Javna agencija Republike Slovenije
za zdravila in medicinske pripomočke
Agency for Medicinal Products
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VSEM IMETNIKOM DOVOLJENJ ZA PROMET Z ZDRAVILI, KI VSEBUJEJO ALOPURINOL, KARBAMAZEPIN, LAMOTRIGIN, FENOBARBITAL, FENITOIN, SULFAMETOKSAZOL, SULFASALAZIN, SULFADIAZIN, SULFAFURAZOL, SULFADOKSIN, MELOKSIKAM, PIROKSIKAM, TENOKSIKAM, NEVIRAPIN

Zahteva za predložitev spremembe tipa IB – dopolnitev povzetka glavnih značilnosti zdravila in navodila za uporabo za zdravila, ki vsebujejo alopurinol, karbamazepin, lamotrigin, fenobarbital, fenitoin, sulfametoksazol, sulfasalazin, sulfadiazin, sulfafurazol, sulfadoksin, meloksikam, piroksikam, tenoksikam in nevirapin

Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) pri Evropski agenciji za zdravila EMA je v oktobru 2011 sprejela ključne informacije, ki morajo biti vključene v povzetek glavnih značilnosti zdravila in v navodila za uporabo za zdravila, ki vsebujejo zgoraj naštete učinkovine. Informavije se nanašajo na možnost pojava Stevens-Johnson-ovega sindroma (SJS) in na možnost pojava toksične nekrolize kože pri uporabi zadevnih zdravil.

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 v 30 dneh ob objave obvestila, 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,

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SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.4

- Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the use of <medicine>.
- Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment. (Adoption to individual drug if such data are available)
- If symptoms or signs of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions) are present, <medicine> treatment should be discontinued.
- The best results in managing SJS and TEN come from early diagnosis and immediate discontinuation of any suspect drug. Early withdrawal is associated with a better prognosis.
- If the patient has developed SJS or TEN with the use of <medicine>, <medicine> must not be re-started in this patient at any time.

Section 4.8
Severe cutaneous adverse reactions (SCARs): Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported (see section 4.4).
Frequency: very rare
(If robust frequency data are available for a particular drug, the frequency may be assigned based on these data).

PACKAGE LEAFLET

Section 2

-Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of <medicine>, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
- These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.
- The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
(Adoption to individual drug if such data are available)

- If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of <medicine>, you must not be re-started on <medicine> at any time.

Choice between these two alternatives depending on the existing information:
- If you develop a rash or these skin symptoms, stop taking <medicine>, seek urgent advice from a doctor and tell him that you are taking this medicine.
[For antiepileptics this sentence can be completed with a warning on danger of epileptic seizure due to drug withdrawal.]
or
-If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Section 4

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).
Frequency: very rare
(If robust frequency data are available for a particular drug, the frequency may be assigned based on these data).