

Drug Information Sheet("Kusuri-no-Shiori")

Internal

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The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: VALACICLOVIR TABLETS 500mg "CEO"

Active ingredient: Valaciclovir hydrochloride

Dosage form: white to slightly yellow tablet, major axis: 17.6 mm, minor axis: 8.8 mm, thickness: 5.3 mm

Print on wrapping: バラシクロビル錠 500mg「CEO」、バラシクロビル, 500mg, VALACICLOVIR 500mg「CEO」、バラシクロビル, 500mg, CEO601



Effects of this medicine

This medicine inhibits viral DNA synthesis and suppresses growth of herpes simplex virus and varicella-zoster virus. It is usually used to treat herpes simplex, herpes zoster, chickenpox, and to suppress onset of herpes simplex infection associated with hematopoietic stem cell transplantation, and to suppress recurrence of genital herpes.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
If you have renal disorder.
If you are on dialysis.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

• Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))

• [Adults]

Herpes simplex: In general, for adults, take 1 tablet (500 mg of valaciclovir) at a time, twice a day.

Suppression of onset of herpes virus infection (herpes simplex) associated with hematopoietic stem cell

transplantation: In general, for adults, take 1 tablet (500 mg of valaciclovir) at a time, twice a day from 7 days prior to hematopoietic stem cell transplantation to 35 days after transplantation.

Herpes zoster: In general, for adults, take 2 tablets (1,000 mg of valaciclovir) at a time, 3 times a day.

Suppression of recurrent genital herpes: In general, for adults, take 1 tablet (500 mg of valaciclovir) at a time, once a day. The dosage or frequency of doses may differ according to the symptoms.

Chickenpox: In general, for adults, take 2 tablets (1,000 mg of valaciclovir) at a time, 3 times a day.

[Children]

Herpes simplex: In general, for children who weigh more than 40kg, take 1 tablet (500 mg of valaciclovir) at a time, twice a day.

Suppression of onset of herpes virus infection (herpes simplex) associated with hematopoietic stem cell

transplantation: In general, for children who weigh more than 40kg, take 1 tablet (500 mg of valaciclovir) at a time, twice a day from 7 days prior to hematopoietic stem cell transplantation to 35 days after transplantation.

Herpes zoster: In general, for children who weigh more than 40kg, take 2 tablets (1,000 mg of valaciclovir) at a time, 3 times a day.

Chickenpox: In general, for children who weigh more than 40kg, take 2 tablets (1,000 mg of valaciclovir) at a time, 3 times a day.

Suppression of recurrent genital herpes: In general, for children who weigh more than 40kg, take 1 tablet (500 mg of valaciclovir) at a time, once a day. For patients with HIV infection (CD4 lymphocytes counts of 100/mm³ and over), take 1 tablet (500 mg of valaciclovir) at a time, twice a day.

In any case, the dosage or frequency of doses may differ according to the underlying disease. Strictly follow the instructions.

- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Take a larger amount of water than usual while you are on this medicine. However, if you have been instructed to restrict fluid intake, consult with your doctor or pharmacist.
- The medicine may cause consciousness disorder. Pay close attention when you perform dangerous operations such

as driving a car. Patients with renal dysfunction are more susceptible to consciousness disorder, so avoid operating dangerous machinery if instructed to do so by your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, decreased consciousness such as sleepiness, abdominal pain, nausea, diarrhea, and hypersensitivity (rash, hives, itch, and photosensitivity). If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- respiratory distress, redness with generalized itching, palpitation [anaphylactic shock, anaphylaxis]
- decreased urine output, edema, headache [acute renal failure]
- decreased consciousness, hallucination, convulsion [neuropsychiatric symptom]
- fever, mucosal redness/erosion, erythema [toxic epidermal necrolysis, Stevens–Johnson syndrome]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [hepatitis, liver dysfunction, jaundice]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.