

### **Annex III**

#### **Amendments to relevant sections of the summary of product characteristics and package leaflet**

Note:

This Summary of Product Characteristics and package leaflet is the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

## A. Summary of Product Characteristics

### Section 4.2 Posology and method of administration:

*[The wording below should be inserted in this section]*

*[...]*

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4 Special warnings and precautions for use).

### Section 4.3 Contraindications:

*[The wording below should be inserted in this section]*

*[...]*

Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

*[...]*

### Section 4.4 Special warnings and precautions for use:

*[The wording below should be inserted in this section]*

*[...]*

Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with diclofenac after careful consideration. As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

*[...]*

### Section 4.8 Undesirable effects:

*[The wording below should be inserted in this section]*

*[...]*

Clinical trial and epidemiological data consistently point towards an increased risk of arterial thrombotic events (for example myocardial infarction or stroke) associated with the use of diclofenac, particularly at high dose (150mg daily) and in long term treatment. (see section 4.3 and 4.4 for Contraindications and Special warnings and special precautions for use).

*[...]*

## B. Package Leaflet

### Section 2 'What you need to know before you take <diclofenac containing medicinal product>

*[The wording below should be inserted in the relevant sections]*

*[...]*

Do not use diclofenac

- if you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)

Make sure your doctor knows, before you are given diclofenac

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

*[...]*