Prescribers checklist for monitoring ongoing therapy in adult patients with:

Ritalin 10 or Artige or Ritalin LA

This checklist is designed to support you in the monitoring of ongoing therapy with Ritalin 10 or Artige or Ritalin LA in a patient aged 18 years or older, 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.
- 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.

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 family/carer(s).

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Monitoring ongoing treatment with methylphenidate (MPH)

Reason for assessment: _____

_____

Patient name: _____

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

Carefully review the following systems as indicated below <u>at each adjustment of dose and at follow-up visits at least every 6 months</u>:

General medical findings	**Evaluated**
Blood pressure and pulse (see separate follow-up chart)	
Physical examination (record any changes in physical observations)	
Document any indication of abuse, misuse or diversion of MPH	
Pregnancy	
Note any other relevant general medical findings	
Evaluate benefit/risk	
New cardiovascular findings *Blood pressure and pulse should be recorded*	**Evaluated**
Palpitations	
Exertional chest pain	
Unexplained syncope	
Dyspnoea	
Other symptoms suggestive of cardiac disease	
Refer for prompt specialist cardiac evaluation	
New neurological findings	**Evaluated**
Severe headache, numbness, weakness or paralysis, impairment of coordination, vision, speech, language or memory	
Seizure frequency increase or new-onset seizures	
MPH should be discontinued	
New psychiatric findings or worsening thereof *Development of de novo or worsening of pre-existing psychiatric disorders should be monitored*	**Evaluated**
Psychotic or manic symptoms	
Consider discontinuation of MPH	
Suicidal ideation or behaviour	
Consider treatment of underlying psychiatric condition *Re-evaluate benefit/risk* *Consider discontinuation of MPH*	
Aggressive and hostile behaviour	
Consider the need for adjustment of treatment	
Anxiety, agitation or tension	
Depressive symptoms	
Motor or verbal tics or worsening thereof	

New vascular findings	Evaluated
Peripheral vasculopathy, including Raynaud's phenomenon	
Consider the need for adjustment of treatment	
Priapism, abnormally sustained or frequent and painful erections	
Seek immediate medical attention	

Treatment duration	Evaluated
Patient is being treated continuously for >12 months	
Data on safety and efficacy of long-term use of MPH are not complete. Patients requiring long-term therapy should be carefully monitored and periodic complete blood counts, differential and platelet counts are advisable during prolonged therapy. In the event of haematological disorders appropriate medical intervention should be considered	
Improvement in symptoms after appropriate dosage adjustment over a 1-month period is observed, otherwise drug discontinuation is recommended	
Consider trial period off medication at least once yearly to determine if continued treatment is still necessary	

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.

End of treatment
Careful supervision is required during drug withdrawal, since this may unmask • **Depression** as well as • **Chronic over activity** Some patients may require long-term follow-up.

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.

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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.

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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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AU-28542. Date of preparation: May 2025.