Elvanse®
(lisdexamfetamine dimesylate) capsules
20 • 30 • 40 • 50 • 60 • 70 mg

Addressing ADHD from adolescence to adulthood

With ADHD, not every well-managed adolescent manages well as an adult.[1-5]

Elvanse is indicated for ADHD as part of a comprehensive treatment program for children (6 years and over) when response to methylphenidate is considered clinically inadequate and in adults with pre-existing childhood ADHD symptoms.[6]

Treatment must be supervised by a specialist in behavioural disorders appropriate to the patient's age.

Elvanse is not indicated for all ADHD patients and the decision to use the medicinal product must consider the patient profile, including symptom severity, chronicity, potential for abuse, misuse or diversion, and clinical response to previous pharmacotherapies for ADHD.[6]

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.

Takeda

Prescribing information can be accessed via the QR codes on the back cover.

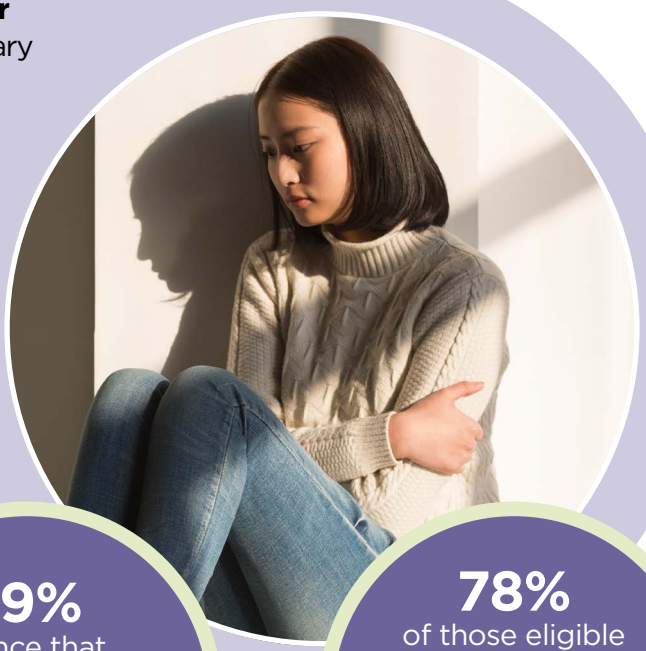
Item code: C-APROM/GB/NS/1167
Date of preparation: February 2025

Meet Mia*

Making the jump into adulthood is difficult for any young person, but can be particularly challenging for those with ADHD[1]

Mia was often seen as an **inattentive daydreamer** who struggled to reach her potential.[7] In secondary school, she was **diagnosed with ADHD**. With the support of CAMHS, her family, and medication, **Mia's ADHD was well-managed**, and she began to thrive.[8]

However when Mia moved to Sixth Form College, she faced **new challenges**, and managing her **ADHD became less of a priority**. Becoming more independent with less parental support, **ADHD management slipped through the cracks of her busy life.**[1,9,10]



In up to **86% of children** diagnosed with ADHD, symptoms persist into adulthood[11]

89% chance that patients **come off medication** between the ages of **16 and 23**[2]

78% of those eligible for adult services will miss their first appointment, and only **6%** will transition optimally[12]

Without the proper support for her ADHD, Mia may struggle to cope with the complexities of adulthood.[9,10]

*Fictional patient.

CAMHS=Child and Adolescent Mental Health Services.

If left untreated, adults with ADHD may have worse outcomes in life vs. healthy controls[3-5]

Serious accidents
up to **50%**
more likely[3*]
(Males, OR: 1.49, 95% CI: 1.46–1.54, n=1,121,032; Females, OR: 1.44, 95% CI: 1.41–1.48, n=1,198,384)

Graduation
27%
less likely[4]
(19%, n=500 vs. 26%, n=501; p<0.0001)

Alcohol abuse
8.5X
more likely[5]
(17%, n=145 vs. 2%, n=108; p<0.001)

Job loss
4X
more likely[5†]
(17%, n=139 vs. 4%, n=97; p<0.001)

Adults with ADHD are 6.7X more likely to commit suicide than those without (unadjusted OR:6.69, 95% CI: 3.24-17.39).[13‡]

*Data from a study analysing accident rates in treated ADHD patients vs. untreated ADHD patients.[3]
†Difference taken from community control data.[5]
‡A meta-analysis of 57 studies, including 330,583 participants (n=90,805 ADHD vs. n=239,778 non-ADHD), found a significant association between ADHD and SSBs (p<0.0001). Pooled unadjusted odds ratio. The ADHD patient population included both treated and untreated patients.[13]

CI=confidence interval; OR=odds ratio; SSBs=suicidal spectrum behaviours.

NICE provides guidance on engaging and supporting young people like Mia[14]

Engage
and involve

"Offer young people help to become involved in their transition planning" and, where appropriate, "discuss the transition with the young person's parents or carers to understand their expectations about transition."[14]

Review
treatment plan

Review progress

Improve communication with the patient

Ensure coordinated care

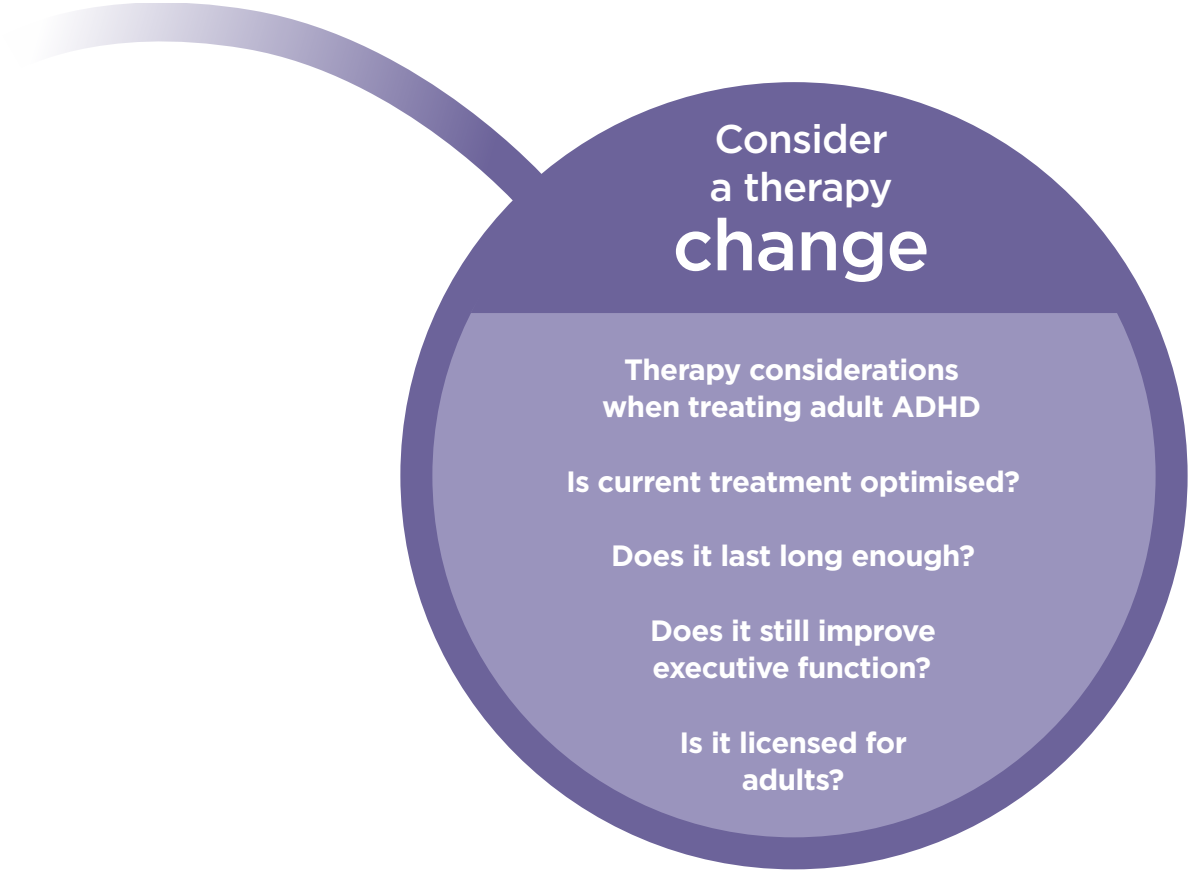
Consider non-pharmacological support[14]

Tips to improve engagement and adherence

- Educate on the importance of continued treatment and the risks of stopping[1]
- Link therapy success to their personal goals[1]
- Promote independence and encourage young people to manage their ADHD themselves[14]
- Build positive therapeutic relationships with their next practitioner[14]

NICE=National Institute for Health and Care Excellence.

As daily demands increase, consider the suitability of treatment for adult life



In collaboration with an ADHD specialist, Takeda has provided an HCP and patient checklist to assist young people as they transition to adult services. Scan or click the QR codes to download.

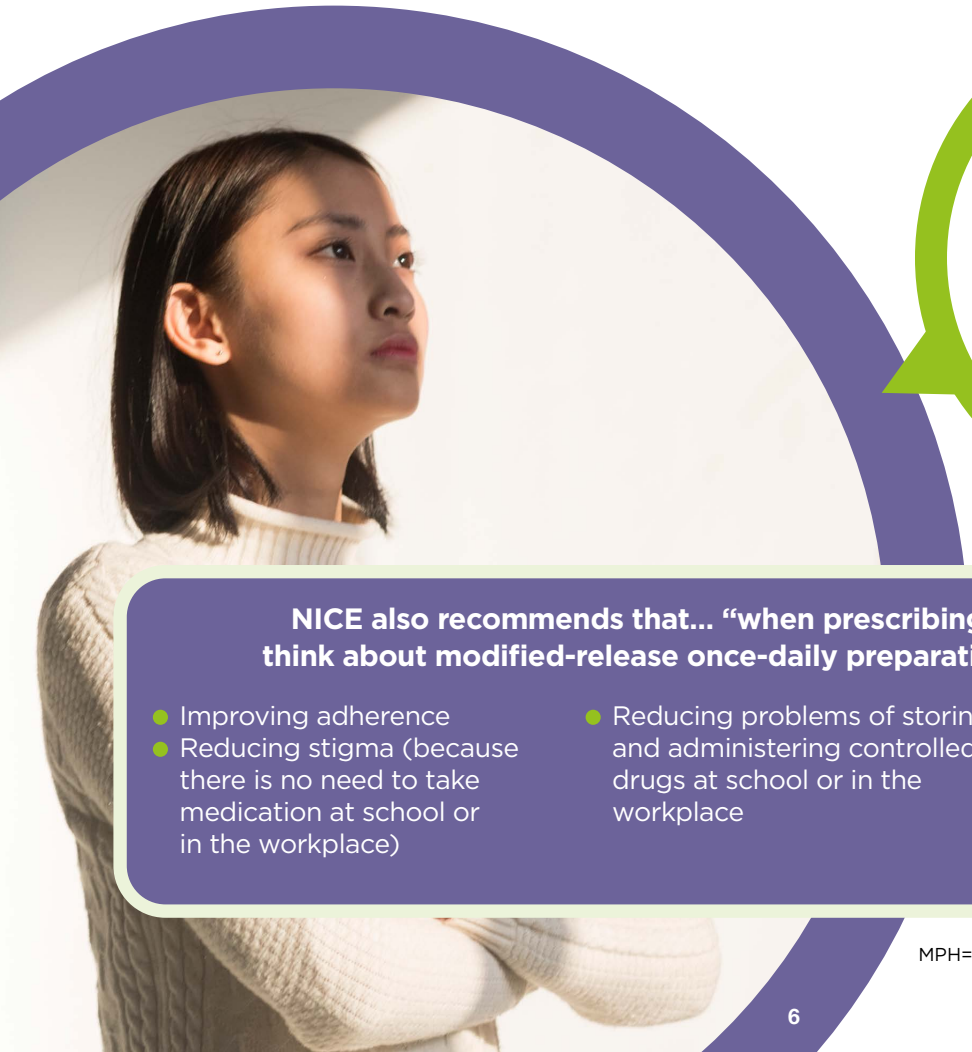
HCP **Patient**

HCP=healthcare professional.

Elvanse is licensed for children, young people and adults[6]

With ONE license, your patients can go through life with consistent care and necessary support.[6]

In children and young people:
Lisdexamfetamine is recommended by NICE for those who have already had a **6-week trial** of methylphenidate at an adequate dose and not derived enough benefit in terms of reduced ADHD symptoms and associated impairment.[15]



In adults (18+):
Lisdexamfetamine or MPH are recommended as **first-line treatment** options for **adults with ADHD**

NICE also recommends that... "when prescribing stimulants for ADHD, think about modified-release once-daily preparations for these reasons:"[15]

- Improving adherence
- Reducing stigma (because there is no need to take medication at school or in the workplace)
- Reducing problems of storing and administering controlled drugs at school or in the workplace
- The risk of stimulant misuse and diversion with immediate-release preparations
- Their pharmacokinetic profiles

MPH=methylphenidate.

Elvanse is preferred by physicians as a first-line treatment option for adults with ADHD[16]

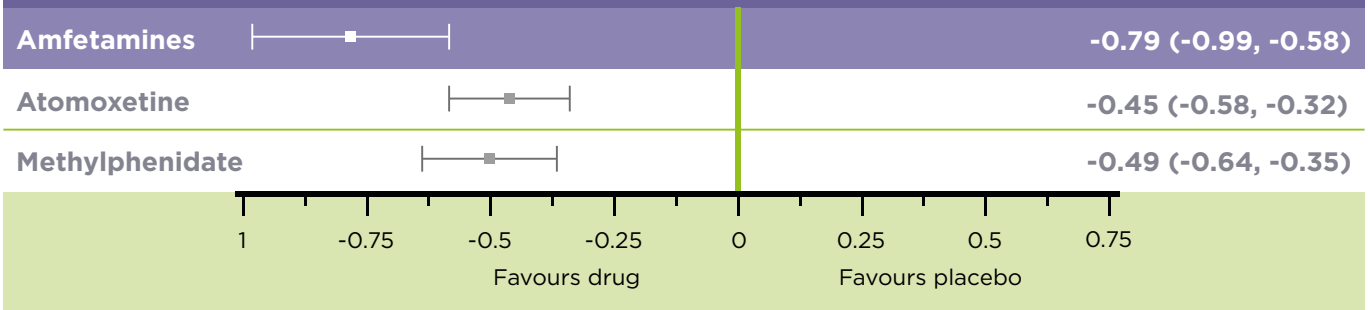
In a meta-analysis of 133 double-blind randomised controlled trials (including 81 in children and adolescents, 51 in adults, and one in both), aimed at comparing the efficacy of ADHD medications, **physicians expressed a preference for amfetamines (e.g. lisdexamfetamine, Elvanse) compared to MPH as a first-choice medication for the short-term treatment of adult ADHD.**[16]

The analysis of efficacy closest to 12 weeks was based on 10068 children and adolescents and 8131 adults.[16]

Please note these trials were not head-to-head comparator trials.

Amfetamines, including lisdexamfetamine, rated as the most efficacious compounds:[16]

Mean change in ADHD symptoms as rated by clinicians



Amfetamines were also the only compounds with better acceptability* than placebo[16]

*Acceptability was defined as the proportion of participants who left the study for any reason.
Plots include all trials for efficacy and tolerability and are compared with placebo as reference.
Adapted from: Cortese S *et al. The Lancet Psychiatry.* 2018;**5(9):**727–38 (https://creativecommons.org/licenses/by/4.0/)

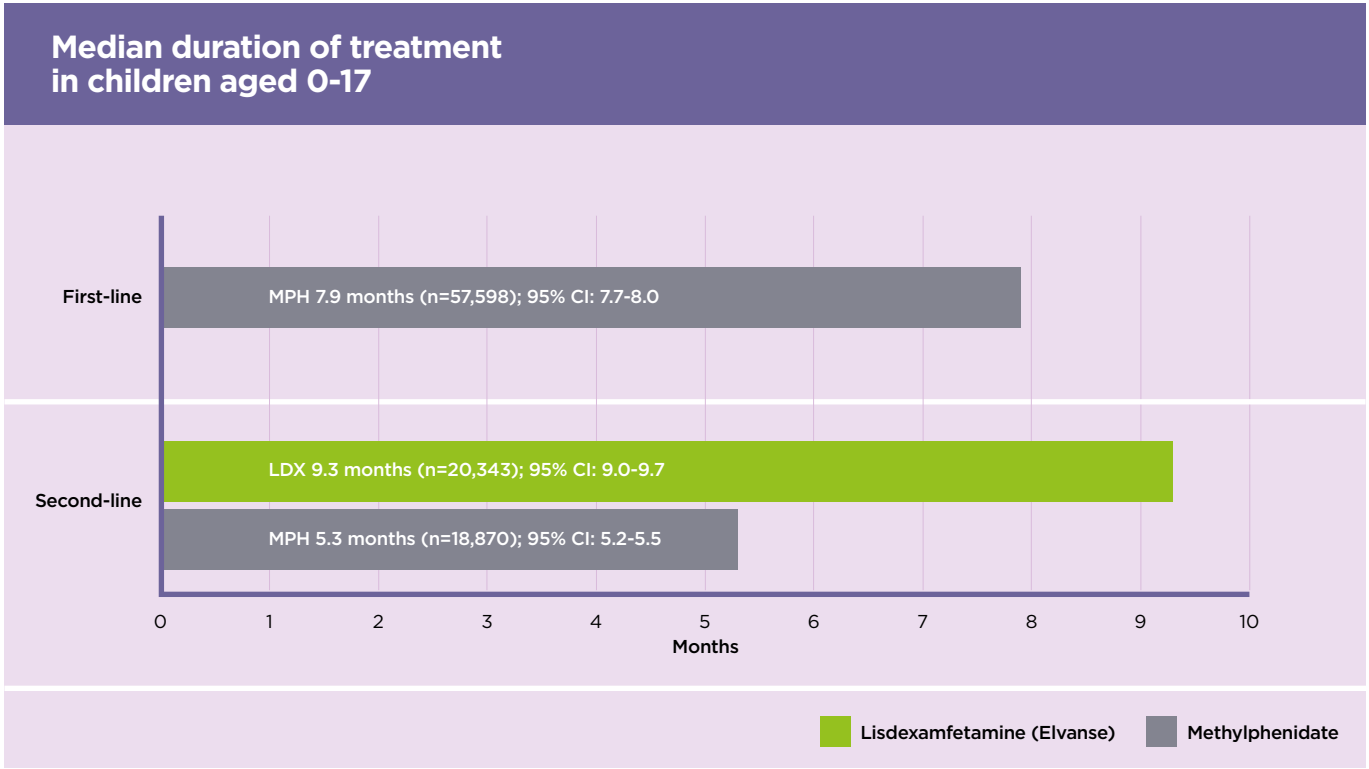
The most frequently reported adverse reactions (≥1/10) with Elvanse in adult patients are decreased appetite, dry mouth, headache and insomnia[2]

MPH=methylphenidate; SMD=standardised mean difference.

Data from Swedish registry study:* LDX showed greater treatment duration vs. MPH in CYP patients[17]

In an observational retrospective study including cross-sectional and longitudinal analyses of patients with ADHD from the Swedish National Patient Register and Prescribed Drug Register (2018 to 2021), **lisdexamfetamine demonstrated a longer treatment duration compared to both first- and second-line treatment with methylphenidate** (n=243,790).[17]

*This study may have limited generalisability to the UK.



Adapted from Giacobini M, *et al.* 2023

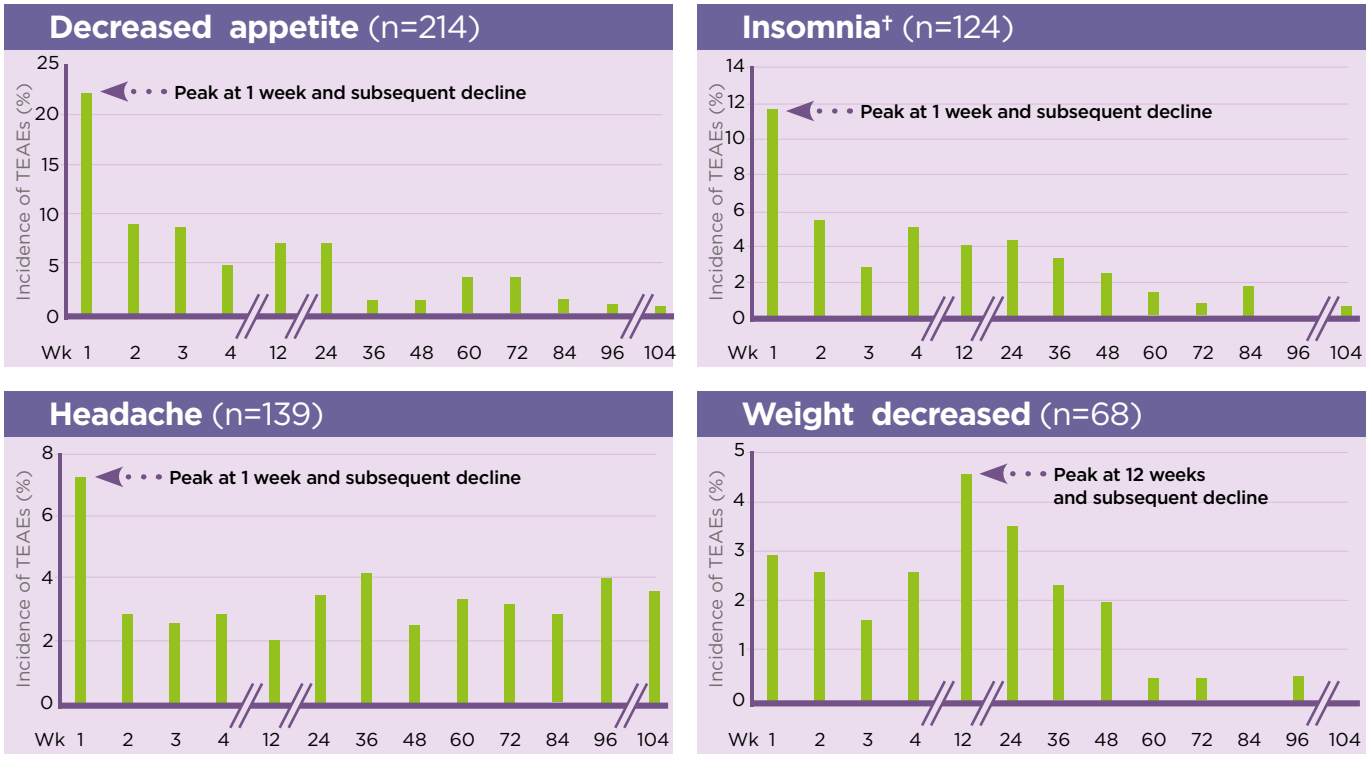
CYP=children and young people; LDX=lisdexamfetamine.

Long-term data in CYP patients taking Elvanse suggest a decline in selected TEAEs of special interest over time[18]

The trial was a phase IV, multicentre, open-label, 2-year study of the long term safety and efficacy of LDX in children (6-12) and adolescents (13-17) with ADHD in Europe (n=191). The primary aim of this study was safety monitoring, with efficacy assessed as a secondary objective using ADHD-RS-IV.[18]

The results show that **the incidence of TEAEs of special interest* peaked in the first 12 weeks and then declined or stabilised over time.[18]**

Proportion of participants with TEAE over time[18]



Some individuals did experience potentially clinically significant changes in cardiovascular parameters or weight, supporting the recommendations for regular monitoring of patients in clinical practice

Adapted from Coghill DR *et al. CNS Drugs* 2017;**31:**625–38.
*Selected TEAEs of special interest (decreased appetite, insomnia†, weight decreased and headache) were pre-specified by the study sponsor based on their reported association with stimulant treatment.[18]
†Including preferred terms insomnia, initial insomnia, middle insomnia and terminal insomnia.[18]

ADHD-RS-IV=ADHD Rating Scale IV; TEAEs=treatment-emergent adverse events.

Elvanse helps children and young people with ADHD meet the growing demands of their lives[6,19,20]

The only ADHD treatment with prodrug technology[6,19]

Can be taken with or without food and delivers consistent and predictable levels of medication throughout the day[6]*

Up to 13 hours of sustained core symptom control in children[6]

In clinical studies conducted in children and adults, the effects of lisdexamfetamine dimesylate were ongoing at 13 hours after dosing in children and at 14 hours in adults when the product was taken once daily in the morning[6]

Improved functioning and health-related quality of life

vs. patients who discontinued LDX[20]

Patients with ADHD from a prior European study and US sites (aged 6-17, with baseline ADHD-RS-IV≥28) received 26 weeks of open-label LDX and then were randomised (1:1) to continue LDX or switch to placebo for a 6-week, double-blind withdrawal period.[20]

Results were measured by a statistical analysis of changes in CHIP-CE: PRF T- scores from baseline to endpoint of the randomised-withdrawal period (n=153; 95% CI)[20]

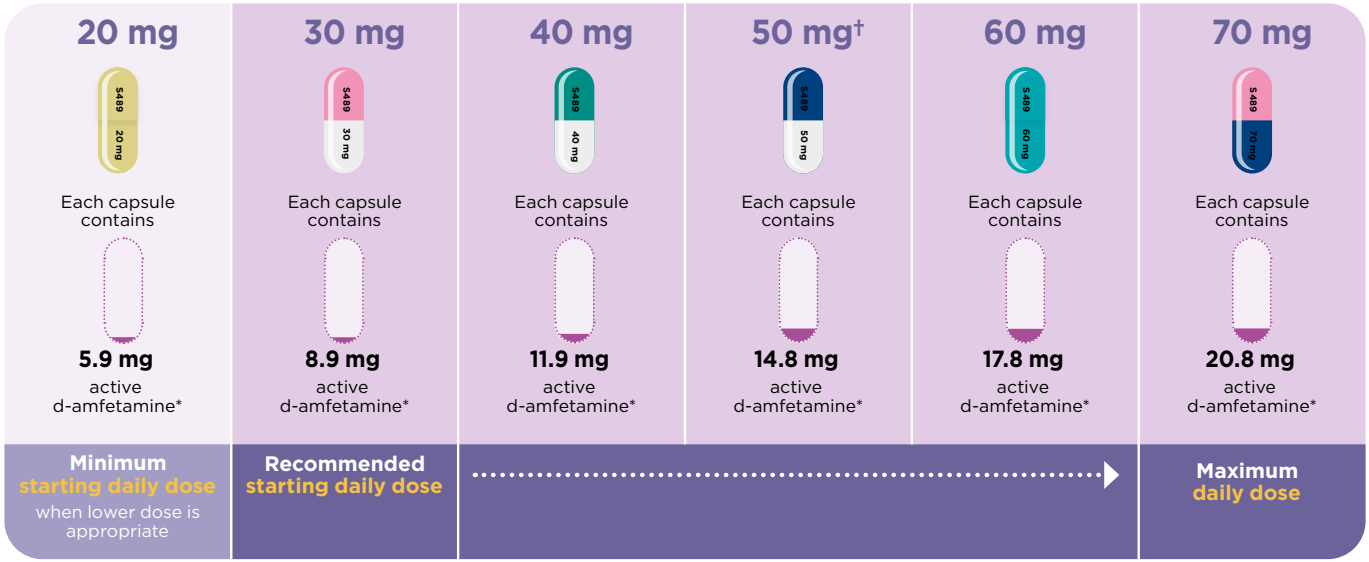
Treatment duration is longer with Elvanse vs. MPH

Elvanse, used second-line, demonstrated a longer treatment duration compared to both first- and second-line treatment with MPH[17†]

2L LDX 9.3 months (n=20,343); 95% CI: 9.0-9.7.
1L MPH 7.9 months (n=57,598); 95% CI: 7.7-8.0.
2L MPH 5.3 months (n=18,870); 95% CI: 5.2-5.5.

*The therapeutic mode of action of amfetamine in ADHD is not fully established.[6]
†Data from Swedish registry study and therefore may have limited generalisability to the UK.[17]
1L=first-line; 2L=second-line; CHIP-CE: PRF=Child Health and Illness Profile-Child Edition: Parent Report Form.

Elvanse is available in six once-daily dose strengths for flexible, precision dosing[6]



- The dose may be increased by 10 or 20 mg increments, at approximately weekly intervals[6]
- Elvanse should be administered at the lowest effective dosage[6]

Across patients, lowest effective dose varies. With six doses available, treatment can be individualised according to therapeutic needs.[6]

*For illustrative purposes only. Based on % of total weight and a 100% full capsule.
†In patients with severe renal insufficiency the maximum daily dose should not exceed 50 mg.

References

1. Janzen T, *et al. Prim Care Companion CNS Disord* 2024;**26(4):**24nr03718; **2.** Newlove-Delgado T, *et al. Eur Child Adolesc Psychiatry* 2018;27:29–35; **3.** Chang Z, *et al. JAMA Psychiatry* 2017;**74(6):**597–603; **4.** Biederman J, *et al. J Clin Psychiatry* 2006;**67(4):**524–40; **5.** Barkley RA, *et al.* ADHD in Adults. New York: Guilford Press, 200: **6.** Elvanse Summary of Product Characteristics; **7.** Quinn PO & Madhoo M. *Prim Care Companion CNS Disord* 2014;**16(3);pii:** PCC.13r01596; **8.** Wigal SB, *et al. Child Adolesc Psychiatry Ment Health* 2009;**3(1):**17; **9.** Price A, *et al. BMC Psychiatry* 2019;**19(1):**404; **10.** Turgay A, *et al. J Clin Psychiatry* 2012;**73(2):**192-201; **11.** Cherkasova MV, *et al. J Am Acad Child Adolesc Psychiatry* 2022;**61:**378–91; **12.** Eke H, *et al. BJPsych* 2020;**217:**616-22; **13.** Septier M, *et al. Neurosci Biobehav Rev* 2019;**103:**109–18; **14.** NICE guidelines NG43 (2016). Available at: https://www.nice.org.uk/guidance/NG43 (accessed February 2025); **15**. NICE guidelines NG87 (2018). Available at: https://www.nice.org.uk/guidance/NG87 (accessed February 2025); **16.** Cortese S, *et al. The Lancet Psychiatry* 2018;**5(9):**727–38; **17.** Giacobini M, *et al. J Atten Disord* 2023;**27(12):**1309–21; **18.** Coghill DR, *et al. CNS Drugs* 2017;**31:**625–38; **19.** Soutullo C, *et al. CNS Drugs* 2013;27(9):743-5; **20.** Banaschewski T, *et al. CNS Drugs* 2014;**28(12):**1191–203.

Elvanse can help adolescents with ADHD manage well during the challenge of transitioning into adulthood[1,20]

Simple, once-daily dosing[6]

Prodrug technology for up to **13 hours of symptom control**[6]

Improved functioning and **health-related quality of life**[20]

Long-term symptom control and well tolerated over 2 years[18]

NICE guidance[15]

Lisdexamfetamine (LDX) is recommended for children and young people who have had a **6-week trial of methylphenidate (MPH)** at an adequate dose, and **not derived enough benefit** in terms of reduced ADHD symptoms and associated impairment.

Lisdexamfetamine is also recommended joint first-line as a treatment for adults (18+) with ADHD.

For Elvanse Prescribing Information, scan or click the QR code.

For Equasym XL (methylphenidate) Prescribing Information, scan the QR code.

Elvanse®
(lisdexamfetamine dimesylate) capsules
20 • 30 • 40 • 50 • 60 • 70 mg

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