intuniv®
(guanfacine)
Prolonged-Release Tablets 1•2•3•4 mg

The ABC of starting patients on INTUNIV

Assess • Begin • Continue

Before starting any new patient on INTUNIV, a number of preliminary assessments can help ensure the patient's suitability. You can complete this form electronically or print and complete manually.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported to the Medicines and Healthcare products Regulatory Agency. 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.

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.[1] INTUNIV must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.[1]

This is not a risk management material. Please refer to the INTUNIV SmPC for detailed information before starting treatment with INTUNIV.

This resource was developed by Takeda for use by Healthcare Professionals only, in conjunction with the INTUNIV SmPC.

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Patient name

Date of assessment

Date of birth

Age

Gender

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Assess

Use this checklist as a reminder of the baseline evaluations required prior to initiating treatment:

General health and family history

Past and present co-morbid medical conditions ☐

History of concomitant medications ☐

Family history of sudden cardiac/unexplained death ☐

Cardiovascular

Pre-existing cardiovascular disorders including: hypotension; heart block; bradycardia; cardiovascular disease or history of syncope, or a condition that may predispose patient 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. ☐

Known history of QT prolongation, risk factors for torsades de pointes (e.g. heart block, bradycardia and hypokalaemia), or known to be taking medicinal products which prolong the QT interval. These patients should receive further cardiac evaluation based on clinical judgement. ☐

Blood pressure and heart rate (pulse) measured and recorded. ☐

Bariatric

Height and weight recorded on growth chart. ☐

Potential weight increase/risk of obesity. ☐

Psychological/neurological

Suicidal ideation ☐

Increased risk of somnolence/sedation ☐

Co-morbid psychiatric disorders or symptoms ☐

Please refer to the INTUNIV SmPC for detailed information on starting treatment with INTUNIV.

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Begin

Each INTUNIV dose should be swallowed whole, with water and can be taken every morning OR evening, as preferred.[1]

To begin therapy, use the following dose titration schedules.

INTUNIV dose titration schedule (mg/day)

Children aged 6-12 years				
Weight group	**Week 1**	**Week 2**	**Week 3**	**Week 4** & continuation*
☐ **25 kg and above** Max dose = 4 mg	1 mg	2 mg	3 mg	4 mg

Adolescents aged 13-17 years							
Weight group[a]	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7** & continuation*
☐ **34 - 41.4 kg** Max dose = 4 mg	1 mg	2 mg	3 mg	4 mg			
☐ **41.5 - 49.4 kg** Max dose = 5 mg	1 mg	2 mg	3 mg	4 mg	5 mg		
☐ **49.5 - 58.4 kg** Max dose = 6 mg	1 mg	2 mg	3 mg	4 mg	5 mg	6 mg	
☐ **58.5 kg and above** Max dose = 7 mg	1 mg	2 mg	3 mg	4 mg	5 mg	6 mg	7 mg[b]

* Dose should be titrated until desired effect is achieved.[1]
[a] Adolescent subjects must weigh at least 34 kg.
[b] Adolescents weighing 58.5 kg and above may be titrated to a 7 mg/day dose after the subject has completed a minimum of 1 week of therapy on a 6 mg/day dose and the physician has performed a thorough review of the subject's tolerability and efficacy.

Weekly monitoring† during titration for signs and symptoms of...

- Somnolence/sedation
- Hypotension
- Bradycardia

† For information on monitoring for special groups please refer to section 4.4 of the INTUNIV SmPC.

Undesirable effects

- Very common (≥1/10) side effects with INTUNIV include: somnolence, headache, abdominal pain and fatigue.[1]
- The occurrence of somnolence/sedation and hypotension was most prominent in the first few weeks of treatment and diminished gradually thereafter.[1]

For further information on titration and a full list of possible side effects, see the INTUNIV SmPC.

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Continue

Make the following regular assessments		
Somnolence/sedation	**First year Every 3 months**	**Subsequent years Every 6 months**
Hypotension		
Bradycardia		
Weight gain/risk of obesity		

For further information on dose adjustments and discontinuation please refer to the INTUNIV SmPC.

Prescribing Information

Intuniv®▼ (guanfacine hydrochloride) 1 mg, 2 mg, 3 mg, 4 mg Prolonged-Release Tablets

PRESCRIBING INFORMATION. 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 frequest 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: 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. 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. 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. Patients with emergent suicidal ideation or behaviour during treatment for ADHD should be evaluated immediately by their physician. 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. 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): 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.
Name and address of MA holder: Shire Pharmaceuticals Ireland Limited, Block 2 & 3 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, IRELAND.
PI approval code: pi-01273.
Date of preparation: February 2021. 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 to the Medicines and Healthcare products Regulatory Agency. 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.

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Reference 1. INTUNIV Summary of Product Characteristics.

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