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The First Leucovorin Rescue With Oral Convenience

As a result of advanced technology, Wellcovorin is the first leucovorin calcium available in convenient tablet form. With Wellcovorin Tablets, no reconstitution of vials, mixing of special solutions, or cumbersome breaking of ampuls is necessary.

For greater flexibility in oral dosing, Wellcovorin Tablets come in two sizes: 5 mg (scored, bottles of 100) and 25 mg (scored, bottles of 25).

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Often discharged from the hospital earlier, many patients can complete their course of therapy on an outpatient basis and return to a more normal, comfortable lifestyle sooner.

Consider Less Costly Care:

Mg for mg, Wellcovorin Tablets are less expensive than injectable leucovorin. Plus, with Wellcovorin Tablets, hospital stays are often shorter and clinic visits less frequent.

Consider Greater Patient Comfort:

Patients no longer need to drink special liquid formulations or endure a series of painful needle punctures. Patients simply take the prescribed number of Wellcovorin Tablets with water.

Consider Assured Blood Levels:

Wellcovorin Tablets are bioequivalent to equal amounts of injectable leucovorin, whether it is administered intravenously or intramuscularly (peak serum concentrations are reached after approximately two hours).


Average serum folates after single 15 mg dose of leucovorin administered either IM or orally. Adapted from Blum, et al.

Please see brief summary of prescribing information on next page.
WELLCOVORIN® TABLETS
(leucovorin calcium)
Leucovorin in convenient
5 mg and 25 mg tablets

Before prescribing WELLCOVORIN® Tablets, please consult complete prescribing information. The following is a brief summary.

INDICATIONS AND USAGE: Wellcovorin (leucovorin calcium) is indicated for the prophylaxis and treatment of undesired hematopoietic effects of folic acid antagonists (see WARNINGS).

CONTRAINDICATIONS: Leucovorin is improper therapy for pernicious anemia and other megaloblastic anemias secondary to the lack of vitamin B12. A hematologic remission may occur while neurologic manifestations remain progressive.

WARNINGS: In the treatment of accidental overdosage of folic acid antagonists, leucovorin should be administered as promptly as possible. As the time interval between antifolate administration (e.g. methotrexate) and leucovorin rescue increases, leucovorin's effectiveness in counteracting hematologic toxicity diminishes.

PRECAUTIONS:
General: Following chemotherapy with folic acid antagonists, parenteral administration of leucovorin is preferable to oral dosing if there is a possibility that the patient may vomit and not absorb the leucovorin. In the presence of pernicious anemia a hematologic remission may occur while neurologic manifestations remain progressive. Leucovorin has no effect on other toxicities of methotrexate, such as the nephrotoxicity resulting from drug precipitation in the kidney.

Drug Interactions: Folic acid in large amounts may counteract the antiepileptic effect of phenobarbital, phenytoin and primidone, and increase the frequency of seizures in susceptible children.

Pregnancy: Teratogenic Effects: Pregnancy Category C.

Animal reproduction studies have not been conducted with Wellcovorin. It is also not known whether Wellcovorin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Wellcovorin should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Wellcovorin is administered to a nursing mother.

Pediatric Use: See "Drug Interactions".

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

OVERDOSAGE: Excessive amounts of leucovorin may nullify the chemotherapeutic effect of folic acid antagonists.

DOSEAGE AND ADMINISTRATION: Leucovorin is a specific antidote for the hematopoietic toxicity of methotrexate and other strong inhibitors of the enzyme dihydrofolate reductase. Leucovorin rescue must begin within 24 hours of antifolate administration. A conventional leucovorin rescue dosage schedule is 10 mg/m² orally or parenterally followed by 10 mg/m² orally every six hours for seventy-two hours. If, however, at 24 hours following methotrexate administration the serum creatinine is 50% or greater than the pre-methotrexate serum creatinine, the leucovorin dose should be immediately increased to 100 mg/m² every three hours until the serum methotrexate level is below 5 x 10⁻⁴ M.¹⁻² The recommended dose of leucovorin to counteract hematologic toxicity from folic acid antagonists with less affinity for mammalian dihydrofolate reductase than methotrexate (i.e. trimethoprim, pyrimethamine) is substantially less and 5 to 15 mg of leucovorin per day has been recommended by some investigators.¹⁻³⁻⁵

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Volume XIV

Edited by

Elmer B. Brown, M.D.

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HERPES SIMPLEX INFECTION IN THE COMPROMISED HOST:
OFTEN SERIOUS, TOO OFTEN UNSUSPECTED

Number one in a series of typical case presentations.

**Esophagitis in a leukemia patient**

In patients with hematologic malignancies, the visceral organ most frequently involved by herpes simplex virus (HSV) infection is the esophagus.1 Extensive ulcerative lesions may develop on the upper two thirds of the esophagus with confluent lesions of the distal third.2 In some cases, however, the mucosa may be grossly unremarkable even when microscopic examination shows evidence of herpetic ulcerative esophagitis.1 Similarly, some patients may display symptoms of dysphagia and burning retrosternal pain,3 whereas others may appear asymptomatic.1 The diagnostic method of choice for patients with suspected herpetic esophagitis is esophagoscopy with visualization of the mucosa and procurement of cytologic and biopsy specimens from ulcerated areas.1

Herpetic infections may result in extensive disease and death

Immunocompromised patients are highly vulnerable to HSV infection. Such infections may interrupt therapy and even lead to death if not detected early and managed aggressively. Although the initial appearance may be mild, HSV infection may progress to severe localized mucocutaneous ulcerations. The greatest threat that herpes simplex poses is an infection that disseminates from a mucocutaneous or unrecognized primary lesion and involves the lungs, liver, esophagus, or central nervous system. Furthermore, herpetic ulcers frequently provide an entry for secondary bacterial and fungal pathogens.

Infections may not be diagnosed correctly without virologic study

Some investigators claim that the actual incidence of serious HSV infection is probably higher than reported because the possibility of herpetic disease is insufficiently considered and appropriate diagnostic viral studies are often not carried out. One study, for example, found histocytologic evidence of visceral herpes infection in 56 patients even though herpetic involvement was not suspected in any of the patients prior to autopsy.

ZOVIRAX I.V. halts viral replication and speeds healing even in debilitated patients

ZOVIRAX I.V. has been shown to be a highly effective treatment for severe mucocutaneous HSV infection in immunocompromised patients. In controlled trials, ZOVIRAX I.V. rapidly halted viral shedding — within 3 days in most patients — and significantly shortened healing time as well as duration of pain. Furthermore, ZOVIRAX I.V. may allow patients to return home sooner and enable patients with intraoral lesions to resume normal eating habits.

ZOVIRAX I.V. is well tolerated by immunocompromised patients

A multicenter collaborative trial of ZOVIRAX I.V. in immunocompromised patients reported that: “Clinical benefits were obtained without appreciable toxicity. The most common reactions were irritation of peripheral veins used for drug infusion and a low incidence of rash. Significant renal or hematologic toxicity did not occur, even in these seriously ill patients who were commonly receiving other drugs concomitantly.”

Note: Approximately 1% of patients receiving intravenous acyclovir have manifested encephalopathic changes. Please see brief summary for more information.

References:

An effective response to a life-threatening infection

ZOVIRAX® I.V. INFUSION (acyclovir sodium) sterile powder
An effective response to a life-threatening infection

ZOVIRAX IV INFUSION (acyclovir sodium) sterile powder

FOR INTRAVENOUS INFUSION ONLY

INDICATIONS AND USAGE: Zovirax Sterile Powder is indicated for the treatment of serious and recurrent genital and cutaneous Herpes simplex (HSV-1 and HSV-2) infections in immunocompromised adults and children. It is also indicated for severe, initial clinical episodes of genital herpes in patients who are not immunocompromised. These indications are based on the results of several double-blind, placebo-controlled studies that evaluated the drug's effect on virus excretion, complete healing of lesions, and relief of pain.

Herpes Simplex Infections in Immunocompromised Patients

In a double-blind, placebo-controlled trial conducted in 28 patients with severe initial episodes of genital herpes with a Zovirax dosage of 5 mg/kg every 8 hours for 5 days (12 patients treated with Zovirax and 16 with placebo), significant treatment effects were seen in elimination of virus from lesions and in reduction of healing times.

In a similar study, 15 patients with initial episodes of genital herpes were treated with Zovirax 5 mg/kg every 8 hours for 5 days and 18 with placebo. Zovirax decreased the duration of viral excretion, new lesion formation, duration of vesicles and provided more rapid healing of all lesions.

Diagnosis

The use of appropriate laboratory diagnostic procedures will help to establish the etiologic diagnosis. Patients with any history of a simplex virus offer a reliable basis for confirmation of the diagnosis. In initial episodes of genital herpes, appropriate excretion of virus should be performed to rule out other sexually transmitted diseases. Whereas cutaneous lesions associated with Herpes simplex infections are often characteristic, the finding of multinucleated giant cells in smears prepared from lesion exudate or scrapings may assist in the diagnosis.

CONTRAINDICATIONS: Zovirax Sterile Powder is contraindicated for patients who develop hypersensitivity to the drug.

WARNING: Zovirax Sterile Powder is intended for intravenous infusion only, and should not be administered topically or intramuscularly subcutaneously, or in the eye. Intravenous infusions must be given over a period of at least (1) hour to avoid renal tubular damage (see PRECAUTIONS AND DOSAGE AND ADMINISTRATION).

PRECAUTIONS:

General: The recommended dosage, frequency and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION).

Although the aqueous solubility of acyclovir sodium (for infusion) is >100 mg/ml, preparations of acyclovir crystals in intravenous solutions in renal tubules can occur if the maximum solubility of free acyclovir (2.5 mg/ml at 37°C in water) is exceeded or if the drug is administered by bolus injection. This complication causes a rise in serum creatinine and blood urea nitrogen (BUN), and a decrease in renal creatinine clearance. Ensuing renal tubular damage can produce acute renal failure.

Renal function (decreased creatinine clearance) can occur as a result of acyclovir administration and depends on the state of the patient's hydration, other treatments, and the presence of baseline renal abnormality. When acyclovir administration is continued, a 30% incidence of renal dysfunction, while in controlled studies, infusion of 5 mg/kg (250 mg/m²) over an hour was associated with a lower frequency — 4.6%.

CAUTION: Renal and hepatic failure, pre-existing renal disease, and dehydration may further reduce renal impairment with acyclovir more likely. In most instances, alteration of renal function is transient and reappears when it is resolved spontaneously with improvement in hydration and electrolyte balance. Drug dosage adjustment or discontinuation of drug administration. However, in some instances, these changes may progress to acute renal failure.

Administration of Zovirax by intravenous infusion must be accompanied by adequate hydration. Since no experience in humans is available regarding clinical differences in the response to intravenous infusions in patients treated with Zovirax and untreated patients or control animals, no data are available to suggest that benefits in lesions and relief of pain appear to shorten the latency of tumors in vivo cell transformation assays. Used to provide preliminary assessment of potential oncogenicity in the development of these definite lifetime bioassays in rodents. Conflicting results were obtained. Acyclovir was positive at the highest dose used in one study, indicated that acyclovir administered in tumors in mammals are incapable of inducing tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system.

No chronic toxicity data are available at the tested intravenous doses of 100 mg/kg acyclovir in rats or Chinese hamsters, higher doses of 500 and 1000 mg/kg were lethal in guinea pigs in acute toxicity studies as a domi- nant lethal study in mice. In 9 of 11 microlernal and mammalian cell assays, no evidence of mutagenicity was observed. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma), no evidence of clastogenicity and chromosomal damage occurred, but only at concentrations at least 25 times the acyclovir plasma levels achieved by this dosage regimen.

Acyclovir is not impairing fertility or reproduction in mice at oral doses up to 450 mg/kg/day. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day.

Pregnancy: Teratogenic Effects. Pregnancy Category C. Acyclovir was not terato- genic in mice (450 mg/kg/day) or rabbits (50 mg/kg/day) during the organogenesis period. Although maximum tolerated doses were tested in teratology studies, the plasma levels obtained did not exaggerate maximum plasma levels that might occur with clinical use of intravenous acyclovir.

There have been no adequate and well-controlled studies in pregnant women. Acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zovirax is administered to a nursing woman.

ADVERSE REACTIONS: The most frequent adverse reactions reported during con- trolled clinical trials of Zovirax in 64 patients were influenza or pharyngitis at the initial dose level (influenza or pharyngitis at the initial dose level). Severe elevations of serum creatinine in 3 (4.7%) and rash or hives in 3 (4.7%). Less frequent adverse reactions were diaphoresis, hematuria, hypotension, headache, and nausea, each of which occurred in 1 patient, and hypocalcemia in 4 (6.2%) patients. Despite apparent trends toward an increased severity of rash in postmarketing experience with Zovirax, no relationship to acyclovir treatment was established.

Among 51 immunocompromised patients, one, a bone marrow transplant recipient with pneumonitis, developed seizures, cerebral edema, coma and expired with cerebral edema consistent with diffuse involvement without evidence of Zovirax in the immunocompromised patient exhibited course and clonus.

The most frequent adverse reaction was elevated serum creatinine. This occurred in 9.8 percent of patients, usually following rapid (less than 10 minutes) intravenous infusion. Less frequently, other extrapyramidal reactions such as asterixis and tremors, each occurring in <4% of patients.

Approximately 1% of patients receiving intravenous acyclovir have manifested encephalitis characterized by lethargy, obtundation, tremors, confusion, hallucinations, agitation, seizures or coma (see PRECAUTIONS). Overdose: Overdosage has been reported following administration of bolus injections, or inappropriately high doses, and in patients whose fluid and electrolyte balance was not properly monitored. This has resulted in elevations in BUN, serum creatinine and subsequent renal failure.

The most common problem associated with acyclovir administration is precipitation in renal tubules which may occur when the solubility (2.5 mg/ml) in the intratubular fluid is exceeded (see PRECAUTIONS). A six-hour hemodial- ysis results in a 60% decrease in acyclovir concentration. Data concerning pentonel dialysis are incomplete but indicate that this method may be significantly less efficient in removing acyclovir from the blood. In the event of acute renal failure and anuria, the patient may benefit from hemodialysis until renal function is restored.

DOSAGE AND ADMINISTRATION: CAUTION — RAPID OR BOLUS INTRAVENOUS AND INTRAMUSCULAR OR SUBCUTANEOUS INJECTION MUST BE AVOIDED.

Dosage: MUCOSAL AND CUTANEOUS HERPES SIMPLEX (HSV-1 and HSV-2) INFECTIONS IN IMMUNOCOMPROMISED PATIENTS — 5 mg/kg infused at a constant rate over 1 hour for 3 days. Days 1 to 3. For patients with normal renal function. In children under 12 years of age, more accurate dosing can be attained by infusing 250 mg/m² at a constant rate over 1 hour every 7 hours (9.75 mg/kg/day) for 7 days.

SEVERE INITIAL CLINICAL EPISODES OF HERPES GENITALIS — The same dose given above — administered for 3 days.

Therapy should be initiated as early as possible following onset of signs and symptoms.

PATIENTS WITH ACUTE OR CHRONIC RENAL IMPAIRMENT: Refer to DOSAGE AND ADMINISTRATION section for recommended doses, and adjust the dosing interval as indicated in the table below.

<table>
<thead>
<tr>
<th>Creatinine Clearance</th>
<th>Dosage (mg/kg)</th>
<th>Dosage Interval (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;90</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>30—59</td>
<td>3.5</td>
<td>24</td>
</tr>
<tr>
<td>10—29</td>
<td>2.5</td>
<td>36</td>
</tr>
<tr>
<td>5—9</td>
<td>2</td>
<td>72</td>
</tr>
<tr>
<td>0—4</td>
<td>1.75</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>1.5</td>
<td>360</td>
</tr>
</tbody>
</table>

Hemodialysis: For patients who require dialysis, the mean plasma half-life of acyclovir during hemodialysis is approximately 5 hours. This results in a 60%, decrease in plasma drug concentrations following a bolus injection. Therefore, the dose and dosing schedule should be adjusted so that a dose is administered after each dialysis.

Method of Preparation: Each 10 ml vial contains acyclovir sodium equivalent to 500 mg acyclovir. The infused volume should be diluted in 10 ml of sterile water for injection or bacteriostatic water for injection containing benzyl alcohol yielding a final concentration of 50 mg/ml of acyclovir (pH approximately 11). When mixed, the solution is well tolerated immediately and subsequent testing of each individual dose does not USE BACTERICIDAL WATER FOR INJECTION CONTAINING PARABENS. It is incompatible with Zovirax Sterile Powder and may cause precipitation.


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Guest Editors:
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#5—Third International Congress on Aspiration Cytology in Transplantation
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