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za zdravila in medicinske pripomočke
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VSEM IMETNIKOM DOVOLJENJ ZA PROMET Z GENERIČNIMI ZDRAVILI, KI VSEBUJEJO GABAPENTIN

Predložitev spremembe tipa IB – dopolnitev povzetka glavnih značilnosti zdravila in navodila za uporabo za generična zdravila, ki vsebujejo gabapentin

Spoštovani,

Skupina za usklajevanje CMD(h) obvešča preko spletne strani Vodij agencij za zdravila (HMA) vse imetnike DzP generičnih zdravil, ki vsebujejo gabapentin, da je imetnik DzP z referenčnim zdravilom (originator) dopolnil informacije o zdravilu z opozorili o z zdravili povzročenim izpuščajem z eozinofilijo in sistemskimi znaki (DRESS). V skladu s to spremembo je treba informacije v povzetku glavnih značilnosti zdravila in navodilih za uporabo generičnih zdravil, ki vsebujejo gabapentin, ustrezno dopolniti.

Imetnike dovoljenj za promet z zadevnimi zdravili, ki vloge za spremembo dovoljenja za promet še niso vložili, prosimo, da Javni agenciji RS za zdravila in medicinske pripomočke v skladu s Pravilnikom o dovoljenju za promet z zdravilom za uporabo v humani medicini (Uradni list RS, št. 109/2010) predložijo **spremembo tipa IB**. Vlogo za zadevna zdravila, ki so pridobila dovoljenje za promet po nacionalnem postopku, imetniki dovoljenj za promet predložijo najkasneje **do 1. oktobra 2012.** Za zdravila, ki so pridobila dovoljenje za promet po mednarodnih postopkih, pa v skladu s časovnico referenčne države članice (RMS). Dodatne informacije in podporna dokumentacija v vlogi niso potrebne.

V nadaljevanju vam podajamo odobreno originalno besedilo spremembe, objavljeno je tudi na spletni strani Vodij agencij za zdravila http://www.hma.eu/222.html.

S spoštovanjem,

Milena Radoha Bergoč, mag. farm.
vodja Oddelka za vigilanco

Pripravila:
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SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.4
Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)
Severe, life-threatening, systemic hypersensitivity reactions such as Drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in patients taking antiepileptic drugs including gabapentin (see section 4.8).
It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. Gabapentin should be discontinued if an alternative etiology for the signs or symptoms cannot be established.
Section 4.8
Not known drug rash with eosinophilia and systemic symptoms (see section 4.4)

PACKAGE LEAFLET

2. Before you take neurontin
Important information about potentially serious reactions
A small number of people taking Neurontin get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know these symptoms to look out for while you are taking Neurontin.
Read the description of these symptoms in section 4 of this leaflet *under 'Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious'*
4. Possible side effects
Neurontin may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalized or to stop Neurontin.
Call your doctor right away if you have any of the following symptoms:
- *skin rash*
- *hives*
- *fever*
- *swollen glands that do not go away*
- *swelling of your lip and tongue*
- *yellowing of your skin or of the whites of the eyes*
- *unusual bruising or bleeding*
- *severe fatigue or weakness*
- *unexpected muscle pain*
- *frequent infections*

These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking Neurontin.