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Direct Healthcare Professional Communication

Zovirax (aciclovir) I.V. 500mg PL 00003/0159: batches identified containing Package Leaflets with incorrect dosing instructions

GlaxoSmithKline UK Ltd and in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary:

- Batches of Zovirax I.V. 500mg (GN8S, J69C, B35J, 9G4B, TC8E-A, 6V8W) have been identified to contain an incorrect version of the Summary of Product Characteristics section 4.2 and the Package Leaflet inside the sealed pack which contains unapproved text.
- The incorrect Package Leaflet contained in affected batches has incomplete or incorrect dosing information, including:
    - incorrect information about calculating the dose in obese adults, and in infants and children aged 3 months to 12 years
    - omits information on dosing in infants and children with renal failure
- Healthcare professionals prescribing and administering this product should refer to the corrected and approved Package Leaflet that accompanies this letter and discard the incorrect version inside the sealed packs.
- Additional copies of the approved Package Leaflet can also be found online on the Electronic Medicines Compendium website at: https://www.medicines.org.uk/emc/product/7595/pil
- The approved Summary of Product Characteristics can be found online on the Electronic Medicines Compendium website at https://www.medicines.org.uk/emc/product/7595/smpc

Please ensure all relevant staff are made aware of the content of this letter.

Background to the safety concern:

Zovirax I.V. 250mg and 500mg is indicated in:

- the treatment of *Herpes simplex* infections in immunocompromised patients and severe initial genital herpes in the non-immunocompromised
- prophylaxis of *Herpes simplex* infections in immunocompromised patients
- treatment of *Varicella zoster* infections or herpes encephalitis
- treatment of *Herpes simplex* infections in the neonate and infant up to 3 months of age

GSK has identified batches of Zovirax I.V. 500mg with incorrect dosing information in the Package Leaflet. No impacted batches for Zovirax 250mg have been implemented on the UK market. The affected batches containing the unapproved Package Leaflet for Zovirax I.V. 500mg are:

Affected batches for Zovirax I.V. 500mg	
Batch	**Expiry**
GN8S	Jan-26
J69C	Jan-26
B35J	Jan-26
9G4B	Jan-26
TC8E-A	Aug-25
6V8W	Jan-26

The discrepancies between the correct version of the Package Leaflet approved by MHRA and the unapproved version are listed in Appendix-1 of this letter. GSK apologizes for this error.

Clinical consequences:

- There have been no report of effects to patients in terms of efficacy or adverse events due to dosing conversion.
- The benefit-risk profile of the impacted IV Zovirax remains favourable and unchanged.

Action required by Health Care Providers:

Please ensure the approved Summary of Product Characteristics and Package Leaflet are followed. A copy of the approved Package Leaflet is provided with this letter.

Call for reporting:

Healthcare professionals are asked to report medication errors and suspected adverse reactions including lack of therapeutic effect to the Yellow Card Scheme electronically.

Report via the website https://yellowcard.mhra.gov.uk, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

Adverse drug reactions where harm occurs as a result of a medication error are reportable as a Yellow Card or through the local risk management systems into the National Reporting and Learning System (NRLS). If reported to the NRLS, these will be shared with the MHRA. If the NRLS is not available and harm occurs, report using a Yellow Card.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information about Zovirax I.V., please contact GSK Medical Information at 980 Great West Road, Brentford, TW8 9GS or via:

Medical Information e-mail: ukmedinfo@gsk.com

Medical Information Direct Line: 0800 221 441

Enclosed: approved Zovirax (aciclovir) IV 500mg and 250mg Package Leaflet

Yours Sincerely,

David M. Brooks MD

Digitally signed by David M. Brooks MD
Date: 2022.05.03 12:13:28 -04'00'

Signature:

David Brooks

Country Medical Director, United Kingdom

Appendix-1:

The discrepancies between the correct Package Leaflet approved by the MHRA and the unapproved version in the affected packs are listed below (**unapproved version is in bold**):

1. Dosage in adults: In obese patients dosed with intravenous aciclovir based on their actual body weight, higher plasma concentrations may be obtained (see SPC section 5.2 Pharmacokinetic properties).

   Dosage in adults: In obese patients dosed with intravenous aciclovir based on using ideal body weight, rather than actual body weight, higher plasma concentrations may be obtained (see SPC section 5.2 Pharmacokinetic properties).

2. Dosage in children: The dose of Zovirax I.V. for infants and children aged between 3 months and 12 years is calculated on the basis of body surface area.

   Children 3 months of age or older with *Herpes simplex* (except herpes encephalitis) or *Varicella zoster* infections should be given Zovirax I.V. in doses of 250 mg per square metre of body surface area every 8 hours if renal function is not impaired.

   In immunocompromised children with *Varicella zoster* infections or children with herpes encephalitis, Zovirax I.V. should be given in doses of 500 mg per square metre body surface area every 8 hours if renal function is not impaired.

   Dosage in infants and children: The dose of Zovirax I.V. for infants and children aged between 3 months and 12 years is calculated on the basis of body weight.

   Infants and children 3 months of age or older with herpes simplex infections should be given Zovirax 20 mg / kg body weight IV every eight hours for 21 days for herpes encephalitis, or for 14 days for disease limited to skin and mucous membrane if renal function is not impaired.

3. Dosage in renal impairment - Dosage adjustments in infants and children:

Creatinine Clearance	Dosage
25 to 50 ml/min/1.73m^2	The dose recommended above (250 or 500 mg/m^2 body surface area or 20 mg/kg body weight) should be given every 12 hours.
10 to 25 ml/min/1.73m^2	The dose recommended above (250 or 500 mg/m^2 body surface area or 20 mg/kg body weight) should be given every 24 hours.

0 (anuric) to 10 ml/min/1.73m^2	In patients receiving continuous ambulatory peritoneal dialysis (CAPD) the dose recommended above (250 or 500 mg/m^2 body surface area or 20 mg/kg body weight) should be halved and administered every 24 hours. In patients receiving haemodialysis the dose recommended above (250 or 500 mg/m^2 body surface area or 20 mg/kg body weight) should be halved and administered every 24 hours and after dialysis

Recommended dosage adjustments in infants and children with renal impairment was omitted in the unapproved version of the Package Leaflet.