Checklist 2: Checklist for the ongoing monitoring and management of patients during guanfacine treatment

This checklist is designed to support you in the ongoing monitoring of Intuniv® ▼ (guanfacine hydrochloride) prolonged-release tablet treatment in child and adolescent patients with attention-deficit/hyperactivity disorder (ADHD) for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.

As detailed in the Summary of Product Characteristics (SmPC), cardiovascular status, psychiatric/neurologic status and growth should be monitored regularly in patients receiving guanfacine. It is recommended that this checklist be used in conjunction with the Intuniv® SmPC **(click here to view)**.

Please download and print this checklist prior to your consultation. It will not be possible for you to store any patient-specific information on this website. The completed checklist can be documented within the patient's records.

As you work through the checklist it may also be useful to refer back to the Intuniv® Patient Information Leaflet (PIL) **(click here to view)** with your patient.

Upward Dose titration

During dose titration, weekly monitoring for signs and symptoms of somnolence and sedation, hypotension and bradycardia should be performed. For all patients the recommended starting dose of Intuniv® is 1 mg of guanfacine once daily. The dose may be adjusted in increments of not more than 1 mg per week.

Monitoring during treatment

During the first year of treatment, the patient should be assessed at least every 3 months for signs and symptoms of somnolence, sedation, hypotension, bradycardia and weight increase/risk of obesity. Six monthly monitoring should follow thereafter, with more frequent monitoring following any dose adjustments. It is recommended that clinical judgement be exercised should any of these adverse events occur.

Physicians who elect to prescribe guanfacine for extended periods (over 12 months) should re-evaluate the effectiveness of guanfacine every 3 months for the first year and then at least yearly based on clinical judgement and consider trial periods without medication to assess the patient's functioning without medication preferably during times of school holiday.

Downward titration and discontinuation

Patients/caregivers should be instructed not to discontinue guanfacine on their own. Tapering guanfacine dosing during discontinuation is recommended to minimise potential risk of blood pressure and pulse increases. In very rare instances, hypertensive emergencies such as hypertensive encephalopathy have been observed, following abrupt discontinuation. It is recommended that blood pressure and pulse should be monitored in all patients during dose downward titration (decrements of no more than 1 mg every 3 to 7 days) and following discontinuation of guanfacine.

Ongoing monitoring of guanfacine treatment

Date of initial assessment:	
Patient name:	
Date of birth:	
Age:	Gender:

	Evaluated
New cardiovascular findings or worsening thereof (Intuniv® SmPC section 4.4 – Special warnings and precautions for use)	
• Syncope (loss of consciousness) ◦ Refer for prompt specialist cardiac evaluation if present	☐
• Document blood pressure and heart rate (pulse) on separate chart for ongoing monitoring. Assess for any changes in blood pressure and heart rate (pulse), signs & symptoms of bradycardia and hypotension ◦ Monitoring of heart rate and blood pressure parameters should continue on a weekly basis during dose titration and stabilisation and at least every three months for the first year, taking into consideration clinical judgement ◦ Six-monthly monitoring should follow thereafter, with more frequent monitoring following any dose adjustments	☐

	Evaluated
New neurocognitive and psychiatric findings or worsening thereof (Intuniv® SmPC section 4.4 – Special warnings and precautions for use)	
• Patients with emergent suicidal ideation or behaviour during treatment for ADHD should be evaluated immediately by their physician	☐
• Sedation and somnolence	☐
• Patients are advised against operating heavy equipment, driving or cycling until they know how they respond to treatment with guanfacine	☐
• Patients should not drink alcohol whilst taking guanfacine	☐

This checklist is intended for use by Healthcare Professionals only, in conjunction with the Intuniv® SmPC.
This resource was developed by Takeda as part of a commitment made in the Risk Minimisation Measures for Intuniv®.

▼ This medicinal product is subject to additional monitoring. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie.
Adverse events should also be reported to Takeda at AE.GBR-IRL@takeda.com.

Version-0015 Date of Approval: July 2022

Checklist 2: Checklist for the ongoing monitoring and management of patients during guanfacine treatment

General medical findings	
• Document changes in body weight on separate ongoing monitoring chart **(Intuniv® SmPC section 4.4 - Special warnings and precautions for use - Effects on height, weight and body mass index [BMI])**	☐
Guanfacine continued:	☐
Treatment discontinuation and downward titration • Patients/caregivers should be instructed not to discontinue guanfacine without consulting their physician, as this may increase blood pressure and pulse	☐

Following the evaluation above, please complete the chart provided to record a baseline measure for ongoing monitoring **(click here to view)**.

This checklist is intended for use by Healthcare Professionals only, in conjunction with the Intuniv® SmPC.
This resource was developed by Takeda as part of a commitment made in the Risk Minimisation Measures for Intuniv®.

▼ This medicinal product is subject to additional monitoring. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie.
Adverse events should also be reported to Takeda at AE.GBR-IRL@takeda.com.

Version-0015 Date of Approval: July 2022