Better Health, Brighter Future

16 October 2023

Direct Healthcare Professional Communication

Guanfacine hydrochloride, Intuniv▼ 1mg, 2mg, 3mg, 4mg prolonged-release tablets
Expected shortage

Dear Healthcare Professional,

Marketing Authorisation Numbers:
Great Britain – PLGB 54937/0005 through to 0008

Takeda UK Limited acting on behalf of Takeda Pharmaceuticals International AG Ireland Branch, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) and with consent of the Department of Health and Social Care (DHSC), would like to inform you of the following:

Summary

- Due to manufacturing challenges, Takeda is anticipating supply disruptions with Intuniv 1mg, 2mg, 3mg and 4mg prolonged-release tablets.
- This disruption is anticipated to be in effect as per dates below.
- Healthcare professionals are advised not to initiate any new patients on any strength of Intuniv until the supply interruption is resolved.
- For existing patients on Intuniv, healthcare professionals will need to decide on an appropriate course of action based on the clinical situation pertaining to individual patients and their own clinical judgement.

Product	Marketing Authorisation Number	Expected unavailability date week commencing	Anticipated date of return week commencing
Intuniv▼ 1 mg prolonged-release tablets	PLGB 54937/0005	23 OCT 2023	04 DEC 2023
Intuniv▼ 2 mg prolonged-release tablets	PLGB 54937/0006	23 OCT 2023	04 DEC 2023
Intuniv▼ 3 mg prolonged-release tablets	PLGB 54937/0007	06 NOV 2023	04 DEC 2023
Intuniv▼ 4 mg prolonged-release tablets	PLGB 54937/0008	18 SEP 2023	27 NOV 2023

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Background
Intuniv 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, not tolerated or have been shown to be ineffective.

Intuniv must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.

A National Patient Safety Alert (NatPSA/2023/011/DHSC) was issued on 27 September 2023 outlining supply disruptions affecting various medication licensed for the treatment of attention deficit hyperactivity disorder.

Dosing options
In accordance with section 4.2 of the Summary of Product Characteristics (available to view in full via the eMC: https://www.medicines.org.uk/emc/search?q=intuniv), please be aware of the following clinical considerations:

Missed dose
If a dose is missed, the prescribed dose can resume the next day. If two or more consecutive doses are missed, re-titration is recommended based on the patient's tolerability to guanfacine.

Downward titration and discontinuation
When stopping treatment, the dose must be tapered with decrements of no more than 1 mg every 3 to 7 days, and blood pressure and pulse should be monitored in order to minimise potential withdrawal effects, in particular increases in blood pressure and heart rate (see section 4.4 of the SmPC).

In a maintenance of efficacy study, upon switching from guanfacine to placebo, 7/158 (4.4%) subjects experienced increases in blood pressure to values above 5 mmHg and also above the 95th percentile for age, sex and stature (see sections 4.8 and 5.1 of the SmPC).

Switching from other formulations of guanfacine
Immediate-release guanfacine tablets should not be substituted on a mg/mg basis, because of differing pharmacokinetic profiles.

Independent clinical judgement
Please consider the most appropriate course of action based on your independent clinical judgement and the individual patient's needs.

Call for reporting

Intuniv▼ is subject to additional monitoring. This will allow quick identification of new safety information. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

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
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website: www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/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.

Healthcare professionals can also report any suspected adverse reactions associated with the use of Intuniv to Takeda UK Ltd via: AE.GBR-IRL@takeda.com

Company Contact Point

Should you have any queries regarding this notification, please contact Takeda using the details provided. Adverse reactions associated with Intuniv use can also be reported by healthcare professionals to Takeda UK Ltd via: AE.GBR-IRL@takeda.com

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Yours sincerely,

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