

ANNEX III

AMENDMENTS TO THE SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE SUMMARY OF PRODUCT CHARACTERISTICS OF KETOPROFEN CONTAINING MEDICINAL PRODUCTS FOR TOPICAL USE

Amendments appear in italics and underlined

4.3 Contraindications

...[]...

Section 4.3 of the SPC should contain the following:

- history of any photosensitivity reaction
- known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAID
- history of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate or UV blocker or perfumes
- sun exposure, even in case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation

4.4 Special warnings and special precautions for use

...[]...

Section 4.4 of the SPC should contain the following:

- Hands should be washed thoroughly after each application of the product.
- Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of octocrylene containing products
- It is recommended to protect treated areas by wearing clothing during all the application of the product and two weeks following its discontinuation to avoid the risk of photosensitisation.

4.8 Undesirable effects

...[]...

Section 4.8 of the SPC should contain the following:

- Local skin reactions such as erythema, pruritis and burning sensations.
- Cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized have occurred rarely.
- Hypersensitivity reactions.
- Dermatological: photosensitisation

LABELLING

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE LABELLING OF KETOPROFEN CONTAINING MEDICINAL PRODUCTS FOR TOPICAL USE

Amendments appear in italics and underlined

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

{NATURE/TYPE}

7. OTHER SPECIAL WARNING(S), IF NECESSARY

...[]...

Pictogram to be agreed with the NCA and inserted here <> along with the below sentence

Do not expose treated areas to sunlight (even hazy) including UV from solarium during the treatment and the 2 weeks after its discontinuation

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PLASTERS

6. OTHER

...[]...

Pictogram to be agreed with the NCA and inserted here <> along with the below sentence

Do not expose treated areas to sunlight (even hazy) including UV from solarium during the treatment and the 2 weeks after its discontinuation

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE PACKAGE LEAFLET OF KETOPROFEN CONTAINING MEDICINAL PRODUCTS FOR TOPICAL USE

Amendments appear in italics and underlined

2. BEFORE YOU <TAKE> <USE> X

Do not <take> <use> X

...[]...

- Do not use if history of allergy to ketoprofen, tiaprofenic acid, fenofibrate, UV blockers or perfumes is known
- Stop using X immediately if you experience any skin reaction including cutaneous reactions after co-application of octocrylene containing products (Octocrylene is one of the excipient of several cosmetic and hygiene products such as shampoo, after-shave, shower- and bath-gels, skin creams, lipsticks, anti-ageing creams, make-up removers, hair sprays in order to delay photodegradation.)
- Do not expose treated areas to sunlight or UV light from solarium during the treatment and the 2 weeks following its discontinuation.

Take special care with X

...[]...

- The exposure to the sun (even hazy) or to UVA of areas in touch with X can induce potentially serious cutaneous reactions (photosensitisation). Therefore it is necessary to:
 - protect treated areas by wearing clothing during the treatment and for two weeks after its discontinuation to avoid any risk of photosensitisation.
 - wash your hands thoroughly after each application of X.
- Treatment should be discontinued immediately upon development of any skin reaction after application of X.

4. POSSIBLE SIDE EFFECTS

...[]...

- allergy skin reactions
- severe skin reaction during an exposure to the sun light
- Cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized have occurred rarely