

IMPORTANT SAFETY INFORMATION

Guanfacine prolonged-release tablets (PL 49718/0136-0142): Important safety information missing from the Summary of Product Characteristics regarding QT/QTc interval prolongation.

Guanfacine 1 mg Prolonged-Release Tablets	PL 49718/0136
Guanfacine 2 mg Prolonged-Release Tablets	PL 49718/0137
Guanfacine 3 mg Prolonged-Release Tablets	PL 49718/0138
Guanfacine 4 mg Prolonged-Release Tablets	PL 49718/0139
Guanfacine 5 mg Prolonged-Release Tablets	PL 49718/0140
Guanfacine 6 mg Prolonged-Release Tablets	PL 49718/0141
Guanfacine 7 mg Prolonged-Release Tablets	PL 49718/0142

Dear Healthcare Professional,

Neuraxpharm UK Ltd. in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of important safety information missing in the Summary of Product Characteristics (SmPC). The missing information is regarding **QT/QTc interval prolongation** associated with guanfacine prolonged-release tablets.

Summary

- Guanfacine is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old for whom stimulants are not suitable, nor tolerated or have been shown to be ineffective.
- Guanfacine must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.
- **Prolonged QT/QTc interval has been reported during post-marketing use of guanfacine.**
- **Electrocardiogram QT prolonged** is a recognised **uncommon** adverse reaction to guanfacine and has also been identified as a potential manifestation of guanfacine overdose.
- In patients who develop **electrocardiogram QT prolongation**, consider **dose reduction or discontinuation of guanfacine based on clinical judgement**.
- In post-marketing cases, **QT/QTc interval prolongation has normalised following dose reduction or discontinuation of guanfacine**.

Background on the safety concern

QT/QTc interval findings are already described in the current product information for guanfacine prolonged-release tablets based on clinical study data. **However, the current product information does not fully reflect the available safety information regarding QT/QTc interval prolongation, including relevant post-marketing findings and associated clinical management recommendations.**

During post-marketing use, cases of prolonged QT/QTc interval have been reported. In reported cases, QT/QTc interval prolongation normalised following dose reduction or discontinuation of guanfacine. **Electrocardiogram QT prolonged is recognised as an uncommon adverse reaction.**

In patients who develop electrocardiogram QT prolongation, **dose reduction or discontinuation of guanfacine may be considered based on clinical judgement.**

Electrocardiogram QT prolonged has also been identified as a potential manifestation of **guanfacine overdose**.

The product information will be updated to reflect this safety information.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.

You can report via:

- the [Yellow Card website](#).
- the free Yellow Card app available from the Apple App Store or Google Play Store.
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing of onset, treatment dates, and product brand name.

Company contact point

If you require further information regarding this communication, please contact:

Neuraxpharm UK Ltd.

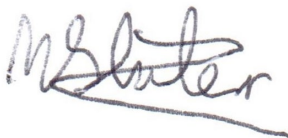
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Yours sincerely,



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