



Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

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Unser Zeichen: PHV-12838047-A-200309
Ihr Zeichen:

PHV-issue: Valaciclovir

Sehr geehrte Damen und Herren,

Aufgrund eines PSUR Follow-Up Assessments (PSUFU) durch den Ausschuss für Risikobewertung im Bereich Pharmakovigilanz (PRAC), dessen Ergebnis durch das CMDh bestätigt wurde, kommt es zu der Änderung der Genehmigungen für das Inverkehrbringen der Arzneimittel mit dem Wirkstoff Valaciclovir.

(siehe: <http://www.hma.eu/611.html>)

Auszug aus dem PSUFU CZ/H/PSUFU/00003086/201812

Recommendations

Based on the review of data submitted, the LMS considers that the product information should be updated as follows:

Update of 4.4 of the SmPC to add warning and recommendation regarding DRESS. The Package leaflet is updated accordingly.

Update of 4.8 of the SmPC to add DRESS with a frequency Not known (cannot be estimated from the available data). The Package leaflet is updated accordingly.

The following changes to the product information of medicinal products containing the active substance valaciclovir are recommended (new text **underlined and in bold**, deleted text

~~strike through~~):

Summary of Product Characteristics

- Section 4.4

Drug reaction with eosinophilia and systemic symptoms (DRESS):

DRESS, which can be life-threatening or fatal, has been reported in association with valaciclovir treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of DRESS appear, valaciclovir should be withdrawn immediately and an alternative treatment considered (as appropriate). If the patient has developed DRESS with the use of valaciclovir, treatment with valaciclovir must not be restarted in this patient at any time.

- Section 4.8

The following adverse reaction should be added under the SOC Skin and subcutaneous tissue disorders with a frequency Not known (cannot be estimated from the available data):

Skin and subcutaneous tissue disorders

Common: Rashes including photosensitivity, pruritus

Uncommon: Urticaria

Rare: Angioedema

Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS) (see section 4.4)

Package Leaflet

Section 2 - What you need to know before you use valaciclovir

DO NOT TAKE valaciclovir - OR - TELL YOUR DOCTOR BEFORE TAKING valaciclovir:

- **If you have ever developed an extended rash associated with fever, enlarged lymph node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.**

Warnings and precautions - Take special care with valaciclovir:

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking valaciclovir and contact your doctor or seek medical attention immediately.

Section 4 – Possible side effects

Frequency Not known (cannot be estimated from the available data)

Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.