

## Guidelines for the Prescribing of Medication in Pregnancy

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<b>Author/Lead Job Title</b>	Simon Price Specialist clinical pharmacist
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**VALIDITY – Documents should be accessed via the Trust intranet to ensure the current version is used.**

### CHANGE RECORD

Version	Date	Change details
1.0	November 2010	
2.0	March 2013	New Guideline format, Chart design modification, no change in contents.
3.0	May 2017	Reviewed and updated
4.0	October 2020	MHRA valproate guidelines added including COVID advice. Trust name & logo updated
5.0	30 November 2023	Reviewed. MHRA links updated, UKTIS links added and RRS updated to MHCIT. Approved at Drugs and Therapeutics Group (30 November 2023).

## Prescribing in pregnancy

Decisions relating to the use of medications can be particularly challenging, as pregnancy or termination can have significant effects on the woman's mental and physical health.

Health care professionals need reliable and up to date information about therapeutics in pregnancy, so that they can give women good advice to assist them in making informed choices. By being over-cautious effective medication may be denied with associated risks of relapse or unwarranted termination can result. Being under-cautious may risk harm to babies as a consequence of drug exposure.

## Valproate medicines

The MHRA advises that all women and girls of childbearing potential being treated with valproate medicines must be supported on a Pregnancy Prevention Programme. Pregnancy should be excluded before initiation of treatment and highly effective contraception must be used during treatment

The forms for initial and annual valproate risk assessment can be found on Lorenzo under the medical tab in 'Notes'.

See details of MHRA advice at:

<https://www.gov.uk/drug-safety-update/valproate-epilim-depakote-pregnancy-prevention-programme-updated-educational-materials>

[Valproate use by women and girls - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/valproate-pregnancy-prevention-programme-temporary-advice-for-management-during-coronavirus-covid-19)

Additional guidance for during COVID pandemic:

<https://www.gov.uk/guidance/valproate-pregnancy-prevention-programme-temporary-advice-for-management-during-coronavirus-covid-19>

## General Principles

- Involve prospective parents fully in the decision-making process
- Seek support and advice from Maternal Health Link Practitioner
- Obtain current specialist advice from [Medicines Information](#)
- Use only information sources recommended by Humber Teaching Foundation NHS Trust
- Assess the benefit/risk ratio for both mother and foetus
- Avoid unnecessary drug use and limit use of over the counter (OTC) products
- Treat only when necessary
- Consider risk of relapse against potential harm to foetus and mother
- Avoid all medication in first trimester when possible
- Use established drugs at minimal effective dose and avoid polypharmacy
- For some drugs there is demonstrated evidence of harm to the foetus during pregnancy, e.g. valproate
- Take account of changes in pharmacokinetics as pregnancy progresses
- Consider potential problems around delivery and future desire to breastfeed
- Monitor neonate for adverse effects and provide feedback on outcome to UK Teratology Information Service (UKTIS)
- Involve other healthcare professionals to avoid giving conflicting advice
- Document all discussions and decisions thoroughly

Healthcare professionals should **never** advise, unequivocally, that a medication is either harmful or safe during pregnancy. Instead, they should make enquiries using Trust-approved sources of information to discuss risks and benefits with the patient on an individual basis.

## **Recommended Information Sources**

### **UKTIS-UK Teratology Information Service**

The UK Teratology Information Service (UKTIS) is commissioned by Public Health England on behalf of UK Health Departments. They provide a national service on all aspects of the toxicity of drugs and chemicals in pregnancy. Available at [UKTIS – Evidence-based safety information about medication, vaccine, chemical and radiological exposures in pregnancy](#). Information is provided to health professionals via a telephone information service and online through [TOXBASE®](#), which holds the full pregnancy review documents produced by UKTIS on maternal exposures to drug and chemicals. Access to [TOXBASE®](#) is free to NHS and NHS-affiliated departments, units and practices in the UK. Please visit [www.toxbase.org](http://www.toxbase.org) to register or contact them on **0344 892 0909**. As they maintain the UK data base for outcomes of exposure, they are the preferred source of advice, as the information is constantly updated. They can be contacted directly and advise the enquirer to inform all members of the health care team that provide care to an individual, to avoid the potential for conflicting advice.

### **Maudsley Prescribing Guidelines and Psychotropic Drug Directory**

These are excellent resources regarding therapeutic considerations; the latest edition should always be used. They advise on the risks of specific mental health conditions during pregnancy and postpartum. Advice on changes in pharmacokinetics during pregnancy and a range of precautions and monitoring parameters, are included. Although a summary of current knowledge regarding specific drugs is given, this should not be used as a sole basis of decision making. Inclusion of information can be taken as a guide but absence of information does not imply anything about the status of a specific medication.

### **BNF**

The most current edition of the British National Formulary gives basic advice on the risks of drug treatment in pregnancy for a specific medication in the drug monograph. It must be noted that the absence of inclusion in the tables does not imply safety. The information provided is not comprehensive enough for decision making.

### **SmPC-Summary of Product Characteristics**

This is produced as part of the drug licensing application process. As it is generally unacceptable to undertake the testing of drugs in pregnancy, the information included is limited. The statement 'Safety in pregnancy un-established' appears frequently and indicates that use in pregnancy is outside of product license. Absence or inclusion of statements about the use of the drug in pregnancy is not sufficient information on which to base decision making.

### **Internet**

Use of the internet as a source of information should be undertaken with extreme caution and restricted to validated sites such as UKTIS. Available at [UKTIS – Evidence-based safety information about medication, vaccine, chemical and radiological exposures in pregnancy](#)

### **Pharmacists**

Where available Pharmacists are able to co-ordinate and advise accordingly, the Trust Pharmacy department can be contacted on 01482 389113.

### **The Hull and East Yorkshire Perinatal Mental Health Liaison Service**

This service works closely with midwives and health visitors (who can refer women through the Mental Health Crisis Intervention Team) and takes referrals from GPs and community mental health teams. Referrals can be made via the Mental Health Crisis Intervention Team on 0800 138 0990

## Flowchart for Prescribing in Pregnancy

