



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 March 2017  
EMA/144306/2017

## New review of valproate use in pregnancy and women of childbearing age

EMA to consider if risks of these medicines require further restrictions of use

The European Medicines Agency (EMA) has started a review looking at the use of valproate-containing medicines in the treatment of women and girls who are pregnant or of childbearing age. These medicines are approved nationally in the EU to treat epilepsy, bipolar disorder and in some countries, migraine, and have been previously reviewed by the Agency.

An EMA review in 2014<sup>1</sup> resulted in measures to strengthen the warnings and restrictions on the use of valproate medicines in women and girls, due to the risk of malformations and developmental problems in babies who are exposed to valproate in the womb. Although sometimes there may be no alternative to using valproate, these measures aimed to ensure that patients are aware of the risks of doing so, and that they take valproate only when clearly necessary. The 2014 review also recommended studies at EU level to measure how effective the proposed measures were.

Some EU member states have since carried out additional assessments of the impact of the measures at national level and concerns have been raised about how effective the measures have been in increasing awareness and reducing valproate use appropriately in its various indications. The French medicines regulator, ANSM, therefore asked EMA to review the effectiveness of the measures and to consider whether further EU-wide action should be recommended to minimise the risks in women who are pregnant or of childbearing age.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will examine the available evidence and will consult with relevant stakeholder groups. This will include holding a public hearing about their concerns. While the review is ongoing, patients prescribed valproate who have any concerns about their medication should discuss them with their healthcare professionals.

---

### More about the medicine

Valproate medicines are used to treat epilepsy and bipolar disorder. In some EU Member States they are also authorised to prevent migraine headaches.

---

<sup>1</sup>[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate\\_and\\_related\\_substances/human\\_referral\\_prac\\_000032.jsp&mid=WCOb01ac05805c516f](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate_and_related_substances/human_referral_prac_000032.jsp&mid=WCOb01ac05805c516f)



The active ingredient in these medicines may be valproic acid, magnesium valproate, sodium valproate, valproate semisodium or valpromide.

Valproate medicines have been authorised via national procedures in all EU Member States and in Norway and Iceland. They are marketed under several brand names including: Absenor, Convival Chrono, Convulex, Delepsine, Depakin, Depakine, Depakote, Depamag, Depamide, Deprakine, Diplexil, Dipromal, Epilim, Episenta, Epival, Ergenyl, Espa-Valept, Hexaquin, Kentlim, Leptilan, Micropakine L.P., Orfiril, Petilin, Valepil, Valhel PR, Valpal, Valpro and Valprolek.

### **More about the procedure**

The review of valproate was initiated on 9 March 2017 at the request of the French medicines regulator ANSM, under [Article 31 of Directive 2001/83/EC](#).

The review will be carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be sent to Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

### **Contact our press officer**

---

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: [press@ema.europa.eu](mailto:press@ema.europa.eu)