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## Valtrex (valacyclovir hydrochloride) - Drug Summary

GlaxoSmithKline LLC

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Valtrex  
(valacyclovir hydrochloride)

#### THERAPEUTIC CLASS

Nucleoside analogue

#### DEA CLASS

RX

#### ADULT DOSAGE & INDICATIONS

##### Herpes Labialis (Cold Sores)

2g q12h for 1 day  
Initiate at earliest symptom

##### Genital Herpes

**Initial Episode:** 1g bid for 10 days  
Most effective when given w/in 48 hrs of onset of signs/symptoms

**Recurrent Episodes:** 500mg bid for 3 days  
Initiate at 1st sign/symptom of episode

##### Suppressive Therapy:

##### Normal Immune Function:

1g qd

**Alternative if ≤9 Recurrences/Year:** 500mg qd

##### HIV-1 Infected Patients:

**CD4+ Count ≥100 cells/mm<sup>3</sup>:** 500mg bid

##### Reduction of Transmission:

**≤9 Recurrences/Year:** 500mg qd for the source partner

##### Herpes Zoster

1g tid for 7 days  
Initiate at earliest sign/symptom  
Most effective if initiated w/in 48 hrs of rash onset

#### PEDIATRIC DOSAGE & INDICATIONS

##### Herpes Labialis (Cold Sores)

**≥12 Years:**  
2g q12h for 1 day  
Initiate at earliest symptom

##### Chickenpox

**2-<18 Years:**  
20mg/kg tid for 5 days  
Initiate at earliest sign/symptom  
**Max:** 1g tid

#### DOSING CONSIDERATIONS

##### Renal Impairment

##### Herpes Labialis:

**CrCl 30-49mL/min:** Reduce dose to 1g q12h for 1 day

**CrCl 10-29mL/min:** Reduce dose to 500mg q12h for 1 day

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**CrCl <10mL/min:** Reduce dose to 500mg single dose

**Genital Herpes (Initial Episode):**

**CrCl 10-29mL/min:** 1g q24h

**CrCl <10mL/min:** 500mg q24h

**Genital Herpes (Recurrent Episode):**

**CrCl ≤29mL/min:** 500mg q24h

**Genital Herpes (Suppressive Therapy):**

**Immunocompetent Patients:**

**CrCl ≤29mL/min:** 500mg q24h

**Alternative if ≤9 Recurrences/Year:**

**CrCl ≤29mL/min:** 500mg q48h

**HIV-1 Infected Patients:**

**CrCl ≤29mL/min:** 500mg q24h

**Herpes Zoster:**

**CrCl 30-49mL/min:** Reduce dose to 1g q12h

**CrCl 10-29mL/min:** Reduce dose to 1g q24h

**CrCl <10mL/min:** Reduce dose to 500mg q24h

**Hemodialysis Patients:**

Administer dose after hemodialysis

## ADMINISTRATION

Oral route

Shake oral sus well before using

### Preparation of Oral Sus

**Ingredients for Preparation:** Valtrex caplets 500mg, cherry flavor, and Suspension Structured Vehicle USP-NF (SSV)

1. Use a pestle and mortar to grind the required number of caplets until a fine powder (5 caplets for 25mg/mL sus; 10 caplets for 50mg/mL sus)
2. Add approx 5mL aliquots of SSV to the mortar and triturate the powder until a paste has been produced
3. Continue to add approx 5mL aliquots of SSV to the mortar, mixing thoroughly between additions, until a concentrated sus is produced, to a minimum total quantity of 20mL SSV and a max total quantity of 40mL SSV for both the 25mg/mL and 50mg/mL sus
4. Transfer the mixture to a suitable 100mL measuring flask
5. Transfer the cherry flavor to the mortar and dissolve in approx 5mL of SSV. Once dissolved, add to the measuring flask
6. Rinse the mortar at least 3X w/ approx 5mL aliquots of SSV, transferring the rinsing to the measuring flask between additions
7. Make the sus to volume (100mL) w/ SSV and shake thoroughly to mix
8. Transfer the sus to an amber glass medicine bottle w/ a child-resistant closure

## HOW SUPPLIED

Tab: 500mg, 1g\* \*scored

## WARNINGS/PRECAUTIONS

Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS) in immunocompromised patients reported at doses of 8g qd; immediately d/c if signs/symptoms occur. Acute renal failure reported. Maintain adequate hydration. CNS adverse reactions (eg, agitation, hallucinations, confusion, delirium, seizures, encephalopathy) reported in patients with or without reduced renal function and in those with underlying renal disease who received higher than recommended doses for their level of renal function; d/c if these occur. Caution in elderly and with renal impairment.

## ADVERSE REACTIONS

Headache, N/V, abdominal pain, dysmenorrhea, arthralgia, nasopharyngitis, fatigue, rash, URTIs, pyrexia, decreased neutrophil counts, diarrhea, elevated ALT/AST.

## DRUG INTERACTIONS

Caution with potentially nephrotoxic drugs.

## PREGNANCY AND LACTATION

Category B, caution in nursing.

## MECHANISM OF ACTION

Nucleoside analogue DNA polymerase inhibitor; rapidly converted to acyclovir, which stops replication of herpes viral DNA by competitive inhibition of viral DNA polymerase, incorporation into and termination of growing viral DNA chain, and inactivation of viral DNA polymerase.

## PHARMACOKINETICS

**Absorption:** Rapid. Absolute bioavailability (54.5% acyclovir). Oral administration of variable doses resulted in different parameters. **Distribution:** Plasma protein binding (13.5-17.9%, 9-33% acyclovir); found in breast milk. **Metabolism:** Hepatic/Intestinal (1st pass) to acyclovir and L-valine. **Elimination:** Urine (46%), feces (47%);  $T_{1/2}$ =2.5-3.3 hrs.

## ASSESSMENT

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Assess for hypersensitivity, immunocompromised state, renal impairment, hydration status, pregnancy/nursing status, and possible drug interactions.

## MONITORING

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Monitor for signs/symptoms of renal toxicity, TTP/HUS, CNS effects, and other adverse reactions.

## PATIENT COUNSELING

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Advise to maintain adequate hydration. Inform that drug is not a cure for cold sores or genital herpes. For patients with cold sores, instruct to initiate treatment at earliest symptom of a cold sore; inform that treatment should not exceed 1 day (2 doses) and that doses should be taken 12 hrs apart. For patients with genital herpes, instruct to avoid contact with lesions or sexual intercourse when lesions and/or symptoms are present to avoid infecting partner(s), and to use safe sex practice in combination with suppressive therapy. For patients with herpes zoster, advise to initiate treatment as soon as possible after diagnosis. For patients with chickenpox, advise to initiate treatment at the earliest sign/symptom.

## STORAGE

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15-25°C (59-77°F).

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