EMA/332400/2024

Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for salicylic acid (topical use), the scientific conclusions are as follows:

In view of available data on the expected risk of topical salicylic acid use during pregnancy from the literature and in view of information about medicinal products of the same therapeutic class, the PRAC considers a causal relationship between the cutaneous formulations of salicylic acid (topical use) and an increased risk of use during pregnancy is at least a reasonable possibility. The PRAC concluded that the product information of products containing salicylic acid (topical use) should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for salicylic acid (topical use) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing salicylic acid (topical use) is unchanged subject to the proposed changes to the product information.

The CMDh recommends that the terms of the marketing authorisation(s) should be varied

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

For products for cutaneous use as ointment, 100 mg/ml solution, patch, gel, and adhesive plaster.

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)>

Summary of Product Characteristics

- Section 4.6

The recommendations for use in pregnancy should be amended as follows:

Pregnancy

There are no or limited amount of data from the use of [product name] during pregnancy.

[product name] should not be used during pregnancy, except for short-term treatment of a small single < area of the skin>/<wart>/<callus>/<partridge's eye >.

It is not known if the systemic [product name] exposure reached after topical administration can be harmful to an embryo/fetus.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed.

Package Leaflet

Section 2. What you need to know before you <take/use> [product name]

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You should not use [product name] during pregnancy except for short-term treatment of a small single <area of the skin>/<wart>/<callus>/<partridge's eye >.

Oral forms (e.g. tablets) of this product class can cause adverse effects in your unborn baby. It is not known if the same risks apply to [product name] when it is used <on the skin>/<on warts>/<on calluses>/<on partridge's eyes >

In case the product information already includes a similar or stricter information regarding use in pregnancy, the similar or stricter advice remains valid and should remain.

For products for cutaneous use as 10% solution or gel on the scalp.

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.3

The contraindication should be added as follows:

- **third trimester of pregnancy**

- Section 4.6

The recommendations for use in pregnancy should be amended as follows:

Pregnancy

There are no or limited amount of data from the use of [product name] during pregnancy.

It is not known if the systemic [product name] exposure reached after topical administration can be harmful to an embryo/fetus. During the first and second trimester of pregnancy, [product name] should not be used unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed. Therefore, [product name] is contraindicated during the last trimester of pregnancy (see Section 4.3).

Package Leaflet

Section 2. What you need to know before you <take/use> [product name]

Do not use <product>

If you are in the last 3 months of pregnancy.

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Do not use [product name] if you are in the last 3 months of pregnancy.

You should not use [product name] during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. tablets) of this product class can cause adverse effects in your unborn baby. It is not known if the same risks apply to [product name] when it is used on the scalp.

In case the product information already includes a similar or stricter information regarding use in pregnancy, the similar or stricter advice remains valid and should remain.

For products for ophthalmic use.

Amendments to be included in the relevant sections of the Product Information (new text **<u>underlined and in bold</u>**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.6

The recommendations for use in pregnancy should be amended as follows:

Pregnancy

<u>At the intended use, no effects during pregnancy are anticipated, since systemic exposure to salicylic acid is negligible. [Product name] can be used during pregnancy.</u>

Package Leaflet

Section 2. What you need to know before you <take/use> [product name]

Pregnancy

<u>You can use [product name] if you are pregnant.</u>

In case the product information already includes a similar or stricter information regarding use in pregnancy, the similar or stricter advice remains valid and should remain.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	8 September 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	7 November 2024