciclovir 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 Valaciclovir

Do not take Valaciclovir

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

→ Don't take Valaciclovir if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir.

Warnings and precautions
Talk to your doctor or pharmacist before taking Valaciclovir if:

- **you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking valaciclovir or aciclovir**
- **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 Valaciclovir.

Take special care with Valaciclovir – Important Information:
Valaciclovir can cause severe skin reactions. Stop using Valtrex and seek medical attention immediately if you notice any of the symptoms of severe skin reactions described in section 4.

Prevent passing genital herpes on to others
If you are taking Valaciclovir 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 Valaciclovir
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 Valaciclovir for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding
Valaciclovir 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 Valaciclovir without checking with your doctor. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir while you're pregnant or breastfeeding.

Driving and using machines
Valaciclovir can cause side effects that affect your ability to drive.

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3. How to take Valaciclovir

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

Treatment of shingles

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

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- The usual dose is 2000mg (two 1000mg tablets or four 500mg tablets) twice a day.
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- You should take Valaciclovir for one day (two doses) only.

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- For the first infection you should take Valaciclovir 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 500mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250mg tablet twice a day.
- You should take Valaciclovir until your doctor tells you to stop.

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

Your doctor may adjust the dose of Valaciclovir if:

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

➔ Talk to your doctor before taking Valaciclovir if any of the above apply.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valaciclovir at the same time each day.
- Take Valaciclovir 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 Valaciclovir 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 Valaciclovir than you should
Valaciclovir 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 aren't there, or become unconscious. Talk to your doctor or pharmacist if you take too much Valaciclovir. Take the medicine pack with you.

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- If you forget to take Valaciclovir, 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.

4. Possible side effects

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

Conditions you need to look out for:

→ **Stop using Valaciclovir and seek medical attention immediately**
if you notice any of the following symptoms:

Severe allergic reactions (*anaphylaxis*). These are rare in people taking Valaciclovir. 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.

Serious skin reactions.
These are very rare in people taking Valaciclovir. Signs include:
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment [acute generalised exanthematous pustulosis (AGEP)].

These frequencies are not known, signs include:
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN)].

The following side effects may also happen with this medicine:

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 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 Valaciclovir a day. They usually get better when Valaciclovir 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*)
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Other rare side effects:
- kidney problems where you pass little or no urine.

Frequency Not Known (cannot be estimated from the available data)
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Reporting of side effects
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By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Valaciclovir

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.
If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

The active ingredient in the Valaciclovir is valaciclovir.
Each tablet contains 500mg valaciclovir (as hydrochloride).
The other ingredients are:
Tablet core: microcrystalline cellulose, crospovidone, povidone, magnesium stearate, silica colloidal anhydrous
Film coat: hypromellose, titanium dioxide, macrogol 400, polysorbate 80, carnauba wax.

What Valaciclovir looks like and contents of the pack
Valaciclovir is white, biconvex, elongated, film-coated tablet with a white to off-white core, engraved 'GX CF1' on one side and plain on other side.
It is available in blister packs of 10 or 42 film-coated tablets.

Manufacturered by:
Delpharm Poznan Spolka Akcyjna, ul. Grunwaldzka 189, Poznan, 60-322, Poland.
OR
GlaxoSmithKline Pharmaceuticals S.A., ul. Grunwaldzka 189, Poznan, 60-322, Poland.
OR
Glaxo Wellcome, S.A., Avda. Extremadura, 3, Pol. Ind. Allendeduero, Aranda de Duero, Burgos, 09400, Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Valaciclovir 500mg film-coated tablets; PL 18799/4010
Leaflet date: 28.07.2026 **POM**

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