All correspondence to:
The Breastfeeding Network
PO Box 11126, Paisley PA2 8YB
Admin Tel: 0844 412 0995
e-mail: admin@breastfeedingnetwork.org.uk
www.breastfeedingnetwork.org.uk

Patient information leaflets – what do they mean?

The information provided is taken from various reference sources. It is provided as a guideline. No responsibility can be taken by the author or the Breastfeeding Network for the way in which the information is used. Clinical decisions remain the responsibility of medical and breastfeeding practitioners. The data presented here is intended to provide some immediate information but cannot replace input from professionals.

Many mothers and healthcare professionals are confused by the fact that patient information leaflets (the inserts in packets of medicines) say "this drug should not be taken during breastfeeding" or "consult your doctor or pharmacist before taking this drug if you are breastfeeding".

The words do not mean that the medicine is harmful to be taken by a breastfeeding mother but are required by law depending on the information supplied to the licensing authority (MHRA) when the medicine was first launched or launched by that manufacturer.

- The manufacturer of any medicinal product must obtain a marketing authorisation from the Licensing Authority prior to promoting and selling the medicine. Part of the application for marketing authorisation includes a clinical expert report, the content of which is governed by European Community legislation. The clinical expert should also discuss "the possible utilisation during pregnancy and breastfeeding". A "statement" on pregnancy and lactation should also appear in the Summary of Product Characteristics. It is not stated what information should be supplied or what, if any, specific animal work is required to generate the data.
- Manufacturers are also required by law to provide patient information leaflets giving full information on the use of the drug, including side effects, treatment of overdose and cautions which generally include details of use during pregnancy and lactation.
- It is obviously unethical to give a drug to a pregnant or lactating mother without full knowledge of safety. Animal studies can provide a limited amount of safety data which may or may not be relevant to human use. In general little information on the safety of drugs which may pass into a mother's breastmilk are available prior to marketing so a manufacturer will not recommend that drug should be given to a lactating woman.

However, we accrue information subsequently from case reports or small scale studies and use knowledge of the pharmacokinetics of the drug (the way in which it is handled by the body) to enable us to make recommendations as to whether a drug is safe to be taken "outside of its licence application" during breastfeeding.

When used in this way the doctor who prescribes, the nurse who recommends or the pharmacist who sells or dispenses the medicine have to take responsibility for doing so and the manufacturers are able to disclaim all responsibility.

When discussing medication use during breastfeeding, several sources are used by myself as a pharmacist, and information provided on that basis as to whether it is safe for a breastfeeding mother

The Breastfeeding Network is a Company Limited by Guarantee Registered in Scotland Company No. 330639
Registered office Whitelaw Wells, 9 Ainslie Place, Edinburgh, EH3 6AT
The Breastfeeding Network is a Registered Scottish Charity No SC027007

to take. If there is any possibility of harm coming to the child from exposure to that medicine, the mother will be provided with that information and also warned of any potential side effects to be aware of in the child e.g. drowsiness, poor weight gain etc.

All the information sheets carry a statement that "The information presented here is intended to provide some immediate information but cannot replace input from the medical profession and breastfeeding experts. No responsibility can be taken by the author or the Breastfeeding Network for the way in which the information is used".

We are aware that other people pass on information or may perceive it differently to that which was intended. Whilst every attempt is made to pass on evidence based information this is frequently perceived as advice, because that is what we are used to receiving from healthcare professionals. Ultimately use of any medicine during breastfeeding remains the responsibility of the mother, but we strive to provide information for her to be able to continue to breastfeed her child safely.

Reference

- Medicines and Healthcare products Regulatory Agency (MHRA) website; www.mhra.gov.uk