ACYCLOVIR- acyclovir tablet
Northwind Pharmaceuticals

NDC: 51655-099-51

MFG: 61442-113-01

Acyclovir 800 MG

40 Tablets

Rx Only

Lot#:

Exp. Date:

Each tablet contains Acyclovir USP....800 MG

Dosage: See package insert

Store between 68-77 degrees F.

Protect form moisture. Store in a tight, light-resistant container (See USP).

Keep out of the reach of children.

Mfg by: Carlsbad Technologies, Inc Carlsbad, CA 92008 Lot #:

Repackaged by Northwind Pharmaceuticals, Indianapolis, IN 46256

Indications and Usage

INDICATIONS AND USAGE

Herpes Zoster Infections

Acyclovir is indicated for the acute treatment of herpes zoster (shingles).

Genital Herpes

Acyclovir is indicated for the treatment of initial episodes and the management of recurrent episodes of genital herpes.

Chickenpox

Acyclovir is indicated for the treatment of chickenpox (varicella)

Information for patients

Patients are instructed to consult with their physician if they experience severe or troublesome adverse reactions, they become pregnant or intend to become pregnant, they intend to breast feed while taking orally administered acyclovir, or they have any other questions. Patients should be advised to maintain adequate hydration.

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

Genital Herpes Infections: Patients should be informed that acyclovir is not a cure for genital herpes. There are no data evaluating whether acyclovir will prevent transmission of infection to others. Because genital herpes is a sexually transmitted disease, patients should avoid contact with lesions or intercourse when lesions and/or symptoms are present to avoid infecting partners. Genital herpes can also be transmitted in the absence of symptoms through asymptomatic viral shedding. If medical management of a genital herpes recurrence is indicated, patients should be advised to initiate therapy at the first sign or symptom of an episode.

Chickenpox: Chickenpox in otherwise healthy children is usually a self-limited disease of mild to moderate severity. Adolescents and adults tend to have more severe disease. Treatment was initiated within 24 hours of the typical chickenpox rash in the controlled studies, and there is no information regarding the effects of treatment begun later in the disease course

Adverse Reactions

Herpes Simplex

Short-Term Administration: The most frequent adverse events reported during clinical trials of treatment of genital herpes with acyclovir 200 mg administered orally 5 times daily every 4 hours for 10 days were nausea and/or vomiting in 8 of 298 patient treatments (2.7%). Nausea and/or vomiting occurred in 2 of 287 (0.7%) patients who received placebo.

Long-Term Administration: The most frequent adverse events reported in a clinical trial for the prevention of recurrences with continuous administration of 400 mg (two 200-mg capsules) 2 times daily for 1 year in 586 patients treated with acyclovir were nausea (4.8%) and diarrhea (2.4%). The 589 control patients receiving intermittent treatment of recurrences with acyclovir for 1 year reported diarrhea (2.7%), nausea (2.4%), and headache (2.2%).

Herpes Zoster

The most frequent adverse event reported during 3 clinical trials of treatment of herpes zoster (shingles) with 800 mg of oral acyclovir 5 times daily for 7 to 10 days in 323 patients was malaise (11.5%). The 323 placebo recipients reported malaise (11.1%).

Chickenpox

The most frequent adverse event reported during 3 clinical trials of treatment of chickenpox with oral acyclovir at doses of 10 to 20 mg/kg 4 times daily for 5 to 7 days or 800 mg 4 times daily for 5 days in 495 patients was diarrhea (3.2%). The 498 patients receiving placebo reported diarrhea (2.2%).

Observed During Clinical Practice

In addition to adverse events reported from clinical trials, the following events have been identified during post-approval use of acyclovir. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, potential causal connection to acyclovir, or a combination of these factors.

General: Anaphylaxis, angioedema, fever, headache, pain, peripheral edema.

Nervous: Aggressive behavior, agitation, ataxia, coma, confusion, decreased consciousness, delirium, dizziness, dysarthria, encephalopathy, hallucinations, paresthesia, psychosis, seizure, somnolence, tremors. These symptoms may be marked, particularly in older adults or in patients with renal impairment.

Digestive: Diarrhea, gastrointestinal distress, nausea.

Hematologic and Lymphatic: Anemia, leukocytoclastic vasculitis, leukopenia, lymphadenopathy, thrombocytopenia.

Hepatobiliary Tract and Pancreas: Elevated liver function tests, hepatitis, hyperbilirubinemia, jaundice.

Musculoskeletal: Myalgia.

Skin: Alopecia, erythema multiforme, photosensitive rash, pruritus, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria.

Special Senses: Visual abnormalities.

Urogenital: Renal failure, renal pain (may be associated with renal failure), elevated blood urea nitrogen, elevated creatinine, hematuria

ACYCLOVIR

acyclovir tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51655-099(NDC:61442-113)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACYCLOVIR (UNII: X4HES1O11F) (ACYCLOVIR - UNII:X4HES1O11F)	ACYCLOVIR	800 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	CTI113
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-099-51	40 in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075382	05/14/2014	

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	repack(51655-099)

Revised: 6/2014 Northwind Pharmaceuticals