



NEVER prescribe valproate:
In a female of child-bearing age without a PPP in place
For migraine or bipolar disorder in pregnancy

prevent
valproate pregnancy
prevention programme

Medication Safety Series: MSS 13

Valproate Pregnancy Prevention Programme (PPP)

Valproate License

- Valproate is now **contraindicated in women or girls of child bearing potential, unless she has a PPP in place.**
- Valproate must not be used in women and girls of childbearing potential unless other treatments are ineffective or not tolerated, **as judged by an experienced specialist.**
- **Absolute contraindication** on use of valproate for migraine or **bipolar disorder during pregnancy.**
- If a woman **becomes pregnant**, treatment with valproate must be **discontinued and switched** to another treatment.
- *Use of valproate to treat epilepsy during pregnancy is contraindicated unless there is no other effective treatment available.*

Supporting documentation

[Patient Guide](#)

[Guide for Healthcare Professionals](#)

[Valproate Risk Acknowledgement Form](#)

[Patient Card](#) (pharmacists to give on dispensing)

For info: Changes to packaging / labelling

- Smaller pack sizes will encourage monthly prescribing.
- Valproate medicines will be available with a detachable patient card from December 2018
- A pictogram / warning image on valproate packaging
- Additional warning labels to be added by pharmacy where original pack does not contain pictogram / warning image and when splitting original packs (to be supplied by Sanofi)

Background information

Safety publications relating to valproate:

- MHRA [Guidance](#)
- MHRA [Drug Safety Update](#)
- [Chief Medical Officer Alert](#)

Specialist Responsibilities

*Specialist defined as Consultant Psychiatrist

Full details: [Guide for Healthcare Professionals](#)

For women & girls of child bearing potential:

- **Exclude pregnancy** (by a serum pregnancy test) **before initiation**
- Discuss the risks with the patient / carer and complete a **Risk Acknowledgement Form** with them **on initiation and at annual review**. A copy of the form must be:
 - Given to the patient
 - Sent to the GP
 - Kept in the patients notes (currently in the paper record)
 - Scan and send a copy to TEWV.pharmacyadmin@nhs.net to maintain a Valproate risk acknowledgement register
- Ensure the need to have, and comply with, highly effective contraception throughout the entire duration of treatment (if necessary), is understood. Please see the guidance [here](#) for further information.
 - The most effective contraceptive methods include contraceptive implants, intrauterine devices with copper or hormones.
 - Two complementary forms of contraception may also be appropriate
- Perform an **annual review** with the patient to assess continuing need and to complete a new risk acknowledgement form, if prescribing continues.
- Review and switch treatment, within days of referral, if there is an unplanned pregnancy
- Review and switch treatment for women planning to become pregnant
- Make PARIS entry recording the key points of the discussion including completion of the Risk Acknowledgement form
- New patients: send a copy of the shared care document (*available soon*) to the GP with the transfer of prescribing request

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