Valproate medicines (Epilim▼, Depakote▼): Pregnancy Prevention Programme materials online

Use materials online now and hardcopies arriving over the coming weeks by post to ensure women and girls of childbearing potential on valproate medicines meet the requirements of the Pregnancy Prevention Programme.

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Neurology, Obstetrics, gynaecology and fertility, Paediatrics and neonatology, Psychiatry

Contents

1. Who should be on a Pregnancy Prevention Programme?
2. Off-label use: restrictions and responsibilities still apply
3. Share best practice

Act now to use the following to support the new Valproate Pregnancy Prevention Programme:

- **Patient Card** – to be given by pharmacists to all female patients who are dispensed valproate medicines to inform them of the risks
- **Patient Guide** – to be provided to girls (of any age) and women of childbearing potential (or their parent/caregiver/responsible person) taking any medicine containing valproate
- **Guide for Healthcare Professionals** – for all prescribers, pharmacists, and other healthcare providers involved in the care of women and girls of childbearing potential using valproate medicines
- **Risk Acknowledgement Form** – for the specialist and patient (or their parent/caregiver/responsible person) to sign at initiation and at treatment reviews at least every year. The patient should receive a copy of the form; one copy should be filed in the specialist notes, and one copy sent to the patient’s GP

You will be aware that an alert was issued last month about new prescribing and dispensing requirements for all valproate medicines (see April 2018 Drug Safety Update). The Marketing Authorisation Holder for Epilim has produced new materials to support the Pregnancy Prevention Programme – branded as Prevent. These are linked to above and will be sent by post to healthcare professionals in the coming weeks. Once received, please dispose of any old materials which you have remaining.

Stickers with warning symbols to attach to the pack for supply to the patient will be included in materials to pharmacists. This is pending the availability of new package labelling with the warning symbols.
Who should be on a Pregnancy Prevention Programme?

Valproate medicines must no longer be used in women or girls of childbearing potential unless a Pregnancy Prevention Programme is in place. The requirement for a Pregnancy Prevention Programme is applicable to all premenopausal female patients unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

Off-label use: restrictions and responsibilities still apply

Valproate is not licensed for treatment of conditions other than epilepsy or bipolar disorder in the UK. However, we are aware that these medicines are sometimes used off-label (for example, in migraine prophylaxis). All women and girls of childbearing potential should meet the conditions of a Pregnancy Prevention Programme, irrespective of indication. All prescribers should be aware of their responsibilities when prescribing medicines off-label (see [April 2009 Drug Safety Update] for more information).

Share best practice

Many organisations and groups have already taken steps to embed these recommendations into clinical practice. Resources are or soon will be available from professional bodies to assist you in ensuring these new prescribing and dispensing requirements are met.

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