UPDATES

MHRA updates valproate safety and education materials

The MHRA says updated safety and educational materials are available for people taking valproate products, to support discussion of reproductive risks.

The Medicines and Healthcare products Regulatory Agency (MHRA) says updated safety and educational materials are now available for valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell). These materials support patient discussions on reproductive risks.

MHRA also says product information has been updated to reflect a risk of lower birth weight (below 2500 grams) and small for gestational age (birth weight below the 10th percentile for the pregnancy's length) in children exposed to valproate during pregnancy.

MHRA advises patients not to stop valproate without specialist advice. Women and girls able to have children must follow the Pregnancy Prevention Programme conditions, and male patients should use effective contraception during treatment and for 3 months after stopping.

What to do

- Do not stop taking valproate without advice from a specialist.
- Women and girls who are able to have children and who are taking valproate must follow the conditions of the Pregnancy Prevention Programme.
- As a precaution it is recommended that male patients taking valproate should use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate.
- If you are on valproate, please attend any offered appointments to discuss your treatment plan and talk to a healthcare professional if you are concerned.
- Report suspected adverse reactions associated with valproate on Yellow Card.

Where this comes from

- mhra

  https://www.gov.uk/drug-safety-update/valproate-belvo-convulex-depakote-dyzantil-epilim-epilim-chrono-or-chronospher