Safety profile proven comparable to acyclovir in clinical trials

In recurrent genital herpes, the most common adverse events with VALTREX versus placebo are mild and include headache (17% vs 14%) and nausea (6% vs 8%). For herpes zoster, the most common adverse events with VALTREX versus acyclovir are mild and include nausea (16% vs 19%) and headache (13% vs 13%).

Reference:

BRIEF SUMMARY
VALTREX®
(acyclovir hydrochloride)

Caplets

CONTRAINDICATIONS: VALTREX is contraindicated in patients with a known hypersensitivity or intolerance to acyclovir, acyclovir or any component of the formulation.

WARNINGS: THROMBOTIC THROMBOCTOPENIC PURPURA/HEMOLYTIC UREMATIC SYNDROME (TTP/HUS), in some cases resulting in death, has been reported in patients with advanced HIV disease and also in bone marrow transplant and renal transplant recipients participating in clinical trials of VALTREX. VALTREX is NOT INDICATED FOR THE TREATMENT OF IMMUNOCOMPROMISED PATIENTS. THIS SYNDROME HAS NOT BEEN OBSERVED IN IMMUNOCOMPETENT PATIENTS TREATED WITH VALTREX IN CLINICAL TRIALS.

PRECAUTIONS: The efficacy of VALTREX has not been established in immunocompromised patients or for the treatment of initial genital herpes infection, disseminated herpes zoster, or suppression of recurrent genital herpes.

Dosage adjustment is recommended when administering VALTREX to patients with renal impairment (see DOSAGE AND ADMINISTRATION). Caution should also be exercised when administering VALTREX to patients receiving potential nephrotoxic agents since this may increase the risk of renal dysfunction and/or the risk of reversible central nervous system symptoms such as those that have been reported in patients treated with intravenous acyclovir.

Information for Patients: Herpes Zoster: There are no data on treatment initiated more than 72 hours after onset of the rash rash. Patients should be advised to initiate treatment as soon as possible after a diagnosis of herpes zoster.

Recurrent Genital Herpes: Patients should be informed that VALTREX is not a cure for genital herpes.

OVERDOSAGE: There have been no reports of overdose from the administration of VALTREX. However, it is known that precipitation of acyclovir in renal tubules may occur when the solubility (0.5 mg/mL) is exceeded in the intratubular fluid. In the event of acute renal failure and death, the patient may benefit from hemodialysis until renal function is restored (see DOSAGE AND ADMINISTRATION).

DOSEAGE AND ADMINISTRATION: For complete dosage and administration information, see full product labeling for VALTREX.

Patients with Acute or Chronic Renal Impairment: In patients with reduced renal function, reduction in dosage is recommended (see Table 2).

Table 1
Incidence (%) of Adverse Events in Herpes Zoster and Genital Herpes Study Populations

<table>
<thead>
<tr>
<th>Group</th>
<th>Median age</th>
<th>Median age</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50 years</td>
<td>69</td>
<td>36</td>
</tr>
<tr>
<td>18-50 years</td>
<td>18-79 years</td>
<td></td>
</tr>
</tbody>
</table>

Table 2
Dosages for Patients with Renal Impairment

<table>
<thead>
<tr>
<th>Creatinine Clearance (mL/min)</th>
<th>Dosage for Herpes Zoster</th>
<th>Dosage for General Herpes</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 or less</td>
<td>1 g every 8 hours</td>
<td>500 mg every 12 hours</td>
</tr>
<tr>
<td>30 - 49</td>
<td>1 g every 12 hours</td>
<td>500 mg every 12 hours</td>
</tr>
<tr>
<td>10 - 29</td>
<td>1 g every 24 hours</td>
<td>500 mg every 24 hours</td>
</tr>
<tr>
<td>&lt;10</td>
<td>500 mg every 24 hours</td>
<td>500 mg every 24 hours</td>
</tr>
</tbody>
</table>

U.S. Patent No. 4957924
December 1995

Glaxo Welcome
Glaxo Welcome Inc.
Research Triangle Park, NC 27709

NOTES THAT FOLLOWED THE ISOLATION OF acyclovir-resistant ACV (ACV) in pregnant women. A perspective epidemiologic registry of acyclovir use during pregnancy has been ongoing since 1994. As of December 1994, outcomes of live births have been documented in 280 women exposed to systemic acyclovir during the first trimester of pregnancy. The occurrence rate of birth defects approxi-
Take Your Antiherpetic Experience Beyond Acyclovir...

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VALTREX is indicated for herpes zoster and episodic treatment of recurrent genital herpes in otherwise healthy adults*

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Two caplets TID x 7 days for herpes zoster‡

Proven effective to reduce the pain and discomfort of recurrent genital herpes
May shorten the duration of postherpetic neuralgia vs acyclovir§

WARNING: Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), in some cases resulting in death, has been reported in some severely immunocompromised patients receiving VALTREX in clinical trials. This syndrome has not been observed in otherwise healthy patients receiving VALTREX.

* VALTREX is not indicated for use in immunocompromised patients.
† No data are available on efficacy of treatment started greater than 24 hours after onset of signs and symptoms.
‡ Most effective when therapy is initiated within 48 hours of rash onset.
§ No data are available on efficacy of treatment started greater than 72 hours after rash onset.
§ In patients ≥ 50 years of age. No effect on the incidence of PHN.
Please see brief summary of Prescribing Information on adjacent pages.
**ZOVIRAX® Capsules**

**ZOVIRAX® Tablets**

**ZOVIRAX® Suspension**

(acyclovir)

The following is a brief summary only, see full prescribing information for complete product information, including references.

**CONTRAINDICATIONS:** ZOVIRAX Capsules, Tablets, and Suspension are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulations.

**WARNINGS:** ZOVIRAX Capsules, Tablets, and Suspension are intended for oral use only.

**PRECAUTIONS:**

General: ZOVIRAX has caused decreased spermatic activity at high parental doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility). The recommended dosage should not be exceeded (see DOSAGE AND ADMINISTRATION section of full prescribing information).

Exposure of herpes simplex and varicella-zoster isolates to acyclovir in vitro can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in humans must be borne in mind when treating patients. The relationship between the in vitro sensitivity of herpes simplex or varicella-zoster virus isolates to acyclovir and therapy expected to be achieved (see CLINICAL PHARMACOLOGY: Microbiology section of full prescribing information).

Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immuno-suppressed patients, the physician should be aware that prolonged (30-45 days) remission of acyclovir-resistant virus may result in selection of resistant viruses which may not be responsive to continued acyclovir therapy. Caution should be exercised when administering ZOVIRAX to patients receiving potentially nephrotoxic agents since this may increase the risk of renal dysfunction.

**Information for Patients:** Patients are instructed to consult with their physician if they experience severe or toxic reactions to acyclovir. Patients should not discontinue acyclovir without consulting their physician, they intend to breed while taking orally administered ZOVIRAX, or they have any other questions.

**Genital Herpes Infections:** Genital herpes is a sexually transmitted disease and patients should avoid intercourse during the period when lesions are present because of the risk of infecting intimate partners. ZOVIRAX Capsules, Tablets, and Suspension are for oral ingestion only. Medication should not be shared with others. The prescribed dosage should not be increased. ZOVIRAX does not eliminate latent virus. Patients are instructed to consult with their health care provider if they think they might have genital herpes for the first time.

There are still unanswered questions concerning reproductive/gonadal toxicity and mutagenicity; long-term studies are continuing. Decreased sperm production has been seen at high doses in some animals. A placebo-controlled clinical study using 400 mg or 1000 mg of ZOVIRAX per day for 6 months in humans did not show similar findings. Chromosomal breaks were seen in vitro after three exposure to high concentrations. Some other currently marketed medications also cause chromosomal breaks, and the significance of this finding is unknown. A placebo-controlled clinical study using 700 mg of ZOVIRAX per day for 1 year in humans does not show any abnormalities in structure or number of chromosomes.

**Herpes Zoster Infections:** Adults aged 50 or older tend to have more severe shingles, and treatment with 800 mg/day for 7 days is recommended for older patients who experience shingles, even if they are not immunocompromised.

**Drug Interactions:** The concomitant use of ivaclovir with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly decreased. Simultaneous use of acyclovir with zidovudine is not recommended.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** The data presented below include references to peak steady-state plasma acyclovir concentrations observed in humans treated with 800 mg given orally 4 times daily and intravenous infusions of 5 mg/kg administered over 1 hour and 30 mg/kg/day administered over 1 hour. The terms reported in this section are defined for the purpose of evaluation in laboratory animals and do not apply to man.

- **Carcinogenesis:** In a 2-year carcinogenicity study in mice, no evidence of a carcinogenic effect was observed in the offspring of acyclovir-treated female mice. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In one 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed.

- **Mutagenesis:** In several in vitro assays (in vitro mammalian gene mutation, in vitro mammalian and human lymphocyte transformation assays), no evidence of mutagenic activity was observed. In addition, there was no increase in the number of chromosomal abberations in bone marrow cells of mice treated with acyclovir in vivo. In one study, there was no evidence of a carcinogenic effect in the offspring of acyclovir-treated female mice. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed.

- **Impairment of Fertility:** The data presented below include references to peak steady-state plasma acyclovir concentrations observed in humans treated with 800 mg given orally 4 times daily and intravenous infusions of 5 mg/kg administered over 1 hour and 30 mg/kg/day administered over 1 hour. The terms reported in this section are defined for the purpose of evaluation in laboratory animals and do not apply to man.

- **Carcinogenesis:** In a 2-year carcinogenicity study in mice, no evidence of a carcinogenic effect was observed in the offspring of acyclovir-treated female mice. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed. In a 2-year carcinogenicity study in rats, no increase in the incidence of tumors in the offspring of acyclovir-treated rats was observed. In a 2-year carcinogenicity study in mice, no increase in the incidence of tumors in the offspring of acyclovir-treated mice was observed.
SPECIAL SELECTION

Multiple Painful Oral Ulcerations
Jacqueline M. Junkins-Hopkins, MD

LETTERS TO THE EDITOR

Cost-effective Evaluation of Heart Murmurs in Children
Jeffrey A. Wong, MD;
Richard A. Meyer, MD

Comments of a Consultant to Primary Care Physicians
George W. Paulson, MD

Promoting the Use of Advance Directives: An Empirical Study
Mary Thoesen Coleman, MD, PhD;
Randy Jernecjic

In Reply
Kimber P. Richter, MA;
Stephen B. Fawcett, PhD;
Adrienne Paine-Andrews, PhD;
Sondra Langel; Lucia Biehler, RN;
Robert Manning, MD

ORIGINAL CONTRIBUTIONS

Addiction to Benzodiazepines—How Common?
Stephen A. King, MD, MS
Roland Grad, MD

Running and Its Effect on Family Life
Daniel S. Fick, MD; Stephen J. Goff, PhD;
Robert Oppliger, PhD

Practice Commentary
Mark Andrews, MD

Long-term Incidence of Lower-Extremity Amputations in a Diabetic Population
Scot E. Moss, MA; Ronald Klein, MD;
Barbara E. K. Klein, MD

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See brief summary of Prescribing Information on next page.
anatomic site, oral stimulation, and body position on estimates of body temperature.

**Results:** Mean rectal temperatures exceeded concurrent oral readings by 0.4°C ± 0.4°C (0.8°F ± 0.7°F), which, in turn, exceeded concurrent tympanic membrane readings (obtained with a digital thermometer [IVAC Corp, San Diego, Calif]) by 0.4°C ± 1.1°C (0.7°F ± 2.0°F). Tympanic membrane readings were significantly more variable (both intrasubject and intersubject) than rectal or oral readings, especially when cerumen was present in the external ear canal being examined (P<.05). Mastication and smoking both caused significant increases in oral temperature that persisted for greater than 20 minutes. Drinking ice water caused a significant but more transient decrease in oral temperature. Of these activities, only mastication appeared to influence tympanic membrane readings. Body position exerted a modest effect on rectal temperature readings, but did not significantly affect oral or tympanic membrane readings.

**Conclusions:** These findings indicate that, in addition to diurnal fluctuations in body temperature, the effects of anatomic site, oral stimulation, and body position should be considered in establishing criteria for the febrile state.


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Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of Candida. Studies have shown that a total parenteral diet containing 10% dextrose and 2.5% sodium caseinate results in overgrowth of Candida alone or in conjunction with other organisms.

**PRECAUTIONS**

**General:** Crystals of ciprofloxacin have been observed rarely in the urine of humans who have received ciprofloxacin. Anuria occurs rarely in the urine of laboratory animals, which is usually alkaline. Crystals of ciprofloxacin in the urine of humans indicates alkaline urine. Alkalization of the urine should be avoided in patients receiving ciprofloxacin. Patients should be advised to consult a physician if they observe a change in the color of their urine.

**Drug Interactions:** Alteration of the dosage regimen is necessary for patients with impaired renal function (see DOSAGE AND ADMINISTRATION). These patients should be advised to consult a physician if the urine becomes more concentrated (less frequent urination) or if urine output decreases. MODERATE to severe photophobia manifested by an exaggerated sunburn reaction has been reported rarely in patients dosed to direct or indirect sunlight while receiving ciprofloxacin therapy. Excessive sunlight should be avoided. Therapy should be discontinued if photophobia becomes incapacitating.

**Allergic Reactions:** Patients should be advised to report any manifestations of an allergic nature (cutaneous or systemic) which are associated with this drug. Discontinue ciprofloxacin therapy if adverse reactions occur.

**Pediatric Use:** Use of ciprofloxacin in children and adolescents less than 18 years of age has not been studied (See WARNINGS.)

**Pregnancy and Nursing Mothers:** Use of ciprofloxacin during pregnancy should be restricted to pregnant women who are known or believed to have an infection that is not effectively treated with alternative, more appropriate agents. In women who are pregnant or lactating, ciprofloxacin should only be used if the potential benefit justifies the potential risk to the fetus.

**CIPRO® (ciprofloxacin hydrochloride) Tablets**

**BRIEF SUMMARY**

COMPLETE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

**INDICATIONS AND USAGE**

CIPRO® (ciprofloxacin hydrochloride) is indicated in the treatment of the following infections caused by susceptible bacteria:

- **Urinary tract infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens, and Staphylococcus aureus.

- **Surgical site infections (abscesses) with Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Serratia marcescens, and Pseudomonas aeruginosa.

- **Bacteremia with Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Serratia marcescens, and Pseudomonas aeruginosa.

- **Pneumonia with Haemophilus influenzae, Streptococcus pneumoniae, and Staphylococcus aureus.

- **Inhalation infections (bronchitis, bronchiectasis, cystic fibrosis, and chronic obstructive pulmonary disease) with Pseudomonas aeruginosa, Haemophilus influenzae, and Streptococcus pneumoniae.

- **Skin and skin structure infections with Pseudomonas aeruginosa, Staphylococcus aureus, and Streptococcus pyogenes.

- **Bone and joint infections with Staphylococcus aureus, Staphylococcus epidermidis, and Staphylococcus pyogenes.

- **Abdominal infections with Enterobacter cloacae, Klebsiella pneumoniae, Proteus mirabilis, and Providencia rettgeri.

- **Gastrointestinal infections (bacillary dysentery, amebiasis, and pseudomembranous colitis) with Clostridium difficile.

- **Escherichia coli bacteraemia.

- **Necrotizing enterocolitis and sepsis in neonates.

- **Central Nervous System infections, including meningitis, with Escherichia coli, Klebsiella pneumoniae, and Staphylococcus epidermidis.

- **Anorectal infections with Escherichia coli, Klebsiella pneumoniae, and Enterobacter cloacae.

- **Non-Hodgkin’s lymphoma.

- **Prostatic infections with Escherichia coli, Klebsiella pneumoniae, and Proteus mirabilis.

**CONTRAINDICATIONS**

CIPRO® (ciprofloxacin hydrochloride) is contraindicated in patients with a known or suspected allergy to any member of the quinoline class of antibacterial agents.

**WARNINGS**

**Serious and Life-Threatening Reactions**

**The Safety and Efficacy of Ciprofloxacin in Children**

**ADDENDUM**

Consult the complete prescribing information before administering ciprofloxacin in children. CFU counts should be monitored to assess treatment response. If a failure to respond occurs, an adequate antibiotic therapy regimen should be administered. The safety and efficacy of ciprofloxacin in children have not been established for the following conditions:

- **Rhinitis**

- **Acute and chronic otitis media**

- **Sinusitis**

- **Lower respiratory tract infections**

- **Pneumonia**

- **Acute and chronic bronchitis**

- **Chronic obstructive pulmonary disease**

- **Lower urinary tract infections (excluding gonococcal) and sexually transmitted diseases**

- **Skin and skin structure infections**

- **Central nervous system infections, including meningitis and meningoencephalitis**

- **Hepatic and biliary infections**

- **Prostatic infections**

- **Acute and chronic prostatitis**

**ADVERSE REACTIONS**

**Clinical Trials**

Ciprofloxacin has been evaluated for safety in over 2,000 patients in therapeutic trials. The incidence of adverse reactions generally parallels the incidence of responses to treatment, and the reactions are generally mild and transient. Local reactions at the injection site are reported in almost all patients in therapeutic trials, and the incidence of adverse reactions generally parallels the incidence of responses to treatment.
RALPH'S UTI DIDN'T KEEP HIM UP LAST NIGHT.

(His granddaughter did.)

For a while, the urgency of a UTI secondary to benign prostatic hyperplasia was keeping Ralph awake nights.

Thanks to Cipro®, with 97% clinical efficacy in UTIs, he's sleeping well again. That is, for as long as his granddaughter allows.

Cipro Tablets are indicated for mild/moderate/severe/complicated UTIs caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Serratia marcescens, Proteus mirabilis, Providencia rettgeri, Morganella morganii, Citrobacter diversus, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus epidermidis, Enterococcus faecalis.

NOTE: SERIOUS AND FATAL REACTIONS HAVE BEEN REPORTED IN PATIENTS RECEIVING CONCURRENT ADMINISTRATION OF CIPROFLOXACIN AND THEOPHYLLINE. IF CONCOMITANT USE CANNOT BE AVOIDED, SERUM LEVELS OF THEOPHYLLINE SHOULD BE MONITORED AND DOSAGE ADJUSTMENTS MADE AS APPROPRIATE.

Most frequently reported adverse events (>1%): nausea; diarrhea; vomiting; abdominal pain/discomfort; headache; rash; restlessness.