Checklist 1: lisdexamfetamine dimesylate checklist before prescribing

This checklist is designed to support you in the appropriate initiation of lisdexamfetamine dimesylate in a child aged six years and above with attention-deficit/hyperactivity disorder (ADHD), when response to previous methylphenidate treatment is considered clinically inadequate.

As detailed in the summary of product characteristics (SmPC) and in the product prescribing information, specific concurrent conditions may exclude the use of lisdexamfetamine dimesylate or may warrant particular attention, including cardiovascular and neuropsychiatric disorders or symptoms. It is recommended that this checklist be used in conjunction with the Tyvense® SmPC **(click here to view)**. Importantly:

- Blood pressure and heart rate (pulse) should be recorded on a centile chart at each adjustment of dose and then at least every six months
- Height, weight and appetite should be recorded at least every six months with maintenance of a growth chart
- Development of *de novo* or worsening of pre-existing psychiatric disorders should be monitored at each adjustment of dose and then at least every six months and at every visit

Please download and print this checklist prior to your consultation. It will not be possible for you to store any patient-specific information on the website. The completed checklist can be documented within the patient's records.

As you work through the checklist it may also be useful to discuss the Tyvense® patient information leaflet (PIL) **(click here to view)** with your patient and their parent(s) or guardian(s).

Before initiating lisdexamfetamine dimesylate therapy

Date of assessment:	
Patient name:	
Date of birth:	
Age:	Gender:

Patients with any of the following conditions, comorbidities and/or co-medications should not receive lisdexamfetamine dimesylate:

Contraindications	
Please note that the following conditions are contraindicated if present **(view Tyvense® SmPC section 4.3 – Contraindications)***:*	
	Evaluated
• **Known hypersensitivity** to sympathomimetic amines, lisdexamfetamine dimesylate or any of the excipients	☐
• During **treatment with monoamine oxidase inhibitors**, or within a minimum of 14 days following the administration of these drugs	☐
• **Hyperthyroidism or thyrotoxicosis**	☐
• **Agitated states**	☐
• **Symptomatic cardiovascular disease**	☐
• **Advanced arteriosclerosis**	☐
• **Moderate–severe hypertension**	☐
• **Glaucoma**	☐

Special warnings or precautions for use

Please also consider the following prior to beginning treatment with lisdexamfetamine dimesylate **(view Tyvense® SmPC section 4.4 – Special warnings and precautions for use)**

Family history **(view Tyvense® SmPC section 4.4)**	
	Evaluated
• Family history of sudden cardiac/unexplained death	☐
• Family history of ventricular arrhythmia	☐
• Family history of tics or Tourette's syndrome	☐

Patient's history and physical exam	
Caution is required when lisdexamfetamine dimesylate is prescribed to patients with certain comorbidities	
	Evaluated
Cardiovascular **(view Tyvense® SmPC section 4.4 – Cardiovascular adverse events)**	
• Pre-existing cardiovascular disorders including hypertension, heart failure, recent myocardial infarction, ventricular arrhythmia, structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease and other serious cardiac problems	☐
• Underlying medical condition which might be compromised by increases in blood pressure or heart rate	☐

	Evaluated
Psychiatric/neurological disorders (view Tyvense® SmPC section 4.4 – Special warnings and precautions for use)	
• Pre-existing psychiatric disorders including history of suicidal ideation	☐
• Pre-existing psychotic symptoms	☐
• Aggressive or hostile behaviour	☐
• Bipolar disorder	☐
• Depressive symptoms (screen for risk of bipolar disorder by detailed psychiatric history including family history of suicide, bipolar disorder and depression)	☐
• Motor or verbal tics or Tourette's syndrome	☐
• Presence of seizures. Patients with history of seizures or prior EEG abnormalities in absence of seizures	☐
Pregnancy, breast-feeding and menstruation (view Tyvense® SmPC section 4.6 – Fertility, pregnancy and lactation)	☐
History of substance abuse or dependence (view Tyvense® SmPC section 4.4 – Abuse and dependence) **and potential for abuse, misuse and diversion of lisdexamfetamine dimesylate** (view Tyvense® SmPC section 4.2 – Pre-treatment evaluation)	☐
Renal impairment (view Tyvense® SmPC section 4.2 – Patients with renal or hepatic impairment)	☐

Potential drug–drug interactions	
Caution is required when lisdexamfetamine dimesylate is prescribed to patients with certain concomitant medications	
	Evaluated
Sympathomimetic drugs (view Tyvense® SmPC section 4.4 – Use with other sympathomimetic drugs)	☐
Pharmacokinetic (view Tyvense® SmPC section 4.5 – Interaction with other medicinal products and other forms of interaction)	
• Extended release guanfacine	☐
• Extended release venlafaxine	☐
Agents and conditions that alter urinary pH (view Tyvense® SmPC section 4.5 – Interaction with other medicinal products and other forms of interaction)	
• Ascorbic acid and other agents and conditions that acidify urine	☐
• Sodium bicarbonate and other agents and conditions that alkalinise urine	☐
Monoamine oxidase (view Tyvense® SmPC section 4.5 – Interaction with other medicinal products and other forms of interaction. Monoamine oxidase inhibitors). Amfetamine should not be administered during or within 14 days following the administration of MAOIs because it can increase the release of norepinephrine and other monoamines	☐
Serotonergic drugs (view Tyvense® SmPC section 4.5 – Interaction with other medicinal products and other forms of interaction). Serotonin syndrome has rarely occurred in association with the use of amphetamines such as Tyvense, when given in conjunction with serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs). It has also been reported in association with overdose of amphetamines, including Tyvense (see section 4.9).	☐
Pharmacodynamic (view Tyvense® SmPC section 4.5 – Interaction with other medicinal products and other forms of interaction)	
• Antihypertensives (including guanethidine or other antihypertensives)	☐
• Narcotic analgesics	☐
• Chlorpromazine	☐
• Haloperidol	☐
• Lithium carbonate	☐

Patient information leaflet	
	Evaluated
Consider using the PIL as a guide to assist you in explaining the treatment of ADHD with lisdexamfetamine dimesylate to your patient and their parent(s) or guardian(s)	☐

Record any additional information here

Following the evaluation above, please complete the chart provided to record a baseline measure for ongoing monitoring **(click here to view)**.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions

Please report any suspected adverse event(s) to Takeda at AE.GBR-IRL@takeda.com and HPRA Pharmacovigilance at www.hpra.ie

This checklist is intended for use by healthcare professionals in Ireland only, in conjunction with the Tyvense® SmPC.
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