



BioAvenir

09/01/22

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלונים של התכשיר : **ACYCLOVENIR**

המרכיב הפעיל: ACICLOVIR

התוויה:

For the treatment of Herpes Simplex infections and severe initial genital herpes in the non immunocompromised.

For the prophylaxis of Herpes Simplex infections in immune-compromised patients.

In the treatment of Varicella zoster infections.

For Herpes Simplex Encephalitis.

For the treatment of herpes simplex infection in the neonate and infant up to 3 months of age.

עדכונים מהותיים בעלון:

4.4 Special warnings and precautions for use

Adequate hydration should be maintained in patients given i.v. or high oral doses of aciclovir.

Intravenous doses should be given by infusion over one hour to avoid precipitation of aciclovir in the kidney; rapid or bolus injection should be avoided.

The risk of renal impairment is increased by use with other nephrotoxic drugs. Care is required if administering i.v. aciclovir with other nephrotoxic drugs.

(...)

Use in patients with renal impairment and in elderly patients:

Aciclovir is eliminated by renal clearance, therefore the dose must be adjusted in patients with renal impairment (see section 4.2 Posology and method of administration). Elderly patients are likely to have reduced renal function and therefore the need for dose adjustment must be considered in this group of patients. Both elderly patients and patients with renal impairment are at increased risk of developing neurological side effects and should be closely monitored for evidence of these effects.

In the reported cases, these reactions were generally reversible on discontinuation of treatment (see section 4.8 Undesirable effects). Prolonged or repeated courses of aciclovir in severely immune-compromised individuals may result in the selection of virus strains with reduced sensitivity, which may not respond to continued aciclovir treatment (see section 5.1).

(...)



BioAvenir

Product contains sodium -

To be taken into consideration by patients on a controlled sodium diet.

(...)

Acyclovenir contains no antimicrobial preservative. Reconstitution and dilution should therefore be carried out under full aseptic conditions immediately before use and any unused solution discarded. The reconstituted or diluted solutions should not be refrigerated.

(...)

Other warnings and precautions

The labels shall contain the following statements:

For intravenous infusion only

Keep out of the reach and sight of children

Store below 25°C

Prepare immediately prior to use

Discard unused solution

(...)

Excipients

This medicinal product contains 45 mg sodium hydroxide per vial.

To be taken into consideration by patients on a controlled sodium diet

4.5 Interaction with other medicinal products and other forms of interaction

(...)

If lithium is administered concurrently with high dose aciclovir IV, the lithium serum concentration should be closely monitored because of the risk of lithium toxicity

(...)

An experimental study on five male subjects indicates that concomitant therapy with aciclovir increases AUC of totally administered theophylline with approximately 50%. It is recommended to measure plasma concentrations during concomitant therapy with aciclovir.

4.6 Fertility, Pregnancy and Lactation

Fertility:

There is no information on the effect of aciclovir on human female fertility.

In a study of 20 male patients with normal sperm count, oral aciclovir administered at doses of up to 1g per day for up to six months has been shown to have no clinically significant effect on sperm count, motility or morphology.

See clinical studies in section 5.2

Pregnancy:

A post-marketing aciclovir pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of the drug. The registry findings have not shown an increase in the number of birth defects amongst aciclovir exposed subjects compared to



BioAvenir

with the general population, and any birth defects showed no uniqueness or consistent pattern to suggest a common cause.

4.7 Effects on ability to drive and use machines

Aciclovir i.v. for infusion is generally used in an in-patient hospital population and information on ability to drive and operate machinery is not usually relevant. There have been no studies to investigate the effect of aciclovir on driving performance or the ability to operate machinery.

4.8 Undesirable effects

Psychiatric and nervous system disorders:

Very rare: headache, dizziness

Gastrointestinal disorders:

Very rare: diarrhoea, abdominal pain.

Renal and urinary disorders:

Very rare: renal impairment and renal pain.

Adequate hydration should be maintained (...) Progression to acute renal failure however, can occur in exceptional cases. Renal pain may be associated with renal failure and crystalluria

General disorders and administration site conditions:

Very rare: fatigue,

Severe local inflammatory reactions sometimes leading to breakdown of the skin have occurred when the drug. has been inadvertently infused into extracellular tissues.

5.2 Pharmacokinetic properties

ראה בעלון המצורף עדכונים

לתשומת לב - בהודעה זו מצוינים שינויים מהותיים והחמרות. בעלון בוצעו שינויים נוספים.
יש לעיין בעלון המצורף לאריזה (ולהודעה זו) לפני השימוש בתכשיר.

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל
הרישום ביואבניר בע"מ, דוד המלך 1 הרצליה פיתוח או בטלפון 09-9544129.

בכבוד רב,

שרית קיראי-קוצ'וק

רוקחת ממונה