

Prescribing tip for information

Pregabalin in Pregnancy

Pregabalin (brand names include Alzain, Axalid, Lecaent, Lyrica)

A recent observational study of more than 2,700 pregnancies exposed to pregabalin has shown **use in the first trimester to be associated with a slightly increased risk of major congenital malformations compared with exposure to no antiepileptic drugs or to lamotrigine or to duloxetine.**

The MHRA has considered the recommendations of the European review, together with the other limited safety data available regarding pregabalin safety in pregnancy and agreed that the product information should be updated to include information from this study. The [Summary of Product Characteristics](#) and [Patient Information Leaflet](#) has now been updated.

The product information continues to advise that effective contraception should be used during treatment and that use in pregnancy avoided unless clearly necessary.

Healthcare professionals are advised:

- To consider MHRA [guidance on effective contraceptive methods](#), and take into account the patient's personal circumstances when advising on contraception.
- To continue to avoid use of pregabalin during pregnancy unless clearly necessary and only if the benefit to the patient clearly outweighs the potential risk to the fetus – ensure the patient has a full understanding of the benefits, risks, and alternatives, and is part of the decision-making process
- To continue to provide counselling to patients using pregabalin on
 - The potential risks to an unborn baby
 - The need to use effective contraception during treatment
- There is a useful MHRA patient safety [leaflet](#)
- To advise patients planning a pregnancy or who become pregnant during treatment to make an appointment to discuss their health condition and any medicines they are taking. Patients should not stop taking pregabalin without discussing with a prescriber. Patients planning a pregnancy should discuss treatment options before stopping contraception
- In cases where the benefit outweighs the risk, and it is clearly necessary that pregabalin should be used during pregnancy, it is recommended to:
 - use the lowest effective dose
 - report any suspected adverse drug reactions, including for the baby, via the [Yellow Card scheme](#)

Other useful resources

The MHRA and NHS Digital are working together on the [Medicines in Pregnancy Registry](#), which is built around a core register of routinely collected prescribing data for all women in England who are taking NHS-prescribed valproate and other antiepileptic medications. Healthcare professionals can use the data provided to review comparative use of antiepileptic medicines in pregnancy.

Clinicians should continue to use resources for prescribers about medicines of potential teratogenic effects. The [UK Teratology Information Service](#) provides independent advice about the risks and benefits of medicines use in pregnancy.

Also, PIL for [bumps - best use of medicine in pregnancy \(medicinesinpregnancy.org\)](#)

To contact the Medicines Optimisation Team please phone 01772 214302

If you have any suggestions for future topics to cover in our prescribing tips, please contact nicola.schaffel@nhs.net