

INFORMATION FOR PATIENTS (MEN AND ADOLESCENTS)

Important information about your treatment with valproate or its derivatives (Depakine, Depakote, Depamide, Micropakine and generics)

Your doctor has prescribed you a medicine containing valproate or one of its derivatives.

A study, requested to the pharmaceutical companies concerned as part of the European monitoring of these medicines, suggests an increased risk of mental and/or motor development disorders in children whose fathers was treated with valproate or one of its derivatives in the three months before conception.

This study does not allow any definitive conclusions to be drawn at this stage. Additional analyses were requested by the European Medicines Agency. In the meantime, we advise you to talk to your doctor or pharmacist.

If you are a man treated with a medicine containing valproate or one of its derivatives:

- Do not stop your treatment without talking to your doctor. If you stop your treatment, your symptoms may reappear.
- An effective method of contraception during your treatment should be discussed with your doctor.
- Tell your doctor if you are thinking about having a baby. He/she will discuss with you this potential risk and possible therapeutic alternatives.
- If you are going to have a child, contact your doctor to discuss any questions you may have.
- If you already have a child and you have questions about his/her health, the doctor may refer you to a specialised coordination and referral platform (PCO) if needed.
- If you donate sperm, specify that you are being treated with valproate or one of its derivatives.

Information on the continuation of the European assessment will be published on the ANSM web site.