

Annex III

Amendments to the relevant sections of the product information

Note:

This product information is the outcome of the referral procedure to which this Commission decision relates.

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 the relevant sections of the product information

The valid product information is the final version achieved during the Coordination group procedure with the following amendments (insertion, replacement or deletion of the text as appropriate) to reflect the agreed wording as provided below:

A. Summary of Product Characteristics

Section 4.2 Posology and method of administration

[The phrase below should be amended as follows]

For oral administration and short term use only (not more than 3 days).

[...]

[The phrase below should be inserted]

This medicine is for short term use and is not recommended for use beyond 3 days.

[...]

Section 4.4 Special warnings and precautions for use

[The wording below should be inserted in this section]

[...]

This medicine is for short term use and is not recommended for use beyond 3 days.

[...]

Hepatic Impairment

[...]

[The wording below should be inserted in this section]

Dose reduction is recommended in patients showing signs of worsening hepatic function. Treatment should be stopped in those patients who develop severe liver failure (see section 4.3).

[...]

Renal Impairment

[...]

[The wording below should be inserted in this section]

Treatment should be stopped in those patients who develop severe renal failure (see section 4.3).

[...]

Section 4.5 Interaction with other medicinal products and other forms of interaction

[...]

[The following wording should be amended as follows]

This medicinal product should not be taken with other medicinal products containing paracetamol, ibuprofen, acetylsalicylic acid, salicylates or with any other anti-inflammatory drugs (NSAIDs) unless under a doctor's instruction.

[...]

Section 4.8 Undesirable effects

[...]

[The following AEs are described as follows:]

'Paraesthesia' to frequency Rare (moved from Very Rare)

'Oedema' to frequency Common (moved from Very Rare)

[...]

Section 5.1 Pharmacodynamic properties

[...]

[The following phrase is deleted as it was duplication]

The exact mechanism of action of ibuprofen is thought to be through peripheral inhibition of cyclooxygenases and subsequent prostaglandin synthesis inhibition.

Section 5.3 Preclinical data

Ibuprofen

[The following phrase is deleted]

The active substance ibuprofen shows an environmental risk for the aquatic environment especially to fish.

Section 6.1 List of excipients

[The following phrase is amended]

[...]

- Macrogol/PEG-4000

[...]

B. Labelling

Carton

[The following wording should be amended as follows]

For oral use. For short term use only (not more than 3 days).

[...]

7. OTHER SPECIAL WARNING(S), IF NECESSARY

[...]

Do not take if you:

[The wording below should be inserted in this section]

[...]

- are under 18 years

Talk to a pharmacist or your doctor before taking if you:

[...]

[The following wording should be amended as follows]

If your symptoms do not get better after 3 days, if they get worse or if you get new symptoms, talk to your doctor.

[...]

15. INSTRUCTIONS ON USE

Adults:

[...]

[The wording below should be inserted in this section]

Do not take for more than 3 days.

Children under 18 years:

[The following wording should be amended as follows]

~~This product is not recommended for~~ Do not give to children under 18 years.

[...]

C. Package Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

[...]

[The wording below should be inserted in this section]

- You should not take this product for longer than 3 days.

[...]

How to take {Paracetamol/Ibuprofen 500 mg/150mg film coated tablets} {Novogesic 500 mg/150 mg film coated tablets}

[...]

[The wording below should be inserted in this section]

Do not take for more than 3 days.

[...]

What {Paracetamol/Ibuprofen 500 mg/150mg film coated tablets} {Novogesic 500 mg/150 mg film coated tablets} contain

[The wording below should be inserted in this section]

[...]

macrogol/PEG 4000

[...]