Checklist 1: Methylphenidate (MPH) checklist before prescribing

The following is designed to support you in the appropriate prescription of an MPH-containing product in a child aged 6 years and above or an adolescent, with attention-deficit/hyperactivity disorder (ADHD).

As outlined in the prescribing information in more detail, specific concurrent conditions may exclude the use of MPH or may warrant particular attention, including cardiovascular, cerebrovascular and neuropsychiatric disorders or symptoms. Importantly:

- Blood pressure and pulse should be recorded at each adjustment of dose and then at least every 6 months
- Height, weight and appetite should be recorded at least 6 monthly with maintenance of a growth chart
- Development of de novo or worsening of pre-existing psychiatric disorders should be monitored at every adjustment of dose and then at least every 6 months and at every visit

It is recommended that this checklist be used in conjunction with the full prescribing information for the individual product that is being prescribed.

Before initiating MPH therapy

Date of Assessment: _____

Reason for Assessment: _____

Patient Name: _____

Date of Birth: _____

Age: _____ Gender: _____

Patients with any of the following conditions, comorbidities and/or co-medications should not receive MPH-containing products:

Contraindications	
Please note that the following conditions are contraindicated if present:	
	Evaluated
• Known sensitivity to MPH or any of the excipients	☐
• Glaucoma	☐
• Phaeochromocytoma	☐
• During treatment with non-selective, irreversible monoamine oxidase inhibitors, or within a minimum of 14 days of discontinuing those drugs, due to risk of hypertensive crisis	☐
• Hyperthyroidism or thyrotoxicosis	☐
• Psychiatric comorbidities Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder, diagnosis or history of severe and episodic (type I) bipolar (affective) disorder (that is not well controlled)	☐
• Cardiovascular comorbidities Pre-existing cardiovascular disorders including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels)	☐
• Cerebrovascular comorbidities Pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke	☐

Special warnings and precautions for use

Before progressing with MPH treatment, please also consider the following prior to treatment with MPH:
Following the evaluation above, please complete the chart provided to record a baseline measure for ongoing monitoring:

Family history	
	Evaluated
• Family history of sudden cardiac or unexplained death	☐
• Family history of malignant arrhythmia	☐
• Family history of Tourette's syndrome	☐

Patient's history and physical exam	
Caution is required when MPH is prescribed to patients with certain comorbidities or concomitant medications	
	Evaluated
Cardiovascular	
• History of cardiovascular disease	☐
• Known cardiac structural abnormalities, cardiomyopathy, serious heart rhythm abnormalities or increased vulnerability to sympathomimetic effects of stimulant medication	☐
• Cardiovascular disease	☐
• Underlying medical condition which might be compromised by increases in blood pressure or heart rate	☐
Psychiatric/neurological disorders	
• Pre-existing psychiatric disorders	☐
• Pre-existing psychotic or manic symptoms	☐
• Aggressive or hostile behaviour	☐
• Motor or verbal tics or Tourette's syndrome	☐
• Anxiety, agitation or tension	☐
• Depressive symptoms (screen for risk for bipolar disorder by detailed psychiatric history including family history of suicide, bipolar disorder and depression)	☐
• Bipolar disorder	☐
• Presence of epilepsy. Epileptic patients with history of seizures, prior EEG abnormalities in absence of seizures	☐
• History of drug or alcohol dependency or misuse of CNS stimulants	☐
Other medical conditions such as:	
• Known intolerance to excipients	☐
• Known renal or hepatic insufficiency	☐
• Presence of leukopenia, thrombocytopenia, anaemia or other alterations, including those indicative of serious renal or hepatic disorders	☐
Pregnancy Evaluate benefit/risk: Methylphenidate is not recommended for use during pregnancy unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy	☐
Breast feeding Evaluate benefit/risk: A decision must be made whether to discontinue breast-feeding or to abstain from methylphenidate therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman	☐
Potential drug–drug interactions	
Pharmacokinetic	
• Coumarin anticoagulants	☐
• Anticonvulsants (eg phenobarbitol, phenytoin, primodone)	☐
• Antidepressants (tricyclics and selective serotonin reuptake inhibitors)	☐
Pharmacodynamic	
• Anti-hypertensive drugs	☐
• Drugs that elevate blood pressure	☐
• Alcohol	☐
• Halogenated anaesthetics	☐
• Centrally-acting alpha-2 agonists (eg clonidine)	☐
• Dopamine antagonists, including antipsychotics	☐
• L-dopa or other dopamine agonists	☐
Patient Information Leaflet	
• Consider using the PIL as a guide to assist you in explaining the treatment of ADHD with MPH to your patient(s) and/or their guardian(s)	☐
As you work through the checklist, it may also be useful for you to discuss the patient information leaflet (PIL) of the individual product that is being prescribed with 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:
(View chart)

You can report any problem or adverse events through:

Novartis Consulting AG.
Saudi Arabia: P.O. Box 16032, Riyadh 11464,
Phone: +996112658100
Fax: +966112658107
Email: adverse.events@novartis.com

Saudi Food and Drug Authority, National Pharmacovigilance and Drug Safety Center
Toll free phone: 8002490000
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa