

Annex III

Amendments of the Summary of Product Characteristics and Package Leaflet

Note: These amendments to the summary of product characteristics and package leaflet are valid at the time of the Commission Decision.

After the Commission Decision the National Competent Authorities will update the product information as required.

Amendments to be included in the relevant sections of the Summary of Product Characteristics and Package Leaflet for nimesulide containing medicinal products for systemic use, as relevant

The following wording is deleted (~~strikethrough text~~), added or moved (underlined text) within the same section of the SmPC and PL as follows:

Summary of Product Characteristics

[...]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of acute pain (see section 4.2)

~~Symptomatic treatment of painful osteoarthritis (see section 4.2)~~

Primary dysmenorrhoea

Nimesulide should only be prescribed as second line treatment. The decision to prescribe nimesulide should be based on assessment of the individual patient's overall risks (see section 4.3 and 4.4).

[...]

4.8 Undesirable effects

[...]

Gastrointestinal disorders

[...]

Uncommon: Gastrointestinal bleeding, Duodenal ulcer and perforation, Gastric ulcer and perforation

[...]

Hepato-biliary disorders

Common: Hepatic enzymes increased

[...]

Package Leaflet

[...]

1. WHAT {*(INVENTED) NAME*} IS AND WHAT IT IS USED FOR

{*(Invented) name*} is a non-steroidal anti-inflammatory drug ("NSAID") with pain-killing properties. It is used for the treatment of acute pain, ~~for the treatment of symptoms of painful osteoarthritis~~ and for the treatment of period pains.

[...]

4. POSSIBLE SIDE EFFECTS

[...]

Side effects that may occur with {*(Invented) name*} are:

[...]

Uncommon: bleeding from stomach or bowel; duodenal or stomach ulcers and burst ulcers.

[...]