EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ulipristal acetate 5mg medicinal products

Procedure started

Under evaluation

PRAC recommendation

CHMP opinion

European Commission final decision

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CURRENT STATUS:
Recommendation provided by Pharmacovigilance Risk Assessment Committee

Overview

PRAC recommends revoking marketing authorisation of ulipristal acetate for uterine fibroids

A review by EMA's safety committee (PRAC) has confirmed that 5-mg ulipristal acetate (Esmya and generic medicines) used for the treatment of symptoms of uterine fibroids can cause liver injury, including the need for liver transplantation. The PRAC has therefore recommended the revocation of the marketing authorisations of these medicines.

The PRAC considered all the available evidence in its review, including reported cases of serious liver injury. Patient and healthcare professional representatives, including experts in gynaecology, were also consulted. Since it was not possible to identify which patients were most at risk or measures that could reduce the risk, the PRAC concluded that the risks of these medicines outweighed their benefits and that they should not be marketed in the EU.

The use of 5-mg ulipristal acetate medicines for uterine fibroids had already been suspended as a precautionary measure while awaiting the outcome of this review.

Ulipristal acetate is also authorised as a single-dose medicine for emergency contraception. This recommendation does not affect the single-dose ulipristal acetate emergency contraceptive (ellaOne and other trade names) and there is no concern about liver injury with these medicines.

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

More about the medicines

Ulipristal acetate was authorised for treating moderate to severe symptoms of uterine fibroids, which are non-cancerous tumours of the womb, in women who have not reached the menopause. It was used for up to 3 months before women had surgery to remove the fibroids and was also used long-term but with treatment breaks in other women.

Esmya (ulipristal acetate) was authorised throughout the EU in 2012. Esmya was the subject of a previous review in 2018. Ulipristal Acetate Gedeon Richter was authorised throughout the EU in 2018. Generic ulipristal acetate medicines have been authorised via national procedures in several EU countries under various trade names.

More information on Esmya and Ulipristal Acetate Gedeon Richter is available on the EMA website.

More about the procedure

The review of Esmya, Ulipristal Acetate Gedeon Richter and generics was initiated at the request of the European Commission, under Article 31 of Directive 2001/83/EC.

The review was carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines.

On 12 March 2020, the PRAC recommended suspension of the marketing authorisations of 5-mg ulipristal acetate (Esmya and generic medicines) while the review was ongoing. The European Commission issued a legally binding decision to suspend the marketing authorisation on 25 March 2020.

The PRAC recommendations will now be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

Ulipristal acetate 5mg medicinal products Article-31 referral- PRAC recommends revoking marketing authorisation of ulipristal acetate for uterine fibroids (PDF/139.75 KB)

Adopted

First published: 04/09/2020
EMA/455818/2020

Key facts

Approved name

Ulipristal acetate 5mg medicinal products

International non-proprietary name (INN) or common name

Ulipristal acetate

Associated names

- Esmya
- Ulipristal Acetate Gedeon Richter

Class

Progesterone receptor modulators

Current status

Recommendation provided by Pharmacovigilance Risk Assessment Committee

Reference number

EMEA/H/A-31/1496

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.

Decision making model

PRAC-CHMP-EC

Authorisation model

Centrally and nationally authorised products (mixed)

Procedure start date

12/03/2020

PRAC recommendation date

04/09/2020

All documents

Procedure started

Ulipristal acetate 5mg medicinal products Article-31 referral - Assessment report on temporary measures (PDF/374.44 KB)

Adopted

First published: 02/04/2020
EMA/70192/2018

Ulipristal acetate 5mg medicinal products Article-31 referral - Review started (PDF/146.89 KB)

First published: 13/03/2020
Last updated: 30/03/2020
EMA/121879/2020

Ulipristal acetate 5mg medicinal products Article-31 referral - Notification (PDF/946.55 KB)

First published: 13/03/2020

Ulipristal acetate 5mg medicinal products Article-31 referral - PRAC list of questions (PDF/222.05 KB)

First published: 13/03/2020
EMA/PRAC/121855/2020

Ulipristal acetate 5mg medicinal products Article-31 referral - Annexes A and Annex I (PDF/174.32 KB)

First published: 13/03/2020
Last updated: 29/04/2020
EMA/134973/2020 Rev.1

Under evaluation

Ulipristal acetate 5mg medicinal products Article-31 referral - Timetable for the procedure (PDF/125.7 KB)

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EMA/PRAC/121857/2020 Rev.1

Recommendation provided by Pharmacovigilance Risk Assessment Committee

Ulipristal acetate 5mg medicinal products Article-31 referral- PRAC recommends revoking marketing authorisation of ulipristal acetate for uterine fibroids (PDF/139.75 KB)

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Document description

- Annex I - List of the medicines affected by the referral
- Annex II - Scientific conclusions of the CHMP or CMDh
- Annex III - Changes to the summary of product characteristics, labelling or package leaflet - available when the CHMP or CMDh recommends changes to the product information. Also includes conditions for lifting of suspensions, if applicable
- Annex IV - Conditions of the marketing authorisation - available when the CHMP or CMDh recommends other measures to be taken for the marketing authorisation such as safety measures or additional studies
- Notification - A letter from a Member State, the European Commission or a marketing-authorisation holder requesting the initiation of a referral procedure
- Rationale for triggering - Background provided by the party triggering the referral explaining the issues leading to the initiation of the procedure
- PRAC list of questions - Questions agreed by the PRAC requesting further information to evaluate the issues identified
- PRAC timetable - Timeframe agreed by the PRAC to receive information, assess the issues and adopt a recommendation
- PRAC / CHMP or CMDh assessment report - The assessment and conclusions of the PRAC and CHMP or CMDh on the issues investigated

News

- PRAC recommends revoking marketing authorisation of ulipristal acetate for uterine fibroids
  04/09/2020
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 31 August - 3 September 2020
  04/09/2020

- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 July 2020
  10/07/2020
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 June 2020
  12/06/2020
- Suspension of ulipristal acetate for uterine fibroids during ongoing EMA review of liver injury risk
  13/03/2020
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9-12 March 2020
  13/03/2020

Related content

- Esmya: EPAR
- Ulipristal Acetate Gedeon Richter: EPAR
- Esmya: Article 20 procedures

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