

Sikkerhetsoppdatering

Kortidsvirkende beta-agonister og risiko for kardial iskemi

April 2010

Tekst til preparatomtale (for preparater med respirasjonsindikasjon)

For products with respiratory-only indications

SUMMARY OF PRODUCT CHARACTERISTICS

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
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.

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.

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.