ZOVIRAX IV
Aciclovir

POWDER FOR IV INFUSION

QUALITATIVE AND QUANTITATIVE COMPOSITION
ZOVIRAX 250 mg: The sodium ion content is approximately 26 mg per vial. White to off-white powder.

CLINICAL INFORMATION
Indications
ZOVIRAX IV for infusion is indicated for the treatment of herpes simplex infections in immune-compromised patients.

ZOVIRAX IV for infusion is indicated for the prophylaxis of herpes simplex infections in severely immune-compromised patients.

ZOVIRAX IV for infusion is indicated in the treatment of primary and recurrent varicella zoster infections in immune-compromised patients.

ZOVIRAX IV for infusion is indicated in the treatment of shingles (recurrent varicella zoster infection) in patients with normal immune response.

ZOVIRAX IV for infusion is indicated for herpes simplex encephalitis patients over age 6 months.

Dosage and Administration
Pharmaceutical form:
Freeze dried powder for injection.

To be given as intravenous infusion over 1 hour.

A course of treatment with *ZOVIRAX IV* for infusion usually lasts 5 days, but this may be adjusted according to the patient's condition and response to therapy. Treatment for herpes encephalitis usually lasts 10 days.

The duration of prophylactic administration of *ZOVIRAX IV* for infusion is determined by the duration of the period at risk.

- **Adults**

Treatment of herpes simplex
Obese patients should be dosed at the recommended adult dose using ideal body weight, rather than actual body weight.

Patients with herpes simplex (except herpes encephalitis) should be given aciclovir IV for infusion in doses of 5 mg/kg body weight every 8 hours if renal function is not impaired.

Patients with herpes encephalitis should be given aciclovir IV for infusion in doses of 10 mg/kg body weight every 8 hours provided renal function is not impaired.

Prophylaxis of herpes simplex in immune-compromised patients
Obese patients should be dosed at the recommended adult dose using ideal body weight, rather than actual body weight.

Refer to adult dosing recommendations for the treatment of herpes simplex with *ZOVIRAX IV* for infusion.

Treatment of varicella and herpes zoster

Obese patients should be dosed at the recommended adult dose using ideal body weight, rather than actual body weight.

Patients with varicella zoster infections should be given aciclovir IV for infusion in doses of 5 mg/kg body weight every eight hours if renal function is not impaired.

Immune-compromised patients with varicella zoster infections should be given aciclovir IV for infusion in doses of 10 mg/kg body weight every eight hours provided renal function is not impaired.

- **Infants and children**

The dose of *ZOVIRAX IV* for infusion for infants and children aged between 6 months and 12 years is calculated on the basis of body surface area.

Children with herpes simplex infections should be given *ZOVIRAX IV* for infusion in doses of 250 mg per square metre body surface area every 8 hours for 7 days if renal function is not impaired.

In immune-compromised children with varicella zoster infections 500 mg/m^2 over a 1 hour period every 8 hours for 7 days.

For children in 6 months to 12 years with herpes simplex encephalitis, more accurate dosing is achieved by infusing 500 mg/m^2 at a constant rate over at least 1 hour every 8 hours for 10 days.

Infants and children with impaired renal function require an appropriately modified dose, according to the degree of impairment.

- **Elderly**

The possibility of renal impairment in the elderly must be considered and the dosage should be adjusted accordingly (*see Renal impairment*).

Adequate hydration should be maintained.

- **Renal impairment**

Caution is advised when administering *ZOVIRAX IV* for infusion to patients with impaired renal function. Adequate hydration should be maintained.

Dosage adjustment for patients with renal impairment is based on creatinine clearance, in units of mL/min for adults and adolescents and in units of mL/min/1.73 m^2 for infants and children less than 13 years of age. The following adjustments in dosage are suggested:

Table 1: Dosage adjustments for IV aciclovir in adults and adolescents with renal impairment for treatment of herpes simplex virus infections.

Creatinine Clearance	Dosage
>50 mL/min	The recommended dose (5 or 10 mg/kg body weight) should be given every 8 hours.
25-50 mL/min	The recommended dose (5 or 10 mg/kg body weight) should be given every 12 hours.
10-25 mL/min	The recommended dose (5 or 10 mg/kg body weight) should be given every 24 hours.
0 (anuric)-10 mL/min	In patients receiving continuous ambulatory peritoneal dialysis (CAPD) the recommended dose (5 or 10 mg/kg body weight) should be halved and administered every 24 hours. In patients receiving haemodialysis, the recommended dose (5 or 10 mg/kg body weight) should be halved and administered every 24 hours and after dialysis.

Contraindications
ZOVIRAX IV for infusion is contraindicated in patients known to be hypersensitive to aciclovir or valaciclovir.

Warnings and Precautions
In patients receiving *ZOVIRAX IV* for infusion at higher doses (e.g. for herpes encephalitis), specific care regarding renal function should be taken, particularly when patients are dehydrated or have any renal impairment.

Reconstituted *ZOVIRAX IV* for infusion has a pH of approximately 11.0 and should not be administered by mouth.

Use in patients with renal impairment and in elderly patients:
Aciclovir is eliminated by renal clearance, therefore the dose must be reduced in patients with renal impairment (*see Dosage and Administration*). Elderly patients are likely to have reduced renal function and therefore the need for dose reduction 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 Adverse Reactions*).

Interactions
No clinically significant interactions have been identified.

Aciclovir is eliminated primarily unchanged in the urine via active renal tubular secretion. Any drugs administered concurrently that compete with this mechanism may increase aciclovir plasma concentrations. Probenecid and cimetidine increase the AUC of aciclovir by this mechanism and reduce aciclovir renal clearance. However, no dosage adjustment is necessary because of the wide therapeutic index of aciclovir.

In patients receiving intravenous *ZOVIRAX*, caution is required during concurrent administration with drugs which compete with aciclovir for elimination, because of the potential for increased plasma levels of one or both drugs or their metabolites. Increases in plasma AUCs of aciclovir and of the inactive metabolite of mycophenolate mofetil, an immunosuppressant agent used in transplant patients, have been shown when the drugs are co-administered.

Care is also required (with monitoring for changes in renal function) if administering intravenous *ZOVIRAX* with drugs which affect other aspects of renal physiology (e.g. cyclosporin, tacrolimus).

Pregnancy and Lactation
Pregnancy
A post-marketing *ZOVIRAX* pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of *ZOVIRAX*. The birth defects described amongst *ZOVIRAX* exposed subjects have not shown any uniqueness or consistent pattern to suggest a common cause.

The use of *ZOVIRAX* should be considered only when the potential benefits outweigh the possibility of unknown risks.

Lactation
Following oral administration of 200 mg *ZOVIRAX* five times a day, aciclovir has been detected in breast milk at concentrations ranging from 0.6 to 4.1 times the corresponding plasma levels. These levels would potentially expose nursing infants to aciclovir dosages of up to 0.3 mg/kg/day. Caution is therefore advised if *ZOVIRAX* is to be administered to a nursing woman.

Effects on Ability to Drive and Use Machines
ZOVIRAX IV 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.

Adverse Reactions
The frequency categories associated with the adverse events below are estimates. For most events, suitable data for estimating incidence were not available. In addition, adverse events may vary in their incidence depending on the indication.

The following convention has been used for the classification of undesirable effects in terms of frequency: Very common ≥1/10, common ≥1/100 and <1/10, uncommon ≥1/1,000 and <1/100, rare ≥1/10,000 and <1/1,000, very rare <1/10,000.

Blood and lymphatic system disorders
Uncommon: Decreases in haematological indices (anaemia, thrombocytopenia, leukopenia).

Immune system disorders
Very rare: Anaphylaxis.

Psychiatric and nervous system disorders
Very rare: Headache, dizziness, agitation, confusion, tremor, ataxia, dysarthria, hallucinations, psychotic symptoms, convulsions, somnolence, encephalopathy, coma.
The above events are generally reversible and usually reported in patients with renal impairment or with other predisposing factors (*see Warnings and Precautions*).

Vascular disorders
Common: Phlebitis.

Respiratory, thoracic and mediastinal disorders
Very rare: Dyspnoea.

Gastrointestinal disorders
Common: Nausea, vomiting.
Very rare: Diarrhoea, abdominal pain.

Hepato-biliary disorders
Common: Reversible increases in liver-related enzymes.
Very rare: Reversible increases in bilirubin, jaundice, hepatitis.

Skin and subcutaneous tissue disorders
Common: Pruritus, urticaria, rashes (including photosensitivity).
Very rare: Angioedema.

Renal and urinary disorders
Common: Increases in blood urea and creatinine.
Rapid increases in blood urea and creatinine levels are believed to be related to the peak plasma levels and the state of hydration of the patient. To avoid this effect, when administered intravenously the drug should not be given as an intravenous bolus injection but by infusion over a one-hour period.
Very rare: Renal impairment, acute renal failure, renal pain.
Adequate hydration should be maintained. Renal impairment usually responds rapidly to rehydration of the patient and/or dosage reduction or withdrawal of the drug. Progression to acute renal failure, however, can occur in exceptional cases.
Renal pain may be associated with renal failure.

General disorders and administration site conditions
Very rare: Fatigue, fever, local inflammatory reactions.
Severe local inflammatory reactions sometimes leading to breakdown of the skin have occurred when *ZOVIRAX IV* for infusion has been inadvertantly infused into extracellular tissues.

Overdose
Symptoms and signs
Overdosage of intravenous aciclovir has resulted in elevations of serum creatinine, blood urea nitrogen and subsequent renal failure. Neurological effects including confusion, hallucinations, agitation, seizures and coma have been described in association with overdosage.

Treatment
Patients should be observed closely for signs of toxicity. Haemodialysis significantly enhances the removal of aciclovir from the blood and may, therefore, be considered a management option in the event of symptomatic overdose.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic Properties
ATC code
Pharmacotherapeutic group: Direct acting antivirals, nucleosides and nucleotides excl. reverse transcriptase inhibitors.

ATC code: J05AB01

Mechanism of action
Aciclovir is a synthetic purine nucleoside analogue with *in vitro* and *in vivo* inhibitory activity against human herpes viruses, including herpes simplex virus (HSV) types 1 and 2, varicella zoster virus (VZV), Epstein Barr virus (EBV) and cytomegalovirus (CMV). In cell culture, aciclovir has the greatest antiviral activity against HSV-1, followed (in decreasing order of potency) by HSV-2, VZV, EBV and CMV.

The inhibitory activity of aciclovir for HSV-1, HSV-2, VZV, EBV and CMV is highly selective. The enzyme thymidine kinase (TK) of normal, non-infected cells does not use aciclovir effectively as a substrate, hence toxicity to mammalian host cells is low; however, TK encoded by HSV, VZV and EBV converts aciclovir to aciclovir monophosphate, a nucleoside analogue, which is further converted to the diphosphate and finally to the triphosphate by cellular enzymes. Aciclovir triphosphate interferes with the viral DNA polymerase and inhibits viral DNA replication with resultant chain termination following its incorporation into the viral DNA.

Pharmacodynamic 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.

Most of the clinical isolates with reduced sensitivity have been relatively deficient in viral TK however, strains with altered viral TK or DNA polymerase have also been reported. *In vitro* exposure of HSV isolates to aciclovir can also lead to the emergence of less sensitive strains. The relationship between the *in vitro* determined sensitivity of HSV isolates and clinical response to aciclovir therapy is not clear.

All patients should be cautioned to ensure they avoid the potential of virus transmission, particularly when active lesions are present.

Pharmacokinetic Properties
Absorption
In adults, mean steady state peak plasma concentrations (C_{ssmax}) following a one-hour infusion of 2.5 mg/kg, 5 mg/kg, 10 mg/kg and 15 mg/kg were 22.7 micromolar (5.1 micrograms/mL), 43.6 micromolar (9.8 micrograms/mL), 92 micromolar (20.7 micrograms/mL) and 105 micromolar (23.6 micrograms/mL), respectively. The corresponding trough levels (C_{ssmin}) 7 h later were 2.2 micromolar (0.5 micrograms/mL), 3.1 micromolar (0.7 micrograms/mL), 10.2 micromolar (2.3 micrograms/mL) and 8.8 micromolar (2.0 micrograms/mL), respectively. In children over 1 year of age similar mean peak (C_{ssmax}) and trough (C_{ssmin}) levels were observed when a dose of 250 mg/m^2 was substituted for 5 mg/kg and a dose of 500 mg/m^2 was substituted for 10 mg/kg.

Distribution
Cerebrospinal fluid levels are approximately 50% of corresponding plasma levels. Plasma protein binding is relatively low (9 to 33%) and drug interactions involving binding site displacement are not anticipated.

Elimination
In adults the terminal plasma half-life of aciclovir after administration of aciclovir IV for infusion is about 2.9 hours. Most of the drug is excreted unchanged by the kidney. Renal clearance of aciclovir is substantially greater than creatinine clearance indicating that tubular secretion in addition to glomerular filtration contributes to the renal elimination of the drug. 9-carboxymethoxy-methylguanine is the only significant metabolite of aciclovir and accounts for approximately 10 to 15% of the dose excreted in the urine. When aciclovir is given one hour after 1 g of probenecid the terminal half-life and the area under the plasma concentration time curve is extended by 18% and 40% respectively.

Special patient populations
In patients with chronic renal failure the mean terminal half-life was found to be 19.5 h. The mean aciclovir half-life during haemodialysis was 5.7 hours. Plasma aciclovir levels dropped approximately 60% during dialysis.

In the elderly total body clearance falls with increasing age, associated with decreases in creatinine clearance, although there is little change in the terminal plasma half-life.

Clinical Studies
There is no information on the effect of *ZOVIRAX IV* for infusion on human female fertility. In a study of 20 male patients with normal sperm count, oral aciclovir administered at doses of up to 1 g per day for up to six months has been shown to have no clinically significant effect on sperm count, motility or morphology.

Non-clinical Information
The results of a wide range of mutagenicity tests *in vitro* and *in vivo* indicate that aciclovir is unlikely to pose a genetic risk to man.

Aciclovir was not found to be carcinogenic in long-term studies in the rat and the mouse.

Largely reversible adverse effects on spermatogenesis in association with overall toxicity in rats and dogs have been reported only at doses of aciclovir greatly in excess of those employed therapeutically. Two-generation studies in mice did not reveal any effect of (orally administered) aciclovir on fertility.

Systemic administration of aciclovir in internationally accepted standard tests did not produce embryotoxic or teratogenic effects in rabbits, rats or mice. In a non-standard test in rats, foetal abnormalities were observed but only following such high subcutaneous doses that maternal toxicity was produced. The clinical relevance of these findings is uncertain.

PHARMACEUTICAL INFORMATION
List of Excipients
Sodium hydroxide.
Water for injections (removed during the freeze-drying process and is not present in the finished product).

Shelf Life
The expiry date is indicated on the packaging.

Storage
Store below 30°C.

The storage conditions are detailed on the packaging.

For storage conditions of the reconstituted or diluted solutions, *see Shelf Life*.

Nature and Contents of Container
Aciclovir is presented as a sterile lyophilised powder in a 17 mL type I glass vial with rubber stopper and aluminium over-seal with plastic flip-top cover. The drug is supplied in a single use vial without a preservative.

Incompatibilities
The reconstituted concentrate and diluted solution for infusion must not be mixed with other medicinal products except those mentioned in *Use and Handling*.

Use and Handling
Reconstitution
The required dose of *ZOVIRAX IV* for infusion should be administered by slow IV infusion over a one-hour period.

ZOVIRAX IV for infusion should be reconstituted using the following volumes of either water for injections BP or sodium chloride injection BP (0.9% w/v) to provide a solution containing 25 mg *ZOVIRAX* per mL:

Formulation	**Volume of fluid for reconstitution**
250 mg vial	10 mL

From the calculated dose, determine the appropriate number and strength of vials to be used. To reconstitute the vial, add the recommended volume of infusion fluid and shake gently until the contents of the vial have dissolved completely.

After reconstitution *ZOVIRAX IV* for infusion may be administered by a controlled-rate infusion pump.

Alternatively, the reconstituted solution may be further diluted to give a *ZOVIRAX* concentration of not greater than 5 mg/mL (0.5% w/v) for administration by infusion:

Add the required volume of reconstituted solution to the chosen infusion solution, as recommended below, and shake well to ensure adequate mixing occurs.

For children, where it is advisable to keep the volume of infusion fluid to a minimum, it is recommended that dilution is on the basis of 4 mL reconstituted solution (100 mg *ZOVIRAX*) added to 20 mL of infusion fluid.

For adults, it is recommended that infusion bags containing 100 mL of infusion fluid are used, even when this would give an *ZOVIRAX* concentration substantially below 0.5% w/v. Thus one 100 mL infusion bag may be used for any dose between 250 mg and 500 mg *ZOVIRAX* (10 and 20 mL of reconstituted solution) but a second bag must be used for doses between 500 and 1,000 mg.

When diluted in accordance with the recommended schedules, *ZOVIRAX IV* for infusion is known to be compatible with the following infusion fluids and stable for up to 12 hours at room temperature (15°C to 25°C):
- Sodium chloride intravenous infusion BP (0.45% and 0.9% w/v);
- Sodium chloride (0.18% w/v) and glucose (4% w/v) intravenous infusion BP;
- Sodium chloride (0.45% w/v) and glucose (2.5% w/v) intravenous infusion BP;
- Compound sodium lactate intravenous infusion BP (Hartmann's solution).

ZOVIRAX IV for infusion when diluted in accordance with the above schedule will give a *ZOVIRAX* concentration not greater than 0.5% w/v.

When reconstituted as directed, *ZOVIRAX IV* for infusion has a pH of approximately 11.

Since no antimicrobial preservative is included, reconstitution and dilution must be carried out under full aseptic conditions, immediately before use, and any unused solution discarded.

Reconstituted or diluted solutions should not be refrigerated.

Should any visible turbidity or crystallisation appear in the solution before or during infusion, the preparation should be discarded.

Not all presentations are available in every country.

Package Quantity and Reg. No.
Box contains 5 vials @ 250 mg. Reg. No. DKI0200500144A1

HARUS DENGAN RESEP DOKTER

Manufactured by
GlaxoSmithKline Manufacturing S.p.A.,
Parma, Italy

Imported by
PT Glaxo Wellcome Indonesia,
Jakarta, Indonesia

Version number	: 01
Reference	: GDS32/IPI08 – New GSK logo, excipient and appearance details
Date of local revision	: 29 July 2024

INFORMASI UNTUK PASIEN

ZOVIRAX IV
Aciclovir 250 mg

Baca keseluruhan brosur ini secara teliti sebelum Anda mulai menggunakan obat ini karena mengandung informasi penting untuk Anda.
- Simpan brosur ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter, perawat atau apoteker.
- Obat ini hanya diresepkan untuk Anda. Jangan diberikan kepada orang lain. Hal tersebut dapat membahayakan mereka, meskipun gejala penyakit mereka sama dengan gejala Anda.

Jika Anda merasakan efek samping, konsultasikan dengan dokter, perawat atau apoteker. Hal ini termasuk kemungkinan efek samping lain yang tidak tertulis dalam brosur ini. *Lihat Bagian 4.*

Apa saja yang ada dalam brosur ini:

1. Apa itu *ZOVIRAX IV* dan Digunakan Untuk Apa

ZOVIRAX IV mengandung zat aktif bernama aciclovir, yang mana masuk ke dalam kelompok obat antivirus. Antivirus bekerja dengan membunuh atau menghambat pertumbuhan virus.

ZOVIRAX IV dapat digunakan untuk:
- Pengobatan infeksi herpes simplex pada pasien dengan gangguan imun.
- Profilaksis infeksi herpes simplex pada pasien dengan gangguan imun berat.
- Pengobatan infeksi varicella zoster primer dan pengulangan pada pasien dengan gangguan imun.
- Infeksi herpes simplex ensefalitis pada pasien usia di atas 6 bulan.

2. Apa yang Perlu Anda Ketahui Sebelum Menggunakan *ZOVIRAX IV*

Jangan gunakan *ZOVIRAX IV*:
Jika Anda **alergi** terhadap aciclovir atau valaciclovir atau bahan lain dari *ZOVIRAX IV* (*tertera di Bagian 6).*

Jangan gunakan *ZOVIRAX IV* jika keadaan di atas terjadi pada Anda. Jika Anda tidak yakin, beritahu dokter atau apoteker Anda sebelum menggunakan *ZOVIRAX IV*.

Perhatian dan Pencegahan
Konsultasikan dengan dokter Anda sebelum menggunakan *ZOVIRAX IV*:
- Jika Anda memiliki penyakit ginjal.
- Jika Anda berumur lebih dari 65 tahun.
- Jika Anda tidak yakin apabila keadaan di atas terjadi pada Anda, konsultasikan dengan dokter atau apoteker Anda sebelum menggunakan *ZOVIRAX IV*. Sangat penting untuk minum air yang banyak ketika menggunakan *ZOVIRAX IV*.

Obat lain dan *ZOVIRAX IV*
Beritahu dokter atau apoteker jika Anda sedang menggunakan, telah menggunakan, atau mungkin menggunakan obat lain – termasuk obat-obatan yang Anda beli tanpa resep atau obat herbal.

Beritahukan dokter atau apoteker jika Anda sedang menggunakan obat-obat sebagai berikut:
- **Probenecid,** digunakan untuk mengobati asam urat.
- **Cimetidine,** digunakan untuk mengobati luka pada lambung.
- **Tacrolimus, ciclosporin,** atau **mycophenolate mofetil,** digunakan untuk menghentikan penolakan tubuh Anda saat menerima transplantasi organ.

Kehamilan, menyusui, dan fertilitas

Jika Anda sedang hamil atau menyusui, curiga mungkin hamil atau berencana untuk memiliki bayi, tanyakan saran dokter atau apoteker sebelum menggunakan obat ini.

***ZOVIRAX IV* mengandung natrium**
ZOVIRAX IV mengandung 26 mg natrium per dosis. Hal ini perlu dipertimbangkan bagi pasien yang sedang menjalani diet natrium terkontrol.

3. Cara Menggunakan *ZOVIRAX IV*

Bagaimana *ZOVIRAX IV* diberikan kepada Anda
Jangan menggunakan obat ini oleh diri Anda sendiri. Obat ini selalu diberikan kepada Anda oleh seseorang yang dilatih untuk melakukannya.

Obat ini akan dilarutkan sebelum diberikan kepada Anda.

ZOVIRAX IV akan diberikan kepada Anda dalam bentuk cairan infus ke pembuluh darah Anda. Melalui inilah obat secara perlahan diberikan kepada Anda selama jangka waktu tertentu.

Dosis, frekuensi, dan durasi dosis yang akan diberikan tergantung pada:
- Jenis infeksi yang Anda miliki
- Berat badan Anda
- Usia Anda.

Dokter Anda dapat menyesuaikan dosis *ZOVIRAX IV* jika:
Anda memiliki penyakit ginjal. Jika Anda memiliki penyakit ginjal, penting bagi Anda untuk menerima banyak cairan saat Anda sedang menjalani pengobatan menggunakan *ZOVIRAX IV*.

Beritahu dokter Anda sebelum menggunakan *ZOVIRAX IV* jika keadaan di atas terjadi pada Anda.

Jika Anda diberikan terlalu banyak *ZOVIRAX IV*
Jika Anda berpikir Anda telah diberikan terlalu banyak *ZOVIRAX IV*, segera hubungi dokter atau perawat Anda.

Jika Anda telah diberi terlalu banyak *ZOVIRAX IV*, Anda mungkin saja:
- Merasa bingung atau gelisah
- Mengalami halusinasi (melihat atau mendengar hal-hal yang tidak ada)
- Mengalami kejang
- Menjadi tidak sadar (koma).

4. Efek Samping yang Mungkin Terjadi

Seperti semua obat-obatan lain, *ZOVIRAX IV* dapat menyebabkan efek samping, tetapi tidak semua orang akan mengalaminya. Berikut adalah efek samping yang mungkin terjadi dengan *ZOVIRAX IV*:

Efek samping yang umum terjadi:
Dapat terjadi pada hingga 1 dari 10 orang
- Bengkak, kemerahan dan nyeri di tempat suntikan
- Mual
- Muntah
- Peningkatan yang bersifat reversibel pada enzim hati
- Gatal-gatal
- Ruam
- Reaksi kulit setelah terpapar cahaya (fotosensitivitas)
- Peningkatan urea dan kreatinin darah.

Efek samping yang tidak umum terjadi:
Dapat terjadi hingga 1 dari 100 orang
- Penurunan jumlah sel darah merah (anemia)
- Penurunan jumlah sel darah putih (leukopenia)
- Mengurangi jumlah trombosit darah (sel-sel yang membantu darah menggumpal) (trombositopenia).

Efek samping yang sangat jarang terjadi:
Dapat terjadi hingga 1 dari 10.000 orang

- Reaksi alergi
- Sakit kepala atau pusing
- Merasa gelisah atau bingung
- Gemetar atau tremor
- Goyah ketika berjalan dan kurangnya koordinasi
- Kesulitan berbicara
- Halusinasi (melihat atau mendengar hal-hal yang tidak ada)
- Gejala psikotik
- Kejang
- Merasa sangat mengantuk atau mengantuk
- Ketidakmampuan untuk berpikir atau menilai dengan jelas
- Tidak sadarkan diri (koma)
- Sesak napas, mengi atau kesulitan bernapas
- Diare
- Sakit perut
- Peningkatan yang bersifat reversibel pada bilirubin (pigmen berwarna kuning pada empedu)
- Kulit dan bagian putih di mata menjadi kuning (penyakit kuning)
- Peradangan hati (hepatitis)
- Pembengkakan wajah, bibir, lidah atau bagian lain dari tubuh Anda
- Masalah ginjal, sedikit atau tidak buang air kencing sama sekali
- Nyeri di punggung bawah Anda, daerah ginjal di punggung Anda atau tepat di atas pinggul Anda (sakit ginjal)
- Merasa Lelah
- Demam
- Reaksi peradangan lokal.

Pelaporan efek samping
Jika Anda merasakan efek samping, harap konsultasikan ke dokter, apoteker, atau perawat. Termasuk kemungkinan efek samping lain yang tidak tertulis dalam informasi ini.

5. Cara Penyimpanan *ZOVIRAX IV*

Simpan obat ini jauh dari jangkauan anak-anak.

Simpan di bawah suhu 30°C.

Jangan menggunakan obat setelah tanggal kedaluwarsa yang tertulis pada karton. Tanggal kedaluwarsa merujuk pada hari terakhir bulan tersebut.

Larutkan obat sesaat sebelum digunakan.

Buang cairan yang tidak digunakan.

Jangan membuang obat apapun di air limbah atau limbah rumah tangga. Tanyakan pada apoteker bagaimana membuang obat yang tidak digunakan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi dari Kemasan dan Informasi Lain

Apa kandungan *ZOVIRAX IV*

- Zat aktif *ZOVIRAX IV* adalah aciclovir.
- Kandungan lainnya adalah: natrium hidroksida dan air untuk injeksi (air untuk injeksi hilang selama proses pengeringan beku dan tidak terdeteksi pada produk jadi).

Apa yang terlihat dan isi kemasan
ZOVIRAX IV tersedia dalam vial kaca, berisi serbuk berwarna putih hingga putih pucat.
ZOVIRAX IV dengan kekuatan 250 mg tersedia dalam vial 17 mL, di dalam dus yang berisi 5 vial.

HARUS DENGAN RESEP DOKTER

ZOVIRAX IV Dus, 5 vial @ 250 mg, Reg. No. DKI0200500144A1

Diproduksi oleh:
GlaxoSmithKline Manufacturing S.p.A.,
Parma, Italia

Diimpor oleh:
PT Glaxo Wellcome Indonesia,
Jakarta, Indonesia

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