

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 "SPKK"

Active ingredient: Valaciclovir hydrochloride

Dosage form: white to slightly yellowish white tablet, major axis: 18.5 mm, minor axis: 7.3 mm thickness: 6.1 mm

Print on wrapping: (face) バラシクロビル錠 500mg「SPKK」, JACF1 (back)

VALACICLOVIR500mg バラシクロビル錠 500mg「SPKK」



Effects of this medicine

This medicine suppresses the increase of viruses by inhibiting virus DNA replication.

It is usually used to treat herpes simplex, herpes zoster, chickenpox and as a prophylaxis of herpes simplex infection in patients with hematopoietic stem cell transplantation and 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 disease.
 - 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) 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) at a time, 3 times a day.
 - Chickenpox: In general, for adults, take 2 tablets (1,000 mg) at a time, 3 times a day.
 - Suppression of recurrent genital herpes: In general, for adults, take 1 tablet (500 mg) at a time, once a day. For a patient with HIV infection (CD4 lymphocyte counts of 100/mm³ and over), take 1 tablet (500 mg) at a time, once a day.
- [Children]
 - Herpes simplex: In general, for children who weigh 40kg or more, 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 40kg or more, take 1 tablet (500 mg) 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 40kg or more, take 2 tablets (1,000 mg) at a time, 3 times a day.
 - Chickenpox: In general, for children who weigh 40kg or more, take 2 tablets (1,000 mg) at a time, 3 times a day.
 - Suppression of recurrent genital herpes: In general, for children who weigh 40kg or more, take 1 tablet (500 mg) at a time, once a day. For a patient with HIV infection (CD4 lymphocyte counts of 100/mm³ and over), take 1 tablet (500 mg) at a time, once a day. The dosage or frequency of doses may be adjusted according to the symptoms.
- 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 not 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

- Please take a larger amount of water than usual while you are on this medicine. However, if you have been instructed to restrict fluid intake, please consult with your doctor or pharmacist.
- This medicine may cause reduced consciousness including sleepiness. Take extra care when driving a car or operating dangerous machinery. 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 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.

- breathing difficulty, angioedema, palpitation [anaphylactic shock, anaphylaxis]
- fever, bleeding tendency, general malaise [blood disorder including pancytopenia/agranulocytosis]
- decreased urine output, edema, general malaise [acute renal failure]
- consciousness disturbed (coma), hallucination, convulsion [neuropsychiatric symptom]
- conjunctival hyperemia, erythema with edema on the center, erosions of oral or perineal mucosa [toxic epidermal necrolysis, oculomucocutaneous syndrome]

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.