

Chlordiazepoxide Librium warning

The Medicines and Healthcare products Regulatory Agency (MHRA) has been made aware of concerns raised following changes to the product information for chlordiazepoxide (Librium) regarding a possible genotoxicity risk and contraception requirements for males and females. This relates to recent implementation of the European Medicines Agency's [SWP recommendations](#) in relation to genotoxic medicines.

We understand that the resulting changes to the product information has led to a number of queries regarding the most appropriate treatment for patients, and as a result the MHRA is reviewing the evidence available to evaluate the potential risk for patients and we are seeking advice from our independent experts. We will consider the information included in all chlordiazepoxide products to ensure that appropriate and proportional warnings are implemented as required.

Once the review has been completed, we will communicate with healthcare professionals involved in prescribing and dispensing chlordiazepoxide. We understand the urgency of this issue and we work urgently to reach a prompt resolution. **Healthcare professionals should continue to use current clinical guidelines while this issue is being evaluated.**

Further information can be found on this statement from the [UK Teratology Information Service](#).

The Medicines and Healthcare products Regulatory Agency (MHRA) Drug Safety Update, Pregabalin, Denosumab

The latest [MHRA Drug Safety Updates](#) includes links to alerts, recalls and safety information and to the monthly Drug Safety Update newsletter.

The April 2022 Drug Safety Update includes:

- Pregabalin (Lyrica): findings of safety study on risks during pregnancy. A new study has suggested pregabalin may slightly increase the risk of major congenital malformations if used in pregnancy. Patients should continue to use effective contraception during treatment and avoid use in pregnancy unless clearly necessary. **All practices are advised to review and act on this MHRA Update** . Practices should contact the medicines optimisation team for support if needed.
- COVID-19 vaccines and medicines: updates for April 2022.
- Letters and medicine recalls sent to healthcare professionals in March 2022.

The May 2022 Drug Safety Update includes:

- [Denosumab 60mg \(Prolia\): should not be used in patients under 18 years due to the risk of serious hypercalcaemia](#): serious and life-threatening hypercalcaemia has been reported with denosumab 60mg (Prolia) in children and adolescents in clinical trials for osteogenesis imperfecta and during off-label use. Denosumab 60mg (Prolia) is authorised for use in adults with osteoporosis and other bone loss conditions – it should not be used in children and adolescents younger than 18 years.
- Covid-19 vaccines and medicines: updates for May 2022.
- Letters and medicine recalls sent to healthcare professionals in April 2022.

Access [The MHRA Central Alerting System alerts](#).

Access [National Patient Safety Alerts](#).