

Sikkerhetsoppdatering

Kortidsvirkende beta-agonister og risiko for kardial iskemi

April 2010

Tekst til preparatomtale (for preparater med både respiratorisk og obstetrisk indikasjon)

Wording proposed for product information for short-acting beta agonists in the EU including salbutamol, terbutaline, bambuterol, fenoterol, ritodrine, procaterol, clenbuterol, tolbuterol, reproterol, ephedrine, orciprenaline, and hexoprenaline. For products with both respiratory and obstetric indications

SUMMARY OF PRODUCT CHARACTERISTICS

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

Tekst til pakningsvedlegg

PACKAGE LEAFLET

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.

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.