Checklist 2: Checklist for the ongoing monitoring of lisdexamfetamine dimesylate therapy

This checklist is designed to support you in the ongoing monitoring of lisdexamfetamine dimesylate therapy in patients with attention-deficit/hyperactivity disorder (ADHD).

As detailed in the summary of product characteristics (SmPC) and in the product prescribing information, growth, psychiatric and cardiovascular status should be monitored regularly in patients receiving lisdexamfetamine dimesylate. 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
- Patients should also be monitored for the risk of diversion, misuse and abuse of lisdexamfetamine dimesylate

Physicians who elect to prescribe lisdexamfetamine dimesylate for extended periods (over 12 months) should re-evaluate the effectiveness of lisdexamfetamine dimesylate at least once a year, with trial periods without medication, in order to assess the patient's functioning without medication. Please see the **Tyvense® SmPC** for more details.

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

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

Ongoing monitoring of lisdexamfetamine dimesylate therapy

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

Carefully review the following systems as indicated below at each dose adjustment and at each follow-up visit (at least every six months):

	Evaluated
General medical findings	
• Document changes in height, body weight and appetite on separate **ongoing monitoring chart (view Tyvense® SmPC section 4.4 – Long-term suppression of growth [height and weight])**	☐
• Patient growth or weight gain are below expectations ◦ Consider interruption of lisdexamfetamine dimesylate treatment	☐
• Document any indication of diversion, misuse or abuse of lisdexamfetamine dimesylate **(view Tyvense® SmPC section 4.4 – Abuse and dependence)**	☐
• Document any indication of dependence or tolerance to lisdexamfetamine dimesylate **(view Tyvense® SmPC section 4.4 – Abuse and dependence)**	☐
• Document any indication of serious skin reactions **(view Tyvense® SmPC section 4.8 - Undesirable effects)**	☐
• Female patients **(view Tyvense® SmPC section 4.6 – Fertility, pregnancy and lactation)** ◦ The physician should discuss lisdexamfetamine dimesylate treatment with female patients who have started menstruation	☐
• Pregnancy **(view Tyvense® SmPC section 4.6 – Pregnancy)** ◦ Evaluate benefit/risk **(view Tyvense® SmPC section 4.6 – Pregnancy)**	☐
• Renal impairment **(view Tyvense® SmPC section 4.2 – Patients with renal or hepatic impairment)** ◦ Dosage reduction may be required in renally impaired patients	☐
New cardiovascular findings or worsening thereof (view Tyvense® SmPC section 4.4 – Cardiovascular adverse events)	
• Exertional chest pain ◦ Refer for prompt specialist cardiac evaluation if any of the above symptoms are present	☐
• Unexplained syncope ◦ Refer for prompt specialist cardiac evaluation if any of the above symptoms are present	☐
• Other symptoms suggestive of cardiac disease ◦ Refer for prompt specialist cardiac evaluation if any of the above symptoms are present	☐
• Document blood pressure and heart rate (pulse) on separate **chart for ongoing monitoring**	☐
• Changes in blood pressure and heart rate (pulse)	☐

New neurological and psychiatric findings or worsening thereof (view Tyvense® SmPC section 4.4 – Special warnings and precautions for use)	
• Development of new psychotic or manic symptoms (for example hallucinations, delusional thinking or mania)	☐
• Worsening of symptoms of behavioural disturbance and thought disorder in patients with pre-existing psychotic disorders	☐
• Aggressive behaviour or hostility	☐
• New onset or worsening of seizures	☐
• Blurring of vision or difficulties with accommodation	☐
Treatment duration	
• Lisdexamfetamine dimesylate used for over 12 months ◦ Consider trial period without medication	☐
Lisdexamfetamine dimesylate treatment must be stopped if symptoms do not improve after appropriate dosage adjustment over a 1-month period. If paradoxical aggravation of symptoms or other intolerable adverse events occur, the dosage should be reduced or lisdexamfetamine dimesylate discontinued.	☐

Lisdexamfetamine dimesylate continued: ☐

Record any additional information here

Following the evaluation above, please complete the **chart for ongoing monitoring**.

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