VALPROATE GUIDE FOR MEN OF REPRODUCTIVE

POTENTIAL

Read this guide along with the Patient Information Leaflet (PIL)

PATIENT GUIDE FOR MEN OF REPRODUCTIVE POTENTIAL: WHAT YOU SHOULD

KNOW

If you are a man of reproductive potential taking any medicine containing valproate*, this guide is for you. It contains key information about the potential risk of taking valproate when fathering a child.

Ask your doctor or pharmacist if you have any questions.

KEEP THIS GUIDE. YOU MAY NEED TO READ IT AGAIN.

*This includes brands such as Xolpict Syrup.





What are the risks of taking valproate when fathering a child

If you father a child while you are being treated with valproate, a risk of impaired mental and/or motor development of the child cannot be excluded.

A study indicated a higher risk of impaired mental and/or motor development in children born to fathers treated with valproate at time of conception, compared to lamotrigine or levetiracetam, other medicines that can be used to treat your disease.



What does this mean for you?

As a precautionary measure your doctor will discuss with you (and/or your parent/ caregiver):

The potential risk of fathering a child if you are treated with valproate.

) The alternative treatments available for you. ()) The need to

use effective contraception.



At treatment initiation and during an annual visit, your doctor will discuss these risks with you to ensure you know and understand the risks related to the use of valproate when fathering a child.



PLEASE REFER TO THE Patient Information Leaflet (PIL)FOR MORE DETAILED INFORMATION

Medizen Pharmaceutical Industries-Pharmacovigilance directorate Address: 426 El-Horeya Avenue, Roushdy, Alexandria Tel: 03-5448585 / 01225659000 E-mail: medizen.pv@gmail.com Date prepared: September 2023