



Pregabalin and risks in pregnancy

This information is relevant to patients taking pregabalin who are able to become pregnant. Pregabalin may also be called by its brand names Lyrica, Alzain, Axalid or Lecaent.

This safety leaflet is to help you understand the latest information about the effects of pregabalin during pregnancy. Please keep this leaflet in a safe place as you may need to read it again.

- Pregabalin is a medicine used to treat nerve pain, anxiety, and some forms of epilepsy
- Taking pregabalin during pregnancy may slightly increase the chance of physical birth abnormalities in the baby; the overall risk is low
- Do not stop taking pregabalin without discussing it with your prescriber; they are the best person to talk to you about your individual situation
- If you are taking pregabalin, you should continue to use effective contraception during treatment
- If you are currently planning to have a baby, it is important to discuss your treatment options with your healthcare professional before you stop using contraception
- If you think you may be pregnant or need advice while taking pregabalin, talk to the healthcare professional who prescribes pregabalin for you

What are the risks to unborn babies who are exposed to pregabalin?

Physical birth abnormalities can be caused by many different things. In the UK it is estimated that 2 or 3 babies in every 100 births are born with physical abnormalities. The risk (or chance) of physical birth abnormalities is raised by certain medical conditions and in some cases the risk can be increased by certain medicines taken during pregnancy. Some physical birth abnormalities may need medical treatment.

We have carefully reviewed the results of a new study from 4 European countries. The study showed that taking pregabalin during early pregnancy was associated with a slightly increased chance of having a baby who is born with a physical birth abnormality. It is important to note that this study could not show that pregabalin was the cause of the physical birth abnormalities.

The study focused on women who took pregabalin during pregnancy. In this study, 6 babies in 100 born to women who took pregabalin in the first 3 months of pregnancy had physical birth abnormalities, compared to 4 babies in every 100 born to women who were not treated with pregabalin or other epilepsy medicines in early pregnancy.

The study also showed a higher risk of physical birth abnormalities in unborn babies exposed to pregabalin compared to another medicine for epilepsy (called lamotrigine) and another medicine for anxiety and some forms of pain (called duloxetine).

If you are planning a pregnancy, or think you may be pregnant

It is vitally important that you talk to a healthcare professional about treatments for your health conditions during pregnancy. If you have a condition that requires long-term treatment, it is especially important to ask your doctor whether any changes are needed to your medicines.

Untreated epilepsy, pain, or anxiety could be harmful to you and your unborn baby. It is important that you talk to your healthcare professional before stopping pregabalin or making any changes to your usual medicines.

If you're planning a pregnancy, before you stop using contraception you should see your GP, specialist, or nurse to jointly decide the best course of action in your individual situation. They will discuss with you the options and the potential risks, including the risks of different treatments and the risk of your medical condition not being treated. You and your healthcare professional may agree that pregabalin is the safest option for you during pregnancy.

If you think you may be pregnant and are currently taking pregabalin, you should set up an appointment with your GP, specialist or nurse at your earliest opportunity, to discuss any concerns you may have. However, do continue to take pregabalin as prescribed until you can speak to them.

When planning a pregnancy, taking folic acid is generally recommended before you become pregnant and in early pregnancy to support your baby's development. Talk to your healthcare professional who can recommend the right dose of folic acid for you.

Always read the Patient Information Leaflet that accompanies your medicine. If you have any questions or concerns about pregabalin, talk to your healthcare professional.

If you are taking pregabalin for epilepsy

If you have epilepsy, never stop taking medicines such as pregabalin without medical advice. Suddenly stopping epilepsy medicine may cause your seizures to start again, or happen more often and last longer than before.

Different epilepsy medicines are associated with different risks in pregnancy. Information on this to help patients and their families is in our Guidance on Epilepsy Medicines and Pregnancy <https://www.gov.uk/government/publications/epilepsy-medicines-and-pregnancy>.

Further sources of information

Further advice can be obtained from your doctor, nurse, specialist or pharmacist. Information and support is available from charities such as:

- Pain UK: www.painuk.org/members/charities
- Anxiety UK: www.anxietyuk.org.uk
- Epilepsy Action: www.epilepsy.org.uk
- Epilepsy Society: www.epilepsysociety.org.uk

Please report any suspected side effects associated with medicines taken during pregnancy or breastfeeding, including any suspected effects on the baby or child. Medicine side effects should be reported directly to the MHRA on the Yellow Card website, or via the free apps ('Yellow Card Scheme' in the Google Play Store or 'Yellow Card – MHRA' in the Apple App Store), or by phoning the free phoneline (0800 731 6789).

Last revised in April 2022 This advice will be reviewed in October 2022. This leaflet is available online at www.gov.uk/guidance/pregabalin-and-risks-in-pregnancy. If you have any feedback regarding this leaflet, please email info@mhra.gov.uk