Prescribing Information

ELVANSE ADULT® (lisdexamfetamine dimesylate) 30 MG, 50 MG AND 70 MG Capsules, Hard. PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND, SCOTLAND, WALES) and NORTHERN IRELAND
Refer to Summary of Product Characteristics (SmPC) before prescribing

Presentation: Lisdexamfetamine dimesylate provided as 30 mg, 50 mg and 70 mg capsules, equivalent to 8.9mg, 14.8 mg and 20.8 mg of dexamfetamine. **Indication:** Elvanse Adult is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults. Elvanse Adult is not indicated in all adult patients and the decision to use the medicinal product must take into consideration the profile of the patient, including a thorough assessment of the severity and chronicity of the patient's symptoms, the potential for abuse, misuse or diversion and clinical response to any previous pharmacotherapies for the treatment of ADHD. Treatment must be under the supervision of a specialist in behavioural disorders. **Dosage and administration:** The starting dose is 30 mg taken once daily in the morning. Dose may be increased by 20 mg increments, at approximately weekly intervals. Administer orally at the lowest effective dosage. Maximum recommended dose is 70 mg/day. Elvanse Adult may be taken with or without food and swallowed whole, or the capsule opened and the entire contents emptied and mixed with soft food such as yoghurt or in a glass of water or orange juice. If the contents include any compacted powder, a spoon may be used to break apart the powder. The contents should be stirred until completely dispersed. The patient should consume the mixture of soft food or liquid immediately; it should not be stored. Renal and hepatic impairment: Patients with severe renal insufficiency should not exceed 50 mg/day. Further dose reduction should be considered in patients on dialysis. No studies have been conducted in patients with hepatic impairment. Long-term Use: Pharmacological treatment of ADHD may be needed for extended periods. The physician who elects to use Elvanse Adult for extended periods (over 12 months) should re-evaluate the usefulness of Elvanse Adult at least yearly, and consider trial periods off medication to assess the patient's functioning without pharmacotherapy. **Contraindications:** Hypersensitivity to sympathomimetic amines or any of the excipients; concomitant use of monoamine oxidase inhibitors or within 14 days after MAOI treatment, hyperthyroidism or thyrotoxicosis, agitated states, symptomatic cardiovascular disease, advanced arteriosclerosis, moderate to severe hypertension, glaucoma. **Warnings and precautions:** Stimulants including Elvanse Adult have a potential for abuse, misuse or diversion that physicians should consider when prescribing these products. Risk of misuse may be greater in adults (especially young adults) than in paediatric use. Stimulants should be prescribed cautiously to patients with a history of substance abuse or dependence. Monitor cardiovascular status carefully as sudden deaths, strokes, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. All patients should be monitored for changes in heart rate and blood pressure as stimulant medications cause a modest increase in average blood pressure and heart rate. Cardiomyopathy has been reported with Elvanse Adult, all patients should be assessed for the presence of cardiac disease. Elvanse Adult has been shown to prolong the QT_c interval in some patients. It should be used with caution in patients with prolongation of the QT_c interval, in patients treated with drugs affecting the QT_c interval, or in patients with relevant pre-existing cardiac disease or electrolyte disturbances. Monitor psychiatric status as treatment may exacerbate symptoms of behaviour disturbance and thought disorder in patients with pre-existing psychotic disorders. Particular care should be taken in using stimulants to treat ADHD patients with comorbid bipolar disorder because of concern for possible induction of mixed/manic episode. Stimulants may cause aggressive behaviour or hostility. Patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behaviour or hostility. Stimulants have been reported to exacerbate tics, Tourette's syndrome, have been associated with weight loss, and may lower the convulsive threshold, and appropriate monitoring should be conducted. Difficulties with accommodation and blurring of

vision have been reported with stimulant treatment. Elvanse Adult should be used with caution in patients who use other sympathomimetic drugs. The least amount of Elvanse Adult feasible should be prescribed or dispensed in order to minimise the risk of possible overdose by the patient. **Interactions:** Extended-release guanfacine, extended-release venlafaxine, ascorbic acid and other agents and conditions that acidify urine, sodium bicarbonate and other agents that alkalinise urine, monoamine oxidase inhibitors, serotonergic drugs, antihypertensives, narcotic analgesics, chlorpromazine, haloperidol, lithium carbonate. **Fertility pregnancy and lactation:** Effects of Elvanse Adult on fertility have not been established. Elvanse Adult should only be used during pregnancy if potential benefit justifies the potential risks to foetus. Infants born to mothers taking amphetamines should be monitored for withdrawal symptoms. Elvanse Adult should not be used during breast feeding. **Effects on ability to drive and use machines:** Elvanse Adult may impair ability to drive or operate machinery. Patients should be warned not to drive or operate machinery until they know how the medicine affects them. **Undesirable effects:** *Very common (≥ 1/10):* decreased appetite, insomnia, headache, dry mouth. *Common (≥1/100, <1/10 patients):* agitation, anxiety, libido decreased, affect lability, psychomotor hyperactivity, bruxism, dizziness, restlessness, tremor, tachycardia, palpitation, dyspnoea, diarrhoea, constipation, upper abdominal pain, nausea, hyperhidrosis, erectile dysfunction, chest pain, irritability, fatigue, feeling jittery, blood pressure increased, weight decreased. *Other Serious undesirable effects:* Anaphylactic reaction, hypersensitivity, seizure, syncope, QT_c prolongation, cardiomyopathy, angioedema, Stevens-Johnson Syndrome. **Refer to the SmPC for details on full side effect profile and interactions. UK Basic NHS Price** (for 28 capsules) 30mg: £58.24, 50mg: £68.60, 70mg: £83.16. **Legal classification:** POM. **Marketing authorisation (MA):** 30mg: PL 16189/0134, 50mg: PL 16189/0135, 70mg: PL 16189-0136. **Business responsible for sale and supply:** Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. Elvanse Adult is a registered trade name. **PI approval code:** pi-02338. **Date of preparation:** February 2023

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

ELVANSE® (lisdexamfetamine dimesylate) 20MG, 30MG, 40MG, 50MG, 60MG AND 70MG CAPSULES, HARD. PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND SCOTLAND AND WALES) AND NORTHERN IRELAND.

Refer to Summary of Product Characteristics (SmPC) before prescribing

Presentation: Each capsule contains 20mg, 30mg, 40mg, 50mg, 60mg and 70mg lisdexamfetamine dimesylate, equivalent to 5.9 mg, 8.9 mg, 11.9 mg, 14.8 mg, 17.8 mg and 20.8 mg of dexamfetamine. **Indication:** As part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate. Elvanse is not indicated in all children with ADHD and the decision to use the drug must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age and potential for abuse, misuse or diversion. **Dosage and administration:** Children (aged 6 years and over) and adolescents: For all patients the starting dose is 30mg taken once daily in the morning. Patients may begin treatment with 20mg daily if the clinician judges a lower dose to be appropriate. The dose may be increased by 10 or 20mg increments, at approximately weekly intervals. Elvanse should be administered orally at the lowest effective dosage. The maximum recommended dose is 70mg/day; higher doses have not been studied. Renal and hepatic impairment: Patients with severe renal insufficiency should not exceed 50 mg/day. Further dose reduction should be considered in patients on dialysis. No studies have been conducted in patients with hepatic impairment. Administration: Elvanse may be taken with or without food and swallowed whole, or the capsule opened and the entire contents emptied and mixed with soft food such as yoghurt or in a glass of water or orange juice and taken immediately. If the contents include any compacted powder, a spoon may be used to break apart the powder. The contents should be stirred until completely dispersed. Long-term Use: Pharmacological treatment of ADHD may be needed for extended periods. The physician who elects to use Elvanse for extended periods (over 12 months) should re-evaluate the usefulness of Elvanse at least yearly, and consider trial periods off medication to assess the patient's functioning without pharmacotherapy, preferably during times of school holidays. **Contraindications:** Hypersensitivity to sympathomimetic amines or any of the excipients; concomitant use of monoamine oxidase inhibitors or within 14 days after MAOI treatment, hyperthyroidism or thyrotoxicosis, agitated states, symptomatic cardiovascular disease, advanced arteriosclerosis, moderate to severe hypertension, glaucoma. **Warnings and precautions:** Stimulants including Elvanse have a potential for abuse, misuse, dependence or diversion for non-therapeutic uses. Stimulants should be prescribed cautiously to patients with a history of substance abuse. Monitor cardiovascular status carefully as sudden cardiac or unexplained death has been reported. Elvanse has been shown to prolong the QT_c interval in some patients. It should be used with caution in patients with prolongation of the QT_c interval, in patients treated with drugs affecting the QT_c interval, or in patients with relevant pre-existing cardiac disease or electrolyte disturbances. Monitor psychiatric status as treatment may exacerbate symptoms of behaviour disturbance and thought disorder in patients with pre-existing psychotic disorders. Particular care should be taken in using stimulants to treat ADHD patients with comorbid bipolar disorder because of concern for possible induction of mixed/manic episode. Elvanse is associated with worsening or emergence of aggressive behaviour, onset or exacerbation of tics, worsening of Tourette's syndrome, worsening of pre-existing anxiety, agitation or tension. Use with caution in those with epilepsy as may increase frequency of seizures. Monitor weight, growth, blood pressure. Difficulties with accommodation and blurring of vision have been reported with stimulant treatment. Elvanse should be used with caution in patients who use other sympathomimetic drugs. The least amount of Elvanse feasible should be prescribed or dispensed in order to minimise the risk of possible overdose by the patient. **Interactions:** Extended-release guanfacine, extended-release venlafaxine, ascorbic acid and other agents that acidify urine, sodium bicarbonate and other agents that alkalinise urine, monoamine oxidase inhibitors, serotonergic drugs, antihypertensives, narcotic analgesics, chlorpromazine, haloperidol, lithium carbonate. **Fertility pregnancy and lactation:** Effects of Elvanse on fertility have not been established. Elvanse should only be used during pregnancy if potential benefit justifies the potential risks to foetus. Infants born to mothers taking amphetamines should be monitored for withdrawal symptoms. Elvanse should not be used during breast feeding. **Effects on ability to drive and use machines:** Elvanse may impair ability to drive or operate machinery. Patients should be warned not to drive or operate machinery until they know how the medicine affects them. **Undesirable effects:** *Very Common (≥1/10*

patients): Decreased appetite, insomnia, headache, upper abdominal pain, weight decreased. *Common (≥1/100 to <1/10):* Anxiety, depression, tic, affect lability, aggression, dizziness, restlessness, somnolence, dry mouth, diarrhoea, constipation, nausea, vomiting, rash, irritability, fatigue, feeling jittery, pyrexia, tremor, tachycardia, palpitation, dyspnoea. *Other Serious undesirable effects:* Anaphylactic reaction, psychotic episodes, seizure, syncope, QT_c prolongation, cardiomyopathy, angioedema, Stevens-Johnson Syndrome. **Refer to the SmPC for details on full side effect profile and interactions.** **UK Basic NHS Price:** (for 28 capsules) 20mg: £54.62, 30mg: £58.24, 40mg: £62.82, 50mg: £68.60, 60mg: £75.18, 70mg: £83.16. **Legal Classification:** POM. **Marketing authorisation (MA):** 20mg: PL 16189/0128, 30mg: PL 16189/0129, 40mg: PL 16189/0130, 50mg: PL 16189/0131, 60mg: PL 16189/0132, 70mg: PL 16189/0133. **Business responsible for sale and supply:** Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. Elvanse is a registered trade name. **PI approval code:** pi-02339. **Date of preparation:** February 2023.

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.

EQUASYM XL (methylphenidate hydrochloride) 10mg, 20mg and 30mg Modified-Release Capsules, Hard.
PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND, SCOTLAND, WALES) AND NORTHERN IRELAND
Refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: Each capsule contains 10 mg, 20 mg and 30 mg methylphenidate hydrochloride, corresponding to 8.65 mg, 17.30 mg and 25.94 mg of methylphenidate. **Indication:** Attention-deficit hyperactivity disorder (ADHD) in children aged 6 years and over as part of a comprehensive treatment programme under the supervision of a specialist in childhood behavioural disorders where remedial measures alone prove insufficient. **Dosage and administration:** Paediatric population (Children (aged 6 years and over) and adolescents): Prior to prescribing, it is necessary to conduct an evaluation of cardiovascular status, psychiatric status and height and weight. *New patients*: The starting dose is 10mg taken before breakfast. Careful dose titration is necessary. The maximum daily dose is 60mg. *Patients currently using methylphenidate*: A 20mg dose of Equasym XL is intended to replace 10mg of immediate release methylphenidate taken at breakfast and lunchtime. Ongoing monitoring: Growth, psychiatric and cardiovascular status should be continuously monitored: Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and then at least every 6 months. Height, weight and appetite should be recorded at least 6-monthly with maintenance of a growth chart. Development of *de novo* or worsening of pre-existing psychiatric disorders should be monitored at every adjustment of dose and then least every 6 months and at every visit. Patients should be monitored for the risk of diversion, misuse and abuse of methylphenidate. Administration: The capsules may be swallowed whole with liquid, or the contents may be sprinkled onto soft food e.g. apple sauce and swallowed immediately, followed by a drink. The capsules and their contents must not be crushed or chewed. Adults and elderly: Safety and efficacy not established. Children under 6 years of age: Safety and efficacy not established. Long-term Use: Long-term use (i.e. over 12 months) has not been evaluated in controlled trials. The continued usefulness of the drug should be re-evaluated at least yearly by trial periods off medication to assess the patient's functioning without pharmacotherapy. **Contraindications:** Hypersensitivity to methylphenidate or excipients; glaucoma, phaeochromocytoma, hyperthyroidism, thyrotoxicosis, treatment with non-selective irreversible monoamine oxidase inhibitors (or within 14 days of their discontinuation), diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder, diagnosis or history of severe and episodic (Type I) bipolar (affective) disorder, pre-existing cardiovascular disorders including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies, pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke. **Warnings and precautions:** Monitor cardiovascular status carefully as sudden cardiac or unexplained death has been reported. Monitor psychiatric status as treatment may exacerbate symptoms in psychotic children, or may precipitate mixed/manic episodes. Equasym XL is associated with worsening or emergence of aggressive behaviour, emergent suicidal ideation or behaviour, onset or exacerbation of tics, worsening of Tourette's syndrome, worsening of pre-existing anxiety, agitation or tension. Use with caution in those with epilepsy as may increase frequency of seizures. Priapism has been reported in association with methylphenidate products, mainly in association with a change in treatment regimen. Monitor abuse potential as chronic abuse may lead to tolerance and dependency with abnormal behaviour. Monitor weight, growth, blood pressure and pulse. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Equasym XL. Supervise drug withdrawal. Should not be used for treatment or prevention of normal fatigue states. There is no experience with the use of methylphenidate in patients with renal or hepatic insufficiency. Haematological effects indicative of serious renal or hepatic disorders, discontinuation of treatment should be considered. **Interactions:** Drugs that elevate blood pressure, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), tricyclics and SSRIs, coumarin anticoagulants, clonidine and other alpha-2 agonists, anti-hypertensives, halogenated anaesthetics, alcohol, dopamine agonists or antagonists including antipsychotics. **Fertility, pregnancy and lactation:** Equasym XL is not recommended during pregnancy. Equasym XL has been found in breast milk and should not be used during breast feeding. **Effects on ability to drive and use machines:** Equasym XL may impair ability to drive or operate machinery. Patients should be warned not to drive or operate machinery until they know how the medicine affects them. **Undesirable effects:** *Very common (≥1/10 patients):* Nervousness, insomnia, headache. *Common (≥1/100, <1/10 patients):*

Arrhythmia, palpitations, tachycardia, hypertension, abdominal pain, nausea, diarrhoea, stomach discomfort and vomiting, dry mouth, changes in blood pressure and heart rate, decreased appetite, moderately reduced weight and height gain during prolonged use, growth retardation during prolonged use, pyrexia, arthralgia, dizziness, dyskinesia, abnormal behaviour, bruxism, aggression, agitation, anorexia, anxiety, depression, irritability, alopecia, rash, pruritus, urticaria, nasopharyngitis, affect lability, psychomotor hyperactivity, somnolence, sedation, tremor, cough, pharyngolaryngeal pain. Other *Serious undesirable effects:* Thrombocytopenia, pancytopenia, anaphylactic reactions, psychotic disorders, auditory, visual and tactile hallucinations, suicidal ideation, Tourette's syndrome, suicidal attempt (including completed suicide), dependence, neuroleptic malignant syndrome (NMS), vasculitis, cerebral haemorrhages, cerebrovascular accidents, cerebral arteritis, cerebral occlusion, grand mal convulsions, angina pectoris, cardiac arrest, myocardial infarction, bradycardia, cerebral arteritis, erythema multiforme, erectile dysfunction, sudden cardiac death, hyperpyrexia. **Refer to the SmPC for details on full side effect profile and interactions. UK Basic NHS price:** (for 30 capsules) 10mg: £25.00, 20mg: £30.00, 30mg: £35.00 **Legal Classification:** CD (Sch 2) POM. **Marketing authorisation (MA):** GB & NI: 10 mg: PL 54937/0001, 20 mg: PL 54937/0002, 30 mg: PL 54937/0003**. Business responsible for sale and supply:** GB & NI: Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code:** pi-02003. **Date of preparation:** June 2022. EQUASYM XL is a registered trade name.

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

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.

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