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Vsem imetnikom dovoljenj za promet z agonisti adrenergičnih receptorjev beta-2 (SABA)

ZAHTEVA ZA PREDLOŽITEV SPREMEMBE TIPA II – dopolnitev povzetka glavnih značilnosti zdravila (SmPC) in navodila za uporabo (PIL) za agoniste adrenergičnih receptorjev beta-2 (SABA)

Spoštovani,

Oktobra 2009 je delovna skupina za farmakovigilanco (PhVWP) ocenila podatke o uporabi SABA kot tokolitičnega zdravila pri bolnikih z ishemično srčno boleznijo in pri bolnikih z značilnim tveganjem za ishemično srčno bolezen. Na podlagi ocene podatkov je izdala priporočilo za dopolnitev povzetka glavnih značilnosti zdravil in navodil za uporabo zadevnih zdravil, vključno s *salbutamolom, terbutalinom, bambuterolom, fenoterooml, ritodrinom, prokaterolom, klenbuterooml, tolbuterolom, reproterolom, efedrinom, orciprenalinom in heksoprenalinom.*

Imetnike dovoljenj za promet z zadevnimi zdravili 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. 59/2006) predložijo spremembo tipa II najkasneje v 30 dneh po prejemu obvestila. Dodatne informacije in podporna dokumentacija v vlogi niso potrebne. Ta dopis je objavljen tudi na spletni strani JAZMP www.jazmp.si .

Odobreno originalno besedilo spremembe je podano v nadaljevanju.

S spoštovanjem,

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Za zdravila z respiratornimi in obstetričnimi indikacijami

SPC

4.3 Contraindications
[product] should not be used as a tocolytic agent in patients with pre-existing ischaemic heart disease or those patients with significant risk factors for ischaemic heart disease
4.4 Special Warnings and Precautions for Use

Cardiovascular effects may be seen with sympathomimetic drugs, including [product]. There is some evidence from post-marketing data and published literature of myocardial ischaemia associated with beta agonists.
Tocolysis
[product] should be used with caution in tocolysis and supervision of cardiorespiratory function including ECG monitoring, should be considered. Treatment should be discontinued if signs of myocardial ischaemia (such as chest pain or ECG changes) develop. [product] should not be used as a tocolytic agent in patients with significant risk factors for or pre-existing heart disease (see section 4.3).
Respiratory indications
Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving [product] should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.
4.8 Undesirable Effects
Unknown : Myocardial ischaemia* (see section 4.4)
** reported spontaneously in post-marketing data therefore frequency regarded as unknown*

PIL

Tell your doctor before starting this medicine:
– If you have a history of heart disease, irregular heart rhythm or angina. Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina). Tell your doctor/midwife if you develop these symptoms whilst receiving treatment with [product], but do not stop using this medicine unless told to do so.

Za zdravila z respiratornimi indikacijami

SPC

4.4 Special Warnings and Precautions for Use
Cardiovascular effects may be seen with sympathomimetic drugs, including [product]. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with beta agonists. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving [product] should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.
4.8 Undesirable Effects
Unknown: myocardial ischaemia* (see section 4.4)
* reported spontaneously in post-marketing data therefore frequency regarded as unknown

PIL

Tell your doctor before starting this medicine:
–If you have a history of heart disease, irregular heart rhythm or angina.
Side effects:
Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina). Tell your doctor/midwife if you develop these symptoms whilst receiving treatment with [product], but do not stop using

this medicine unless told to do so.

NOTE: *In the event that no reports of myocardial ischaemia (spontaneous or otherwise) have been received for [product], a warning should be included in section 4.4 of the SPC (and a contraindication in section 4.3 for products with obstetric indications), but it will not be necessary to include 'myocardial ischaemia' in section 4.8.*