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