Prescribers checklist for initiating treatment of paediatric patients with:

Ritalin 10 or Artige or Ritalin LA

This checklist is designed to support you in the appropriate prescription of Ritalin 10 or Artige or Ritalin LA to a child aged 6 years and above or an adolescent, with attention-deficit/hyperactivity disorder (ADHD).

As outlined in the Product Information in more detail, specific concurrent conditions may exclude the use of methylphenidate (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.
- Children or adolescents who are being considered for treatment with stimulant medicine should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease.

DEPENDENCE: Ritalin and Artige should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow up.

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

Please use this checklist prior to your consultation. The completed checklist can be documented within the patient records.

As you work through the checklist, it may also be useful for you to discuss the Consumer Medicine Information (CMI) of the individual product that is being prescribed with your patient and their parent(s) or guardian(s).

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Before initiating methylphenidate (MPH) therapy

Reason for assessment: _____

_____

Patient name: _____

Date of assessment: _____ **Date of birth:** _____ **Age:** _____ **Gender:** _____

Contraindications

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

Please note MPH is contraindicated if the following conditions are present:	**Evaluated**
Anxiety and tension states	
Agitation	
A family history or a diagnosis of Tourette's syndrome	
Known hypersensitivity to MPH or to any component of the formulation	
Glaucoma	
Phaeochromocytoma	
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	
Severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms	
Pre-existing cardiovascular disorders including uncontrolled hypertension, heart failure, arterial occlusive disease especially coronary arteries, angina pectoris, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, cardiac arrhythmia and channelopathies (disorders caused by the dysfunction of ion channels)	
Known drug dependence or alcohol abuse	

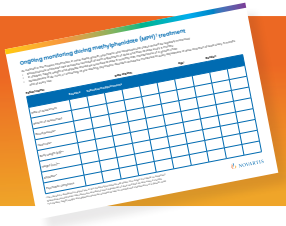
Special warnings and precautions for use

Before progressing with MPH treatment, please also consider the following:

Family history	**Evaluated**
Family history of sudden cardiac or unexplained death	
Family history of malignant arrhythmia	
Family history of psychiatric disorders	
Patient's history and physical exam *Caution is required when MPH is prescribed to patients with certain comorbidities or concomitant medications*	**Evaluated**
Cardiovascular	
Pre-existing hypertension	
History of cardiovascular disease	
Known cardiac structural abnormalities, cardiomyopathy, serious heart rhythm abnormalities or increased vulnerability to sympathomimetic effects of stimulant medication	
Cardiovascular disease	
Patients with pre-existing central nervous system (CNS) abnormalities, e.g., cerebral aneurysm and/or other vascular abnormalities such as vasculitis or pre-existing stroke should not be treated with MPH	
Underlying medical condition which might be compromised by increases in blood pressure or heart rate	
Misuse of stimulants of the central nervous system, including MPH may be associated with sudden death and other serious cardiovascular adverse events	

Psychiatric/neurological disorders	
Pre-existing psychiatric disorders	
Pre-existing psychotic or manic symptoms	
Aggressive or hostile behaviour	
Motor or verbal tics	
Bipolar disorder (screen for risk for bipolar disorder by detailed psychiatric history including family history of suicide, bipolar disorder and depression)	
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	
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	**Evaluated**
Pharmacokinetic	
Coumarin anticoagulants	
Anticonvulsants (eg. phenobarbital [phenobarbitone], phenytoin, primidone)	
Antidepressants (tricyclics and selective serotonin reuptake inhibitors)	
Pharmacodynamic	
Anti-hypertensive drugs	
Drugs that elevate blood pressure	
Alcohol	
Anaesthetics	
Centrally-acting alpha-2 agonists (eg. clonidine)	
Dopamine antagonists, including antipsychotics	
L-dopa or other dopamine agonists	
Serotonergic drugs such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs)	

Record any additional information here:



Following the evaluation above, please complete the separate chart for *'Ongoing monitoring during methylphenidate (MPH) treatment'* provided to record and track changes from baseline and during treatment.

Ritalin® 10 & Ritalin® LA: PBS and Product Information

PBS Information: Ritalin 10®. Authority required.
Use in attention deficit hyperactivity disorder, in accordance with State/Territory law.
Ritalin LA®. Authority required. Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours.

DRUG DEPENDENCE:

Ritalin should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow up.

PRIT0625

For healthcare professionals only. Please review full Product Information before prescribing. Scan QR code for full Ritalin® and Ritalin® LA Product Information

Alternately, please contact Medical Information at 1 800 671 203 or visit: https://www.novartis.com.au/products/healthcare-professionals/products to access the full Product Information

Artige®: PBS and Product Information

PBS Information: Artige®. Authority required.
Use in attention deficit hyperactivity disorder, in accordance with State/Territory law.

DRUG DEPENDENCE:

Artige should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow up.

PART0625

For healthcare professionals only. Please review full Product Information before prescribing. Scan QR code for full Artige Product Information

Alternately, please contact Medical Information at 1 800 671 203 or visit: https://www.novartis.com.au/products/healthcare-professionals/products to access the full Product Information

For the most up-to-date Product Information go to https://www.novartis.com.au/products/healthcare-professionals/products

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