

Patient Information Brochure for Women of Childbearing Age

About this brochure

This brochure contains important information about your treatment with **[Product Name]** in relation to minimising the risks of possible birth defects with this medicine. You will need to read this brochure carefully before you start taking **[Product Name]**.

This brochure describes some of the important facts about **[Product Name]** that you need to be aware of, however, it does not replace the advice given to you by a healthcare professional such as your doctor, nurse or pharmacist. Further to this brochure, very important information about **[Product Name]** including how to take it, special warnings and side effects are included in the patient information leaflet which is supplied in each **[Product Name]** package. Please remember to read the package leaflet very carefully when using **[Product Name]**.

If you have any further questions or concerns about taking **[Product Name]** after you have read this brochure, you should talk to your healthcare professional (HCP).

[Product Name] and birth defects

No medicine is completely free from adverse effects. One of the most serious side effects you risk with **[Product Name]** use is severe and serious birth defects if you become pregnant. Your **[Product Name]** capsules would also put a female friend or relative in danger of a deformed baby if you shared them. Treatment with **[Product Name]** during pregnancy should be avoided. If an unborn child is exposed to **[Product Name]** this can result in severe and serious defects (malformations) in the child.

Important information for **FEMALE** patients

- You must not take **[Product Name]** if you are pregnant.
- You must not become pregnant while taking **[Product Name]**, or for 1 month after you stop taking **[Product Name]**.
- Severe birth defects have occurred in babies of women taking **[Product Name]** during pregnancy. There is a very high risk that your baby could be born deformed if you are pregnant or become pregnant while taking **[Product Name]**.
- Your doctor will ask you to read and sign a risk acknowledgement form to show that you understand some of the serious risks associated with **[Product Name]**.
- You will not get your first prescription for **[Product Name]** until you have had at least one negative medically supervised pregnancy test or if you are not at risk of becoming pregnant.
- If you are at risk of becoming pregnant you should have a pregnancy assessment at least once a month during your **[Product Name]** therapy. You can only get a prescription each month by returning to your HCP to have a pregnancy assessment.
- You will need to discuss effective contraception with your HCP. If you are at risk of becoming pregnant you must use at least one, and preferably two, effective forms of contraception at the same time for at least one month before beginning treatment and during treatment. Any contraceptive method can fail, including oral contraceptives (the pill) and injectable/implantable contraceptive devices – therefore it is strongly recommended that you use two forms of contraception at the same time, and that one of the two methods is a barrier method such as a male condom.
- You should contact your HCP immediately, if you have unprotected sex, miss your period or become pregnant while you are taking **[Product Name]**.

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- Talk to your doctor if you plan to take other medicines or herbal products. This is especially important for women using contraceptive pills and other types of hormonal contraceptives. Certain medicines and herbal supplements such as St John's wort may make contraceptives less effective.
- It is important that you do not share this medicine with anyone else, particularly other females, even if they have the same condition as you.