Annex III

Amendments to relevant sections of the Product Information

Note:

These amendments to the relevant sections of the Summary of Product Characteristics and package leaflet are 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.

The existing product information shall be amended (insertion, replacement or deletion of the text as appropriate) to reflect the agreed wording as provided below.

Summary of product characteristics

4.3 Contraindications

[The following contraindication should be included]

[…]

<Invented name and strength(s)> is contraindicated in patients with a known or suspected allergy to cow's milk (see section 4.4).

4.4 Special warnings and precautions for use

[The following warning should be included]

Immune System Effects

[…]

Cow's milk allergy [The following clarification in brackets should be included in case of combined SmPC with strength(s) not included in Annex I] (the following paragraphs only apply to <invented name and strength(s)>)

<Invented name and strength(s)> contains lactose <monohydrate> produced from bovine origin as an excipient and may therefore contain trace amounts of cow's milk proteins (the allergens of cow's milk). Serious allergic reactions, including bronchospasm and anaphylaxis, were reported in patients allergic to cow's milk proteins who were treated for acute allergic conditions. Patients with known or suspected allergy to cow's milk must not be administered <invented name and strength(s)> (see section 4.3).

Allergic reactions to cow's milk proteins should be considered in patients receiving <invented name and strength(s)> for the treatment of acute allergic conditions in whom symptoms worsen or who are presenting new allergic symptoms (see section 4.3). Administration of <invented name and strength(s)> should be stopped, and the patient's condition should be treated accordingly.

[…]

Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

[…]

7. OTHER SPECIAL WARNING(S), IF NECESSARY

[A warning should be included as follows]

Do not use in cow's milk allergy patients.

[…]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

[…]

6. OTHER

[A warning should be included as follows]

Do not use in cow's milk allergy patients.

[…]

Package leaflet

[…]

2. What you need to know before you are given <invented name>

Do not use <invented name and strength(s)>:

[…]

[A warning should be included as follows. In case of combined package leaflet with strength(s) not included in Annex I, the strength(s) of products in Annex I should be specified in the subheading above]

If you are allergic or suspected to be allergic to cow's milk.

[…]

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you have any of the following conditions.

[A warning should be included as follows]

[…]

<invented name and strength(s)> contains cow's milk proteins

If you are allergic or suspected to be allergic to cow's milk, you must not be given this medicine as it may contain trace amounts of cow's milk proteins. Serious allergic reactions have occurred in patients allergic to cow's milk.