Bundesamt für Sicherheit
im Gesundheitswesen

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Betreff: *Penciclovir* **– hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes**

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: **UK/H/PSUR/0066/001 und UK/H/PSUR/0066/002**) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller Penciclovir– hältigen Arzneispezialitäten aufzunehmen.

Sollten diese bereits aufgenommen worden sein, betrachten Sie dieses Schreiben als gegenstandslos.

UK/H/PSUR/0066/001 und UK/H/PSUR/0066/002

Fachinformation

4.3 Contraindications

Known hypersensitivity to penciclovir, famciclovir or any of the excipients in the formulation (e.g. propylene glycol).

4.4 Special warnings and precautions for use

The cream should only be used on cold sores on the lips and around the mouth. It is not recommended for application to mucous membranes (e.g. in the eyes, mouth, or nose or on the genitals). Particular care should be taken to avoid application in or near the eyes.

Severely immunocompromised patients (e.g. AIDS patients or bone marrow transplant recipients) should be encouraged to consult a physician in case oral therapy is indicated. Information concerning excipients

The cream contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

It also contains propylene glycol, which may cause skin irritations.

4.5 Interaction with other medicinal products and other forms of interaction

Clinical trial experience has not identified any interactions resulting from concomitant administration of topical or systemic drugs with Vectavir Cream.

4.6 Fertility, pregnancy and lactation

There is unlikely to be any cause for concern regarding adverse effects when the cream is used in pregnant and/or lactating women as systemic absorption of penciclovir following topical administration of Vectavir Cream has been shown to be minimal

There is no information on excretion of penciclovir in human milk.

Since the safety of penciclovir in human pregnancy has not been established, Vectavir Cream should only be used during pregnancy or in nursing mothers on the advice of a doctor and if the potential benefits are considered to outweigh the potential risks associated with treatment.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects

Summary of the safety profile

Vectavir Cream has been well-tolerated in human studies. Clinical trial experience has shown that there was no difference between Vectavir Cream and placebo in the rate or type of adverse reactions reported. The most common events are application site reactions.

Tabulated list of adverse reactions

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: *very common* (≥1/10); *common* (≥1/100 to < 1/10); *uncommon* (≥1/1,000 to < 1/100); *rare* (≥ 1/10,000 to < 1/1,000); *very rare* (<1/10,000); *unknown* (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

The following adverse events are reported from clinical trials

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Table 1

General disorders and administration site condition	Common: application site reactions (including skin burning sensation, pain of skin, hypoaesthesia)

Post-marketing surveillance has revealed the following adverse events (all reactions were either localised or generalised). Adverse events from post-marketing experience are difficult to calculate a frequency and therefore the events are listed as unknown.

Table 2

Immune system disorders	hypersensitivity, urticaria
Skin and subcutaneous disorders	dermatitis allergic (including rash, pruritus, blisters and oedema)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.. Healthcare professionals are asked to report any suspected adverse reactions via the “national reporting system”}.

4.9 Overdose

No untoward effects would be expected even if the entire contents of a container of Vectavir Cream were ingested orally; penciclovir is poorly absorbed following oral administration. However, some irritation in the mouth could occur. No specific treatment is necessary if accidental oral ingestion occurs.

Oben angeführte Textabschnitte stellen eine Mindestanforderung dar, zusätzliche nationale Hinweise in diesen Abschnitten sind zu belassen.