

AXCEL VALACYCLOVIR-500 TABLET

Valacyclovir Hydrochloride Dihydrate (500mg)

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What Axcel Valacyclovir-500 Tablet is used for

Axcel Valacyclovir-500 Tablet is used for:

- treatment of herpes zoster (shingles)
- treatment of herpes simplex infections (viral infections that produce cold sores around the mouth or sores in the genital area)
- prevention (suppression) of recurrent herpes simplex infections
- reduction of transmission of genital herpes

How Axcel Valacyclovir-500 Tablet works

Valacyclovir works by stopping the herpes virus from multiplying and attacking the nearby healthy cells. This action helps to treat herpes viral infection of the skin.

Before you use Axcel Valacyclovir-500 Tablet

When you must not use it

Do not use Axcel Valacyclovir-500 Tablet:

- If you are allergic or hypersensitive to valacyclovir or acyclovir.

Before you start to use it

Tell your doctor:

- If you have kidney or liver problems.
- If you are pregnant or breastfeeding.

Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Valacyclovir-500 Tablet:

- Cimetidine (medicine used to treat and prevent heartburn from acid indigestion in the stomach)
- Probenecid (medicine used to treat gout)
- Cyclosporin, tacrolimus, and mycophenolate mofetil (medication to prevent rejection of organ transplant)

How to use Axcel Valacyclovir-500 Tablet

How much to use

Treatment of herpes zoster:

Adult: 1g, three times daily for 7 days.

Treatment of herpes simplex infections:

Adult: 500mg twice daily. For recurrent episode, treatment should be for 5 days; for initial episodes, which can be more severe, treatment may have to be extended to 10 days. Dosing should begin as early as possible. For recurrent episodes of herpes simplex, this should ideally be during the prodromal period or immediately the first signs or symptoms appear.

Suppression (Prevention) of recurrences of herpes simplex infections

In immunocompetent (with a normal immune system) adult:

500mg to be taken once daily. Some people with very frequently recurrences (e.g. 10 or more per year) may gain additional benefit from the daily dose of 500mg being taken as a divided dose (250mg, twice daily).

For immunocompromised (with a impaired immune system) adult:

500 mg twice daily.

Reduction of transmission of genital herpes:

In immunocompetent heterosexual adult with 9 or fewer recurrences per year, 500mg daily should be taken by infected partner in order to reduce

transmission to a sexual partner negative for HSV-2 antibodies (have not been infected by HSV-2 virus). Safer sex practices (particularly condom use) should be maintained, and sexual contact avoided if lesions are present. There are no data on the reduction of transmission beyond 8 months in other populations.

If you have kidney problems:

Dosage may need to be reduced if you have kidney problems, as shown in the table below.

Indication	Creatinine clearance (ml/min)	Dose
Herpes zoster	15-30	1g twice a day
	Less than 15	1g once a day
On haemodialysis	-	1g daily after haemodialysis
Herpes simplex (treatment)	15-30	No modification
	Less than 15	500mg once a day
On haemodialysis	-	500mg daily after haemodialysis

Indication	Creatinine clearance (ml/min)	Dose
Prevention of herpes simplex	Less than 15	250mg once a day
	-	250mg daily after haemodialysis
On haemodialysis	-	500mg once a day
Immuno-compromised	Less than 15	500mg once a day
On haemodialysis	-	500mg daily after haemodialysis

If you have kidney problems:

Studies do not indicate the need for dosage adjustment; however, clinical experience is limited.

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Dosage in children:

There are no data available on the use of valacyclovir in children.

Dosage in elderly:

Dosage modification is not required unless kidney function is significantly impaired (see If you have kidney problems above). Adequate hydration should be maintained.

When to use it

Your doctor will decide when it is appropriate for you to take Axccl Valacyclovir-500 Tablet according to the type of condition you have.

How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

If you forget to use it

- Do not double up the dosage as Axccl Valacyclovir-500 Tablet may give you unacceptable side effects.

If you use too much (overdose)

You must inform your doctor immediately if you have taken too much Axccl Valacyclovir-500 Tablet. Symptoms of overdosage after oral administration include:

- Nausea
- Vomiting
- Headache
- Confusion

While you are using it

Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if you need to take any other medicines.
- Take the Axccl Valacyclovir-500 Tablet according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

Things to be careful of

- Avoid prolonged use with high dosage.

Side effects

Like all medicines, Axccl Valacyclovir-500 Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information.

Common side effects:

- Headache
- Nausea

Rare side effects:

- Dizziness
- Abdominal discomfort
- Vomiting
- Diarrhea
- Pruritus (itching)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting).

Storage and disposal of Axccl Valacyclovir-500 Tablet

Storage

Keep Axccl Valacyclovir-500 Tablet out of reach of children.

Store below 25°C. Keep container well closed and protect from light.

Disposal

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.

Product description

What it looks like

Axccl Valacyclovir-500 Tablet is a white to off white, film-coated, oblong tablet.

Ingredients

Active Ingredient:

Valacyclovir Hydrochloride Dihydrate

Inactive Ingredients:

Microcrystalline Cellulose, Povidone K90, Povidone CL, Magnesium Stearate, Colloidal Silicon Dioxide, Isopropyl Alcohol and Purified Water

MAL Number

MAL09042417A

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

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16/06/2015

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