







New Infographic on medicines safety information

Infarmed publishes information about valproate/valproic acid during pregnancy

The Infarmed published an <u>infographic</u> on the website about the treatment with valproate and valproic acid during pregnancy. These medicines are authorised for the treatment of epilepsy and bipolar disorder and for the prevention of migraine.

The benefits of these drugs are higher than the risks, but their prescription during pregnancy should be carefully and quickly evaluated, because these substances <u>can cause severe malformations in babies and affect their development</u>.

Pregnancy in women who use these drugs should be planned. If these treatments are the only option, women should be advised on the use of effective contraception, until they have consulted their doctor.

If there is already a pregnancy - or a suspicion - the treatment should only be <u>immediately</u> interrupted when used for the prevention of migraine.

In other diseases - **bipolar and epilepsy** – **this treatment should not be interrupted**. This decision is to be taken by the doctor, so it is advised to schedule an appointment as soon as possible.

The Infarmed is carefully analysing all the information related to the use of these substances, following the close evaluation by the European Medicines Agency (EMA), especially since 2014.

In the package leaflet of the product, updated on 02-10-2016 and available on the *website* of the Infarmed, there is a warning about the risk of malformations and developmental problems in babies. When prescribing these medicines, the doctors should take these adverse effects into account. These drugs remain in additional monitoring.

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