Pseudoephedrine-containing medicinal products - referral

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Current status

Recommendation provided by Pharmacovigilance Risk Assessment Committee

Referral Human

Procedure started

Under evaluation

PRAC recommendation

CHMP opinion

European Commission final decision

Overview

PRAC recommends measures to minimise the risk of serious side effects with medicines containing pseudoephedrine

EMA's safety committee, PRAC, has recommended new measures for medicines containing pseudoephedrine to minimise the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

PRES and RCVS are rare conditions that can involve reduced blood supply to the

brain, potentially causing serious, life-threatening complications. With prompt diagnosis and treatment, symptoms of PRES and RCVS usually resolve.

PRAC has recommended that medicines containing pseudoephedrine are not to be used in patients with high blood pressure that is severe or uncontrolled (not being treated or resistant to treatment), or with severe acute (sudden) or chronic (long-term) kidney disease or failure.

The PRAC also recommended that healthcare professionals should advise patients to stop using these medicines immediately and seek treatment if they develop symptoms of PRES or RCVS, such as severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures and visual disturbances.

The recommendations follow a review of all available evidence, including post-marketing safety data, which concluded that pseudoephedrine is associated with risks of PRES and RCVS. During the review, PRAC sought advice from an expert group of general practitioners, otorhinolaryngologists (specialists in diseases of the ear, nose, throat, head and neck), allergologists (specialists in the treatment of allergies) and a patient representative. PRAC also considered information submitted by a third party representing healthcare professionals.

The product information for all pseudoephedrine-containing medicines will be updated to include the risks concerning PRES and RCVS and the new measures to be taken. Restrictions and warnings are already included in the product information of these medicines to reduce cardiovascular and cerebrovascular ischaemic (involving reduced blood supply to the heart and brain) risks.

The PRAC recommendations will now be sent to EMA's human medicines committee (CHMP), which will adopt the Agency's final opinion.

More about the medicine

More about the procedure

Pseudoephedrine-containing medicines Article-31 referral - Review started

First published: 01/12/2023
Reference Number: EMA/535476/2023

English (EN) (115.15 KB - PDF) View

Key facts

About this medicine

Approved name	Pseudoephedrine-containing medicinal products
International non-proprietary name (INN) or common name	pseudoephedrine
Class	Nasal decongestants for systemic use

About this procedure

Current status	Recommendation provided by Pharmacovigilance Risk Assessment Committee
Reference number	EMEA/H/A-31/1526
Type	Article 31 referrals This type of referral is triggered when the interest of the Union is involved, following concerns relating to the quality, safety or efficacy of a medicine or a class of medicines.
Authorisation model	Centrally and nationally authorised products (mixed)
Decision making model	PRAC-CHMP-EC

Key dates and outcomes

Procedure start date	09/02/2023

All documents

Procedure started

Pseudoephedrine-containing medicines Article-31 referral - Notification

First published: 10/02/2023

English (EN) (59.73 KB - PDF) View

Pseudoephedrine-containing medicines Article-31 referral - PRAC List of questions

First published: 10/02/2023
Reference Number: EMA/PRAC/55342/2023

English (EN) (127.12 KB - PDF) View

Under evaluation

Pseudoephedrine-containing medicines Article-31 referral - Annex A and Annex I

Draft
First published: 10/02/2023
Last updated: 12/05/2023
Reference Number: EMA/55341/2023 Rev. 1 Corr. 1

English (EN) (586.12 KB - PDF) View

Pseudoephedrine-containing medicines Article-31 referral - Timetable for the procedure

First published: 10/02/2023
Last updated: 29/09/2023
Reference Number: EMA/PRAC/55340/2023 Rev. 3

English (EN) (114.43 KB - PDF) View

Recommendation provided by Pharmacovigilance Risk Assessment Committee

Pseudoephedrine-containing medicines Article-31 referral - Review started

First published: 01/12/2023
Reference Number: EMA/535476/2023

English (EN) (115.15 KB - PDF) View

Description of documents published

Please note that some of the listed documents apply only to certain procedures.

- Overview - lay-language summary of the stage of the procedure
- Notification – a letter from a Member State, the European Commission or the marketing authorisation holder requesting the initiation of the procedure
- Scientific background – further background information from the triggering Member State on the issues leading to the initiation of the procedure (if applicable)
- List of questions – questions agreed by the Committee requesting further information from the marketing authorisation holder(s) / applicant(s) to evaluate the issues identified
- Timetable for the procedure – agreed timeframe to respond to the list of questions, to assess the issues and to adopt a conclusion
- List of medicines concerned by the procedure – medicine(s) / active substance(s) concerned, and marketing authorisation holder(s) / applicant(s)
- List of questions to be addressed by the stakeholders – call for data to be submitted by stakeholders (e.g. healthcare professionals, patient organisations, individual patients) (if applicable)
- Stakeholder submission form – form to be used by stakeholders to submit data (if applicable)
- Scientific conclusions – scientific conclusions of the PRAC and/or CHMP and/or CMDh
- Assessment report – PRAC or CHMP assessment and conclusions on the issues investigated, including divergent positions (if applicable)
- Divergent positions – divergent positions of the CHMP or CMDh members for pharmacovigilance procedures (if applicable)
- Changes to the summary of product characteristics, labelling and package leaflet (amended sections or fully revised version) (if applicable)
- Condition(s) to the marketing authorisation(s) – condition(s) for the safe and effective use of the medicine(s) (if applicable)
- Condition for lifting the suspension – condition to be fulfilled for the suspension of the marketing authorisation(s) to be lifted (if applicable)
- Timetable for implementation of CMDh position – agreed timeframe to submit and finalise the variation(s) implementing the outcome of the procedure (if applicable)

Note that older documents may have different titles.

News

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 27-30 November 2023

01/12/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 23-26 October 2023

27/10/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 25-28 September 2023

29/09/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 28-31 August 2023

01/09/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3 - 6 July 2023

07/07/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 5 - 8 June 2023

09/06/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 10 - 12 May 2023

12/05/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 11-14 April 2023

14/04/2023

PRAC starts safety review of pseudoephedrine-containing medicines

10/02/2023

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6 - 9 February 2023

10/02/2023

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