Prevalgan 450mg Tablets

(Valganciclovir)

پری وَلگن

(ولگنسی کلور)

۴۵۰ ملی گرام

گولیاں

COMPOSITION
Each film coated tablet contains:
Valganciclovir Hydrochloride (USP)
Eq. to Valganciclovir 450mg
Product complies USP specs.

WARNING: HEMATOLOGIC TOXICITY, CARCINOGENICITY, TERATOGENICITY, AND IMPAIRMENT OF FERTILITY

See full prescribing information for complete Boxed Warning.
Clinical toxicity of valganciclovir, which is metabolized to ganciclovir, includes granulocytopenia, anemia, and thrombocytopenia.
• In animal studies, ganciclovir was carcinogenic, teratogenic, and caused aspermatogenesis.

MECHANISM OF ACTION:
In the body the active ingredient in the tablets, valganciclovir, is changed into ganciclovir. Ganciclovir prevents a virus called cytomegalovirus (CMV) from multiplying and invading healthy cells. In patients with a weakened immune system, CMV can cause an infection in the body's organs. This can be life-threatening.

INDICATIONS:
• For the treatment of CMV infections of the retina of the eye in adult patients with acquired immunodeficiency syndrome (AIDS). CMV infection of the retina of the eye can cause vision problems and even blindness.
• To prevent CMV-infections in adults and children who are not infected with CMV and who have received an organ transplant from somebody who was infected by CMV.

WARNINGS AND PRECAUTIONS
• Allergic to aciclovir, penciclovir, valaciclovir or famciclovir, which are medicines used to treat other virus infections.
• Low numbers of white blood cells, red blood cells or platelets (small cells involved in blood clotting) in your blood. Your doctor will carry out blood tests before you start taking Valganciclovir 450 mg Film-coated Tablets and more tests will be done while you are taking the tablets.
• If you are having radiotherapy or blood dialysis.

Mutagenicity, Teratogenicity, Carcinogenicity, Fertility, and Contraception
Prior to the initiation of valganciclovir treatment, patients should be advised of the potential risks to the fetus. In animal studies, ganciclovir was found to be mutagenic, teratogenic, carcinogenic, and a suppressor of fertility. Prevalgan should, therefore, be considered a potential teratogen and carcinogen in humans with the potential to cause birth defects and cancers. Based on clinical and nonclinical studies it is also considered likely that Prevalgan causes temporary or permanent inhibition of spermatogenesis. Women of child bearing potential must be advised to use effective contraception during and for at least 30 days after treatment.
Valganciclovir has the potential to cause carcinogenicity and reproductive toxicity in the long term.

Myelosuppression
Severe leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia, bone marrow failure and aplastic anemia have been observed in patients treated with Prevalgan (and ganciclovir). Therapy should not be initiated if the absolute neutrophil count is less than 500 cells/µl, or the platelet count is less than 25000/µl, or the hemoglobin level is less than 8 g/dl.
It is recommended that complete blood counts and platelet counts should be monitored regularly during therapy. Increased hematological monitoring may be warranted in patients with renal impairment and pediatrics.

DRUG INTERACTIONS:
Tell your doctor if you are already taking medicines that contain any of the following:

• Imipenem-cilastatin (an antibiotic). Taking it with Valganciclovir 450 mg Film-coated Tablets can cause convulsions (fits).
• Zidovudine, didanosine, stavudine, tenofovir, or similar kinds of medicines used to treat AIDS.
• Adefovir (used to treat Hepatitis B).
• Probenecid (a medicine used to treat gout). Taking probenecid and Valganciclovir 450 mg film coated tablets at the same time could increase the amount of ganciclovir in your blood.
• Mycophenolate mofetil, ciclosporin or tacrolimus (used after transplantations).
• Vincristine, vinblastine, doxorubicin, hydroxyurea or similar kinds of medicines to treat cancer.
• Trimethoprim, trimethoprim/sulpha combinations and dapsone (antibiotics).
• Pentamidine (medicine to treat parasite or lung infections).
• Flucytosine or amphotericin B (anti-fungal agents).

PREGNANCY, BREAST-FEEDING AND FERTILITY
If you are pregnant, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
You should not take Valganciclovir 450 mg Film-coated Tablets if you are pregnant unless your doctor recommends it. Taking Valganciclovir 450 mg film coated tablets when you are pregnant could harm your unborn baby.

Breast-feeding
Do not take Valganciclovir 450 mg Film-coated Tablets if you are breast-feeding. If your doctor wants you to begin treatment with Valganciclovir 450 mg film coated tablets you must stop breast-feeding before you start to take this medicine.
Women of child-bearing age must use effective contraception when taking Valganciclovir 450 mg Film-coated Tablets and for at least 30 days after treatment has finished.
Men whose partners could become pregnant should use condoms while taking Valganciclovir 450 mg film coated tablets and should continue to use condoms for 90 days after treatment has finished.

DRIVING AND USING MACHINES
Do not drive or use any tools or machines if you feel sleepy, dizzy, tired, shaky or confused while taking this medicine.
Ask your doctor or pharmacist for advice before taking any medicine.

DOSAGE:
Adults
Prevention of CMV disease in transplant patients: The recommended dose is two tablets taken ONCE daily within 10 days of transplant.

Treatment of active CMV retinitis in AIDS patients (called induction treatment:
The recommended dose is two tablets taken TWICE a day for 21 days (three weeks).

Longer term treatment to prevent recurrence of active inflammation in AIDS patients with CMV retinitis (called maintenance treatment):
The recommended dose is two tablets taken ONCE daily. You should try to take the tablets at the same time each day.

Elderly people:
Valganciclovir 450 mg Film-coated Tablets has not been studied in elderly patients.

Patients with kidney problems:
If your kidneys are not working properly, your doctor may instruct you to take fewer tablets each day or only to take your tablets on certain days each week.

Patients with liver problems:
Valganciclovir 450 mg Film-coated Tablets has not been studied in patients with liver problems.

Use in children and adolescents:
Prevention of CMV disease in transplant patients:
Children should start to take this medicine within 10 days of their transplant. The dose given will vary depending on the age of the child and should be taken ONCE daily. Your doctor will decide the most appropriate dose based on your child's height, weight and kidney function. Your child should continue with this dose for up to 100 days following their transplant. If your child has received a kidney transplant, your doctor may advise to take the dose for 200 days.

OVERDOSE:
Contact your doctor or hospital immediately if you have taken, or think that you have taken, more tablets than you should. Taking too many tablets can cause serious side effects, particularly affecting your blood, liver or kidneys. Other side effects may include stomach pain, being sick, diarrhoea, fits and shaking. You may need hospital treatment.

If you forget to take Valganciclovir 450 mg Film-coated Tablets
If you forget to take your tablets take the missed dose as soon as you remember and take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Valganciclovir 450 mg Film-coated Tablets
Do not stop taking your medicine unless your doctor tells you to.

ADVERSE EFFECTS:
• Frequent infections, such as fever, chills, sore throat or mouth ulcers.
• Feeling short of breath or tired, palpitations or pale skin.
• Loss of appetite, headache , diarrhea, feeling of being sick & tiredness.
• Bleeding or bruising more easily than usual, blood in urine or stools or bleeding from gums, the bleeding could be severe.
• Inflammation of the pancreas (pancreatitis): where you may notice severe upper stomach pain and back, often with nausea and vomiting, sepsis, macular oedema & retinal detachment.

PRESENTATION
Prevalgan 450mg tablet is available in blister packs of 30's.
Prevalgan 450mg tablet is available in blister packs of 60's.

STORAGE CONDITIONS AND INSTRUCTIONS
• Store below 30°C in a dry place, protect from light.
• To be dispensed on the prescription of a registered medical practitioner only.
• Keep out of the reach of children.

ہدایات:

- خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

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