

## **PhVWP: Salbutamol and the risk of myocardial ischemia-finalised SPC/PIL wording**

(22.12.2006)

### **PROPOSED SPC WORDING FOR SALBUTAMOL – PRODUCTS WITH RESPIRATORY INDICATIONS ONLY** (Proposed changes in bold text)

#### *Section 4.4: Special Warnings and Precautions for use*

**There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease, tachyarrhythmia or severe heart failure) who are receiving salbutamol for respiratory disease, should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease.**

#### *Section 4.8: Undesirable effects*

Very rare: Cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles), **myocardial ischaemia.**

#### *Patient Information Leaflet*

Tell your doctor before starting to take this medicine:

- **If you have a history of heart disease or angina**

Side effects:

**Very rarely, some people may experience chest pain (due to heart problems such as angina). Tell your doctor as soon as possible, but do not stop using this medicine unless told to do so.**

### **PROPOSED SPC WORDING FOR SALBUTAMOL – PRODUCTS WITH BOTH OBSTETRIC AND RESPIRATORY INDICATIONS** (Proposed changes in bold text)

#### *4.3: Contraindications*

**Salbutamol 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*

**There is some evidence from post-marketing data and published literature of myocardial ischaemia associated with salbutamol, in both the respiratory and obstetric indications.**

##### **Tocolysis**

**Salbutamol 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. Salbutamol should not be used as a tocolytic agent in patients with risk factors for or pre-existing heart disease (see Contraindications).**

##### **Respiratory indications**

**Patients with underlying severe heart disease (e.g. ischaemic heart disease, tachyarrhythmia or severe heart failure) who are receiving salbutamol for respiratory disease, should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease.**

#### *4.8: Undesirable Effects*

**There is some evidence from post-marketing data and published literature for the occurrence of myocardial ischaemia in association with salbutamol.**

##### *Patient Information Leaflet*

Tell your doctor before starting this medicine:

- **If you have a history of heart disease or angina.**

Side effects:

**Some people may experience chest pain (due to heart problems such as angina). Tell your doctor/midwife if you develop these symptoms whilst receiving treatment with salbutamol, but do not stop using this medicine unless told to do so.**