Some of the medicines listed below may not be available/licensed for ADHD in your home country. Please refer to the respective Summary of Product Characteristics (SmPC) in your country before prescribing.

ELVANSE™ (lisdexamfetamine dimesylate) (Please consult the full Summary of Product Characteristics (SmPC), before prescribing)
Active Ingredient: Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg, and 70mg. **Indication:** ELVANSE is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years 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:* The starting dose is 30mg taken once daily in the morning. When in the judgement of the clinician a lower initial dose is appropriate, patients may begin treatment with 20mg once daily in the morning. 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. *Administration:* ELVANSE may be swallowed whole, or the capsule opened, and the entire contents emptied and mixed with a soft food such as yogurt 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 in the soft food or liquid. The contents should be stirred until completely dispersed. The patient should consume the entire mixture of soft food or liquid immediately; it should not be stored. **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 (MAOI) 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 that physicians should consider when prescribing these products. Stimulants should be prescribed cautiously to patients with a history of substance abuse or dependence. Stimulants should not be used in children or adolescents with known serious structural cardiac abnormalities, or other serious cardiac problems. Monitor cardiovascular status carefully as sudden cardiac or unexplained death has been reported. ELVANSE has shown to prolong the QTc interval in some patients. It should be used with caution in patients with prolongation of the QTc interval, in patients treated with drugs affecting the QTc interval, or in patients with relevant preexisting cardiac disease or electrolyte disturbances.ELVANSE is contraindicated in patients with symptomatic cardiovascular disease and also in those patients with moderate to severe hypertension 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 when 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 psychosis, emergence of psychotic or manic symptoms, slowed weight gain and reduction in attained height, and visual disturbance. Use with caution in epileptics as the drug 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 and venlafaxine, ascorbic acid and other agents that acidify urine, sodium bicarbonate and other agents that alkalinise urine, monoamine oxidase inhibitors, antihypertensives, narcotic analgesics, chlorpromazine, haloperidol, lithium carbonate, serotonergic drugs. **Fertility, pregnancy and lactation:** Dexamfetamine, the active metabolite of ELVANSE crosses the placenta. Exposure to amphetamine during the first 20 weeks of pregnancy could increase the risk of preeclampsia, and preterm birth. Newborns exposed to amphetamine during pregnancy may experience withdrawal symptoms. Elvanse should only be used during pregnancy if the potential benefit justifies the potential risk to the foetus. Elvanse should not be used during breast-feeding. **Driving:** Caution is advised. **Undesirable Effects:**

Children:

Very common (frequency ≥1/10):	Decreased appetite, insomnia, headache, weight decreased, Upper abdominal pain.
Common (≥1/100 to <1/10):	Affect lability, aggression, constipation, diarrhoea, dizziness, dry mouth, fatigue, irritability, nausea, pyrexia, rash, somnolence, tachycardia, tic, vomiting.
Uncommon (≥1/1000 to <1/100):	Agitation, anxiety, blood pressure increased, bruxism, chest pain, depression, dermatillomania, dyskinesia, dysgeusia, dysphoria, dyspnoea, feeling jittery, hallucination, hyperhidrosis, hypersensitivity, logorrhea, mania, mydriasis, palpitation, psychomotor hyperactivity, Raynaud's phenomenon, restlessness, syncope tremor, urticaria, vision blurred.

Adolescents:

Very common (frequency ≥1/10):	Decreased appetite, insomnia, headache, weight decreased.
Common (≥1/100 to <1/10):	Anxiety, depression, diarrhoea, dizziness, dry mouth, dyspnoea, fatigue, feeling jittery, irritability, nausea, palpitation, pyrexia, restlessness, somnolence, tachycardia, tremor, upper abdominal pain, vomiting.
Uncommon (≥1/1000 to <1/100):	Affect lability, aggression, agitation, blood pressure increased, bruxism, cardiomyopathy, chest pain, constipation, dermatillomania, dyskinesia, dysgeusia, dysphoria, erectile dysfunction, euphoria, hallucination, hyperhidrosis, hypersensitivity, logorrhea, mania, mydriasis, psychomotor hyperactivity, rash, syncope, tic, urticaria.

Overdose: The prolonged release of dexamfetamine after administration of ELVANSE should be considered when treating patients with overdose.
Name and Address of MA Holder: Shire Pharmaceutical Contracts Limited, 1 Kingdom Street, London, W2 6BD, UNITED KINGDOM. **Material code: pi-01200**
API Date of preparation: January 2021
Further information is available on request.

Suspected adverse events should be reported to Takeda at: drugsafety@shire.com (Shire is now part of Takeda).

(Please consult the Summary of Product Characteristics (SmPC), before prescribing)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

INTUNIV▼ 1 mg, 2 mg, 3 mg and 4 mg prolonged-release tablets.
Active Ingredient: Guanfacine hydrochloride equivalent to 1 mg, 2 mg, 3 mg and 4 mg of guanfacine. **Uses:** 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. INTUNIV must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures. **Dosage and Administration:** Treatment must be initiated under the supervision of an appropriate specialist in childhood and/or adolescent behavioural disorders. For all patients, the recommended starting dose is 1 mg of guanfacine, taken orally once a day. The dose may be adjusted in increments of not more than 1mg per week. Dose should be individualised according to the patient's response and tolerability. Depending on the patient's response and tolerability for INTUNIV the recommended maintenance dose range is 0.05 - 0.12 mg/kg/day. Dose adjustments (increase or decrease) to a maximum tolerated dose within the recommended optimal weight-adjusted dose range may occur at any weekly interval after the initial dose. When stopping Intuniv, the dose must be tapered with decrements of no more than 1 mg every 3 to 7 days, and blood pressure and pulse should be monitored in order to minimise potential withdrawal effects, in particular increases in blood pressure and heart rate. *Administration:* Oral use. INTUNIV is taken once daily either morning or evening. INTUNIV should not be crushed, chewed or broken before swallowing because this increases the rate of guanfacine release. Treatment is recommended only for children who are able to swallow the tablet whole without problems. INTUNIV can be administered with or without food but should not be administered with high fat meals, due to increased exposure. INTUNIV should not be administered together with grapefruit juice. **Long-term Use:** The physician who elects to use INTUNIV for extended periods (over 12 months) should re-evaluate the usefulness of INTUNIV every 3 months for the first year and then at least yearly based on clinical judgement (see section 4.4), and consider trial periods off medication to assess the patient's functioning without pharmacotherapy, preferably during times of school holidays. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings:** INTUNIV can cause syncope, hypotension and bradycardia. Syncope may involve risks of falls or accidents, which could result in serious harm. Prior to initiation of treatment, patient's cardiovascular status, including heart rate and blood pressure parameters, family history of sudden cardiac deaths /unexplained death, should be assessed to identify patients at increased risk of hypotension, bradycardia, and QT-prolongation/risk of arrhythmia. Monitoring of heart rate and blood pressure parameters should continue on a weekly basis during dose titration and stabilisation and at least every 3 months for the first year. 6 monthly monitoring should follow thereafter, with more frequent monitoring following any dose adjustment. 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 an end stage renal disease (GRF<15 ml/min or requiring dialysis.) Hypertensive encephalopathy has been very rarely reported upon abrupt discontinuation of Intuniv. **Precautions:** INTUNIV should be prescribed with caution in patients with a known history of QTprolongation, risk factors for torsade de pointes (e.g. heart block, bradycardia, hypokalemia) or patients who are taking medicinal products known to prolong the QT interval. 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. Weekly monitoring during dose titration and stabilisation, and every 3 months during the first year is recommended. Before INTUNIV is used with any other centrally active depressants (such as alcohol, sedatives, phenothiazines, barbiturates, or benzodiazepines) the potential for additive sedative effects should be considered. Patients should not drink alcohol whilst taking INTUNIV. 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. Monitor height, weight and BMI prior to initiation of therapy and then every 3 months for the first year. 6 monthly monitoring should follow thereafter, with more frequent monitoring following any dose adjustment. Patients with rare hereditary problems of galactose intolerance should not take INTUNIV. **Interactions:** When INTUNIV is used concomitantly with CYP3A4/5 inhibitors or inducers, plasma concentrations of guanfacine may be elevated or lowered, potentially affecting the efficacy and safety of INTUNIV. Concomitant use of INTUNIV with QT-prolonging medicinal products is generally not recommended. Caution should be used when INTUNIV is administered concomitantly with valproic acid, antihypertensive medicinal products, CNS depressant medicinal products. **Pregnancy and Lactation:** INTUNIV is not recommended during pregnancy and in women of childbearing potential not using contraception. It is unknown whether guanfacine and its metabolites are excreted in human milk. A risk on the breast-fed infant cannot be excluded. **Driving:** INTUNIV can cause dizziness and somnolence. Syncope has also been observed. Caution is advised. **Adverse Reactions:** *Very common:* Somnolence, headache, abdominal pain, fatigue. *Common:* 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. Consult the SmPC in relation to less frequent adverse reactions. **Pharmaceutical Precautions:** No special storage conditions required. **Name and Address of MA Holder:** Shire Pharmaceuticals Ireland Limited, 5 Riverwalk, Citywest Business Campus, Dublin 24, IRELAND
Further information is available on request.
INTUNIV is a registered trade name.
Material code: pi-00504 Date of Preparation of the API: June 2018

Suspected adverse events should be reported to Shire at: drugsafety@shire.com

ELVANSE Adult™ (lisdexamfetamine dimesylate)
(Please consult the full Summary of Product Characteristics (SmPC), before prescribing.)
Active Ingredient: Lisdexamfetamine dimesylate 30mg, 50mg and 70mg.
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. **Dosage and Administration:** *Adults:* The starting dose is 30 mg taken once daily in the morning. The dose may be increased by 20 mg increments, at approximately weekly intervals. ELVANSE ADULT should be administered orally at the lowest effective dosage. The maximum recommended dose is 70mg/day. Patients with severe renal insufficiency should not exceed a maximum daily dose of 50mg/day. Further dose reduction should be considered in patients on dialysis. *Administration:* ELVANSE ADULT may be swallowed whole, or the capsule opened and the entire contents emptied and mixed with a soft food such as yogurt 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 in the soft food or liquid. The contents should be stirred until completely dispersed. The patient should consume the entire mixture of soft food or liquid immediately; it should not be stored. **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. The 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. ELVANSE ADULT has shown to prolong the QTc interval in some patients. It should be used with caution in patients with prolongation of the QTc interval, in patients treated with drugs affecting the QTc interval, or in patients with relevant pre-existing cardiac disease or electrolyte disturbances. ELVANSE ADULT is contraindicated in patients with symptomatic cardiovascular disease and also in those patients with moderate to severe hypertension. Cardiomyopathy has been reported with ELVANSE ADULT, all patients should be assessed for the presence of cardiac disease. 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 and 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:** Dexamfetamine, the active metabolite of ELVANSE ADULT crosses the placenta. Exposure to amphetamine during the first 20 weeks of pregnancy could increase the risk of preeclampsia, and preterm birth. Newborns exposed to amphetamine during pregnancy may experience withdrawal symptoms. ELVANSE ADULT should only be used during pregnancy if the potential benefit justifies the potential risk to the foetus. ELVANSE ADULT should not be used during breastfeeding.
Driving: Caution is advised.
Undesirable Effects:
ADULTS

Very common (frequency ≥1/10):	Decreased appetite, dry mouth, headache, insomnia.
Common (≥1/100 to <1/10):	Affect lability, agitation , anxiety, blood pressure increased, bruxism, constipation, diarrhoea, dizziness, dyspnoea, erectile dysfunction, fatigue, feeling jittery, hyperhidrosis, irritability, libido decreased, nausea, palpitation, chest pain, psychomotor hyperactivity, restlessness, tachycardia, tremor, upper abdominal pain, weight decreased.
Uncommon (≥1/1000 to <1/100):	Depression, dermatillomania, dysphoria, dyskinesia, dysgeusa, euphoria, hypersensitivity, logorrhea, mania, pyrexia, rash, somnolence, syncope, tic, urticaria, vision blurred, vomiting

Overdose: The prolonged release of dexamfetamine after administration of ELVANSE ADULT should be considered when treating patients with overdose. **Date of Revision:** Nov 2020. **Name and Address of MA Holder:** Shire Pharmaceutical Contracts Limited, 1 Kingdom Street, London, W2 6BD, UNITED KINGDOM.
Further information is available on request.
Material code: pi-01204 API Date of Preparation: January 2021

Suspected adverse events should be reported to Takeda at: drugsafety@shire.com (Shire is now part of Takeda).