

Annex III

Amendments to relevant sections of the Product Information

Note:

These amendments to the relevant sections of the Product Information 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.

Amendments to relevant sections of the Product Information

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

A. Summary of Product Characteristics

Section 4.1 Therapeutic indications

The acne indication should be revised to read as follows:

- Oral contraception
- **Treatment of moderate acne after failure of suitable topical therapies or oral antibiotic treatment in women who elect to use an oral contraceptive.**

The decision to prescribe [x] should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with [x] compares with other combined hormonal contraceptives (CHCs) (see sections 4.3 and 4.4).

Section 4.2 Posology and method of administration

In relation to the acne indication the posology should be revised with the addition of the following statement:

Apparent improvement of acne usually takes at least three months and further improvement has been reported after six months of treatment. Women should be assessed 3-6 months after treatment initiation and periodically thereafter to review the need for continuation of treatment.

C. Package Leaflet

This wording regarding the acne indication should be revised to read as follows:

1. What [x] is and what it is used for

- [x] is a medicinal product
- to prevent pregnancy (contraceptive "pill").
 - **For treatment of women with moderate acne who agree to receive a contraceptive pill after failure of suitable local or oral antibiotic treatments.**

2. What you need to know before you take [x]

[...]

Your acne will usually improve between three and six months of treatment, and could continue to improve even after six months. You should discuss with your doctor the need to continue your treatment three to six months after the start and regularly thereafter.