Checklist 1: Checklist for use prior to initiating treatment with guanfacine

This checklist is designed to support you in the appropriate initiation 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), specific concurrent conditions may exclude the use of guanfacine or may warrant particular attention, such as cardiovascular disorders or symptoms. 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 the website. The completed checklist can be documented within the patient's records.

Before initiating guanfacine treatment

Prior to prescribing, it is necessary for you to conduct a baseline evaluation to identify patients at increased risk of somnolence and sedation, hypotension and bradycardia, QT-prolongation arrhythmia and weight increase/risk of obesity.

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

Contraindications (Intuniv® SmPC section 4.3 – Contraindications):

Patients with any of the following conditions, co-morbidities and/or co-medications should not receive guanfacine:

	Evaluated
• **Known hypersensitivity** to guanfacine or any of the excipients	☐
Excipients (Intuniv® SmPC section 4.4 – Special warnings and precautions for use – Excipients)	
• **Contains lactose.** Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product	☐

Consider the following prior to beginning treatment with guanfacine

Special warnings or precautions for use (Intuniv® SmPC section 4.4 – Special warnings and precautions for use)

Family history	
	Evaluated
• Family history of sudden cardiac/unexplained death should be assessed to identify patients at increased risk of hypotension, bradycardia and QT prolongation/ risk of arrhythmia	☐

Patient's history and physical exam	
	Evaluated
Cardiovascular	
• Pre-existing cardiovascular disorders including hypotension, heart block, bradycardia, or cardiovascular disease or who have a history of syncope or a condition that may predispose them to syncope, such as hypotension, orthostatic hypotension, bradycardia, or dehydration	☐
• Underlying medical condition which might be compromised by decreases in blood pressure or heart rate. Exercise caution when treating patients who are taking anti-hypertensives or other medicinal products that can reduce blood pressure or heart rate or increase the risk of syncope	☐
• Known history of QT prolongation, risk factors for torsades de pointes (e.g. heart block, bradycardia and hypokalaemia) or patients who are taking medicinal products known to prolong the QT interval. These patients should receive further cardiac evaluation based on clinical judgement.	☐
• Blood pressure and heart rate (pulse) should be assessed and recorded	☐
	Evaluated
Psychiatric/neurological disorders	
• Suicidal ideation	☐
• Increased risk of sedation and somnolence. Before Intuniv® is used with other centrally active depressants (e.g. sedatives, phenothiazines, barbiturates or benzodiazepines) the potential for additive effects should be considered	☐

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.

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• 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	☐
Effects on height, weight and Body Mass index (BMI)	
• Height, weight and BMI should be recorded **(use enclosed chart)**	☐

Potential drug–drug interactions (Intuniv® SmPC section 4.5 – Interaction with other medicinal products and other forms of interaction)	
	Evaluated
• CYP3A4 and CYP3A5 Inhibitors (including grapefruit juice, certain antibiotics, certain antifungals and antiviral drugs (consider reducing) Intuniv® dose)	☐
• CYP3A4 Inducers (including St John's Wort) (consider increasing Intuniv® dose)	☐
• Given the effect of guanfacine on heart rate, the concomitant use of guanfacine with QT prolonging drugs is generally not recommended	☐
• Antihypertensives (including guanethidine or other antihypertensives)	
• Valproic acid	
• CNS depressant medicinal products (e.g. alcohol, sedatives, hypnotics, benzodiazepines, barbiturates and antipsychotics)	☐

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

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