

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 tolperisone, the scientific conclusions are as follows:

Tolperisone overdose

Based on the analysis of data reported from a poison centre in Switzerland on tolperisone overdose from patients taking tolperisone alone or in combination with non-steroidal anti-inflammatory drugs, the PRAC recommends updating the information on tolperisone overdose in the product information of tolperisone-containing medicinal products.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

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

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing tolperisone are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

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

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 4.9 Overdose

Symptoms in overdose may include somnolence, gastrointestinal symptoms (nausea, vomiting, epigastric pain), tachycardia, hypertension, bradykinesia and vertigo. In severe cases seizure, respiratory depression, apnoea and coma were reported.

There is no special antidote for tolperisone, and symptomatic treatment is recommended.

Package Leaflet

- Section 3: If you take more X than you should:

Symptoms in overdose may include sleepiness, gastrointestinal symptoms (such as feeling sick, vomiting, pain in the upper part of the stomach), fast heartbeat, high blood pressure, slowness of movement, and a sense of spinning dizziness. In severe cases seizure, slowing or cessation of breathing and coma were reported.

In case of overdose, you should contact your doctor or pharmacist or an emergency department immediately.

Annex III

Timetable for the implementation of this position>

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| Adoption of CMDh position: | January 2020 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 15 March 2020 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 14 May 2020 |