EMA starts new review of valproate use in pregnancy and women of childbearing age.

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Information on valproate-containing medicines

- Valproate medicines are used to treat epilepsy and bipolar disorder. In some EU Member States (not in Malta) they are also authorised to prevent migraine headaches.
- 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.

In Malta the following products are authorised:

Medicine Name	Active Ingredients	Pharmaceutical Forms	Classific-ation	Authorisation Number	Authorization Holder
Epilim 200 Enteric Coated Tablets	Valproate sodium 200 milligram(s)	Gastro-resistant tablet	POM	AA082/04311	Sanofi Malta Limited
Epilim 500 Enteric Coated Tablets	Valproate sodium 500 milligram(s)	Gastro-resistant tablet	POM	AA082/04312	Sanofi Malta Limited
Epilim Intravenous	Valproate sodium 400 milligram(s)	Powder and solvent for solution for infusion or injection	POM	MA082/04303	Sanofi Malta Limited
Epilim Liquid, 200mg/5ml, liquid	Valproate sodium 200 milligram(s)/5 millilitre	Oral solution	POM	MA082/04311	Sanofi Malta Limited
Epilim Chrono 200 Controlled Release	Valproate sodium 200 milligram(s)	Prolonged-release tablet	POM	MA082/04301	Sanofi Malta Limited
Epilim Chrono 500 Controlled Release	Valproate sodium 500 milligram(s)	Prolonged-release tablet	POM	MA082/04302	Sanofi Malta Limited
Epilim Chrono 300 Controlled Release	Valproate sodium 300 milligram(s)	Prolonged-release tablet	POM	MA082/04310	Sanofi Malta Limited
Sodium Valproate (400mg/4ml) Solution for Inj/Inf 100mg/ml	Valproate sodium 100 milligram(s) /millilitre	Solution for infusion or injection	POM	MA154/10201	Wockhardt UK Limited
Sodium Valproate (1000mg/10ml) Solution for Inj/Inf 100mg/ml	Valproate sodium 100 milligram(s)	Solution for infusion or injection	POM	MA154/10202	Wockhardt UK Limited

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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 (see circular No P24/2014) 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.
- Sometimes there may be no alternative to using valproate however 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.

In Malta

Information for healthcare professionals and patients

- Healthcare professionals are encouraged to refer to the product information when prescribing valproate-containing medicines. Such information can be accessed from the Medicines Authority's website by searching for the product in the online database.
- Risk minimisation measures (RMMs) can be found on the Medicines Authorities website at www.medicinesauthority.gov.mt/rmm. A guide for healthcare professionals and a patient information booklet are available for valproate.
- While the review is ongoing, patients prescribed valproate who have any concerns about their medication should discuss them with their healthcare professionals.

For more information on this issue please refer to the European Medicines Agency's press release.

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Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on valproate-containing medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form (available from: http://www.medicinesauthority.gov.mt/adrportal) and sent by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or email to postlicensing.medicinesauthority@gov.mt or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required).

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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