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.