Intuniv®▼ (guanfacine hydrochloride) 1 mg, 2 mg, 3 mg, 4 mg Prolonged-Release Tablets.
PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND, SCOTLAND, WALES) AND NORTHERN IRELAND
Refer to Summary of Product Characteristics (SmPC) before prescribing

Presentation: Prolonged-release tablets, 1 mg, 2 mg, 3 mg and 4 mg; each tablet contains guanfacine hydrochloride equivalent to 1 mg, 2 mg, 3 mg and 4 mg guanfacine respectively. **Indication:** 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. Use as a part of a comprehensive ADHD treatment programme. **Dosage and administration:** Oral, take once daily morning or evening, with or without food, but not with high fat meals. Do not crush, chew or break before swallowing. Do not take with grapefruit juice. Initiate treatment under the supervision of an appropriate specialist in childhood and/or adolescent behavioural disorders. Pre-treatment screening: Baseline evaluation to identify patients at increased risk of somnolence and sedation, hypotension and bradycardia, QT-prolongation arrhythmia and weight increase/risk of obesity. Posology: Careful dose titration and weekly monitoring is necessary at the start of treatment since clinical improvement and risks for several clinically significant adverse reactions (syncope, hypotension, bradycardia, somnolence and sedation) are dose and exposure related. Recommended starting dose is 1 mg of guanfacine which may be adjusted in increments of not more than 1 mg per week. Dose should be individualised according to the patient's response and tolerability. Recommended maintenance dose range is 0.05-0.12 mg/kg/day. Ongoing monitoring: During the first year of treatment, the patient should be assessed at least every three months for signs and symptoms of somnolence and sedation, hypotension, bradycardia and weight increase/ risk of obesity. It is recommended to exercise clinical judgment during this period. Six monthly monitoring should follow thereafter, with more frequent monitoring following any dose adjustments. When stopping Intuniv, the dose must be tapered with decrements of no more than 1mg every 3 to 7 days and blood pressure and pulse monitored in order to minimise potential withdrawal effects, in particular increases in blood pressure and heart rate. For further information on dose adjustments, dose titration and discontinuation plus monitoring requirements, refer to the Intuniv SmPC. Renal and hepatic impairment: Dose reduction may be required in patients with different degrees of hepatic impairment, and in patients with severe renal impairment (GFR 29-15 ml/min) and end stage renal disease (GFR<15 ml/min or requiring dialysis). Children under 6 years: Intuniv should not be used because efficacy and safety has not been studied. Patients treated with CYP3A4/5 inhibitors/inducers: Patients on moderate/strong CYP3A4/5 inhibitors: a dose reduction is recommended. *Patients on strong CYP3A4 inducers:* a dose increase within the recommended range is recommended. Prescribers should consult the summary of product characteristics in relation to other adverse reactions. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Warnings and precautions:** Hypotension, bradycardia and syncope: Intuniv can cause syncope, hypotension and bradycardia. Caution is advised when treating patients with a history of hypotension, heart block, bradycardia, or cardiovascular disease, who have a history of syncope or a condition that may predispose them to syncope. Caution also advised with patients treated concomitantly with antihypertensives or other medicinal products that can reduce blood pressure or heart rate or increase the risk of syncope. Patients should be advised to drink plenty of fluid. Blood pressure and heart rate increase upon discontinuation: Blood pressure and pulse may increase following discontinuation of guanfacine. QTc interval: Prescribe with caution in patients with a known history of QT prolongation, risk factors for torsade de pointes or patients taking medicinal products that prolong the QT interval. These patients should receive further cardiac evaluation based on clinical judgement. Sedation and somnolence: Intuniv may cause somnolence and sedation predominantly at the start of treatment and could typically last for 2-3 weeks and longer in some cases, therefore it is recommended that patients are monitored weekly during dose titration and stabilisation. Suicide ideation: There have been post-marketing reports of suicide-related events. It is recommended that caregivers and patients monitor patients for signs of suicide-related events, including at dose initiation/ optimisation and drug discontinuation. Patients and caregivers should be encouraged to report any distressing thoughts or feelings at any time to their healthcare professional. Aggression: Aggressive behaviour or hostility has been reported in clinical trials and in the post-marketing experience of guanfacine. Effects on height, weight and Body Mass index (BMI): Children and adolescents treated with Intuniv may show an increase in their BMI, therefore, monitoring of height, weight and BMI should be done prior to initiation of therapy and then every 3 months for the first year. Six monthly monitoring should follow thereafter with more frequent monitoring following any dose adjustment. Excipients: Intuniv contains lactose. Patients with rare hereditary problems of

galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Intuniv. **Interactions:** All drug-drug interaction studies have been performed in adults. However, the outcome is expected to be similar in the indicated paediatric age range. *QT-Prolonging medicinal products*: Intuniv causes a decrease in heart rate, therefore concomitant use of Intuniv with QT prolonging medicinal products is generally not recommended. *CYP3A4, MATE1, OCT1 and CYP3A5 inhibitors:* See SmPC for further details. *Valproic acid:* Co-administration can result in increased concentrations of valproic acid. Adjustments in the dose of valproic acid and Intuniv may be indicated when co-administered. *Antihypertensive medicinal products:* Caution when administered concomitantly due to the potential for hypotension and syncope. *CNS depressant medicinal products:* Caution when administered concomitantly due to the potential for sedation and somnolence. **Fertility, pregnancy and lactation:** Effects of Intuniv on fertility have not been established. Not recommended during pregnancy and lactation. **Effects on ability to drive and use machines:** May cause drowsiness and somnolence. **Undesirable effects:** *Very common* (≥1/10 patients): somnolence, headache, abdominal pain, fatigue; *Common* (≥1/100, <1/10 patients): decreased appetite, depression, anxiety, affect lability, insomnia, middle insomnia, nightmare, sedation, dizziness, lethargy, bradycardia, hypotension, orthostatic hypotension, vomiting, diarrhoea, nausea, constipation, abdominal/ stomach discomfort, dry mouth, rash, enuresis, irritability, blood pressure decreased, weight increased. *Other serious undesirable effects:* hallucination, convulsion, syncope, hypertensive encephalopathy, erectile dysfunction. **Refer to the SmPC for details on full side effect profile and interactions.** **UK Basic NHS price:** 28 tablet pack: 1 mg: £56.00; 2 mg: £58.52; 3 mg: £65.52; 4 mg: £76.16. **Legal Classification:** POM. **Marketing authorisation (MA):** GB: 1mg: PLGB 54937/0005, 2mg: PLGB 54937/0006, 3mg: PLGB 54937/0007, 4mg: PLGB 54937/0008; NI: 1mg: EU/1/15/1040/001-002, 2mg: EU/1/15/1040/003-005, 3mg: EU/1/15/1040/006-007, 4mg: EU/1/15/1040/008-009. **Business responsible for sale and supply:** GB & NI: Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code:** pi-01719. **Date of preparation:** February 2022. INTUNIV is a registered trade name.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com.