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Ritalin ®
Image

RITALIN® 10/RITALIN® LA PI
RITALIN® 10 CMI
RITALIN® LA CMI

Explore our Ritalin® LA and 10 information to discover how you can help your ADHD patients

- HCP Resources
- Patient Resources

Methylphenidate or dexamfetamine or lisdexamfetamine should be offered as the first-line pharmacological treatment for people with ADHD, where ADHD symptoms are causing significant impairment.[1]

Medication choice – children and adolescents (aged 5 to 17 years) adults (aged 18 years and above).

Reference: 1. Australasian ADHD Professionals Association. 2022

Efficacy

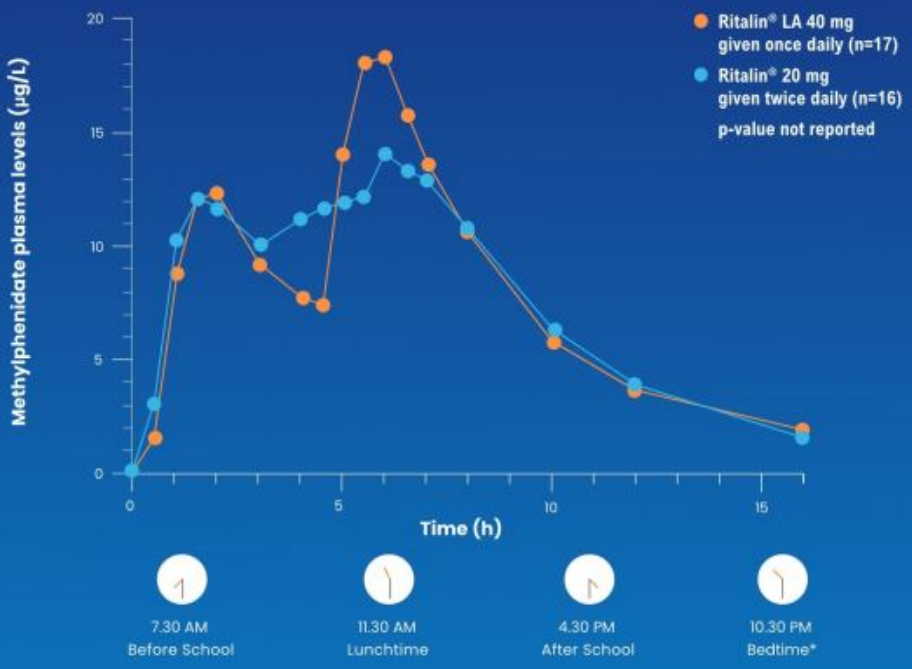
Help your ADHD patients start the day well

The early peak of Ritalin® LA Covers the start of the school or work day and second peak prepares for the rest of the day.[4-7]

This study was conducted in adults aged 21-34 years.

Image

Figure 1: Methylphenidate mean plasma levels after Ritalin LA 40 mg OD and Ritalin IR 20 mg BD in adults [1,3]



* Approaching pre-dose levels.

Time and activities displayed with clocks are for illustrative purposes only.

Adapted from Ritalin LA US PI20

BD: Twice-daily | IR: Immediate-release | LA: Long-acting | PI: Prescribing Information

Methylphenidate in the classroom – the formulation matters

Comparative efficacy of Ritalin® LA (20 mg and 40 mg) and Concerta® (18 mg and 36 mg) in children with ADHD in a five-way, randomised, placebo-controlled, single-blind, crossover study conducted in a classroom setting.[2]

Methods

Children 6–12 years of age diagnosed with ADHD and stabilized on MPH (20–40 mg/day) participated in a five-way, randomised, placebo-controlled, single-blind, crossover study conducted in a laboratory classroom setting. Children alternately received single doses of extended-release MPH (Ritalin® LA) 20 and 40 mg, modified-release MPH (Concerta®)18 and 36 mg, and placebo over 6 consecutive weeks. Efficacy was assessed using SKAMP rating subscales and written math tests. Data were examined using between-treatment comparisons of area under the curve (AUC) for change from pre dose values during hours 0–4, 0–8, 8–12, and 0–12.

Results

- Fifty-three children completed the study
- For all efficacy measures, improvements from pre dose were significantly greater with Ritalin® LA40 mg than with Concerta® 36 mg in terms of AUC_{0-4} ($p \leq 0.005$), AUC_{0-8} ($p \leq 0.006$), and AUC_{0-12} ($p \leq 0.035$)
- For most measures, Ritalin LA® 20 mg was equivalent to both doses (18 mg and 36 mg) of Concerta® in $AUC_{0-4,}$ $AUC_{0-8,}$ andAUC_{0-12}
- No serious adverse events were reported

Conclusions

- The efficacy of Ritalin LA20 mg is similar to that of Concerta® 18 and 36 mg during the first 8 hours post dose.
- Statistically greater benefits are observed with Ritalin® LA 40 mg than with Concerta® 36 mg and persist through hour 8 ($p<0.001$).

- Active treatments show comparable efficacy from 8 to 12 hours post dose.
- Both doses of each MPH formulation are well tolerated.

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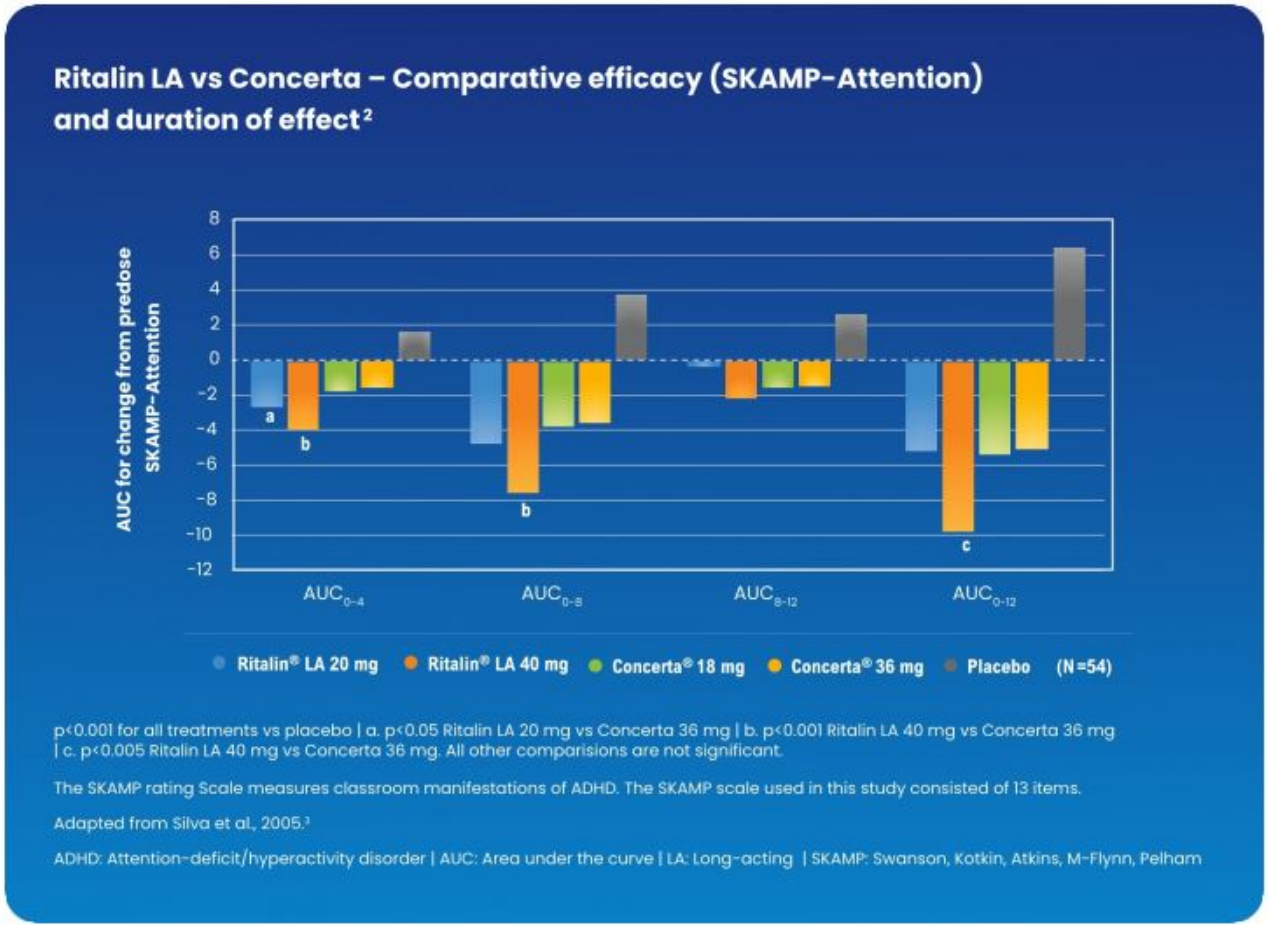


References:

1. Maldonado R. Comparison of the pharmacokinetics and clinical efficacy of new extended-release formulations of methylphenidate. Expert Opin Drug Metab Toxicol 2013;9(8):1001-14.

2. Silva R, Muniz R et al. Efficacy of two long-acting methylphenidate formulations in children with attention- deficit/hyperactivity disorder in a laboratory classroom setting. J Child Adolesc Psychopharmacol 2005;15(4):637-54.

3. Ritalin Canadian Prescribing Information. Novartis Pharmaceuticals.

4. Markowitz et al. Pharmacokinetics of Methylphenidate After Oral Administration of Two Modified-Release Formulations in Healthy Adults Clin Pharmacokinet 2003;42(4):393-401.

5. Lopez F et al. Pediatric Drugs 2003;5(8):545-555

6. Rafael Maldonado (2013) Comparison of the pharmacokinetics and clinical efficacy of new extended-release formulations of methylphenidate, Expert Opinion on Drug Metabolism & Toxicology, 9:8, 1001-1014, DOI: 10.1517/17425255.2013.7860412.

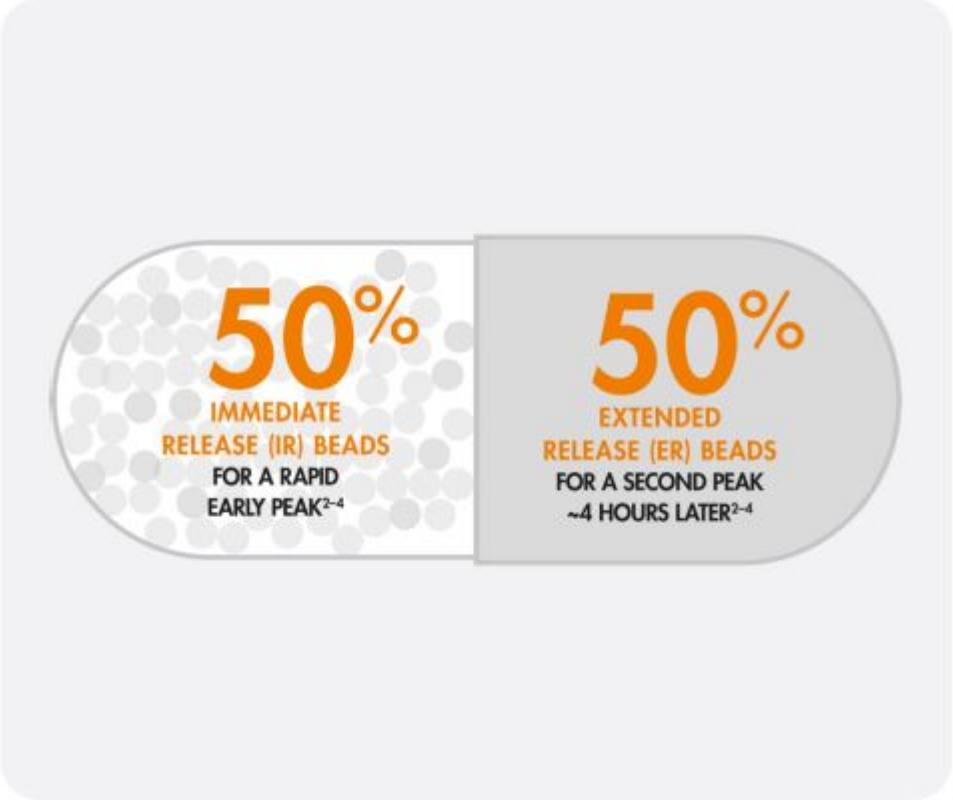
7. Data on File 2020.

MOA

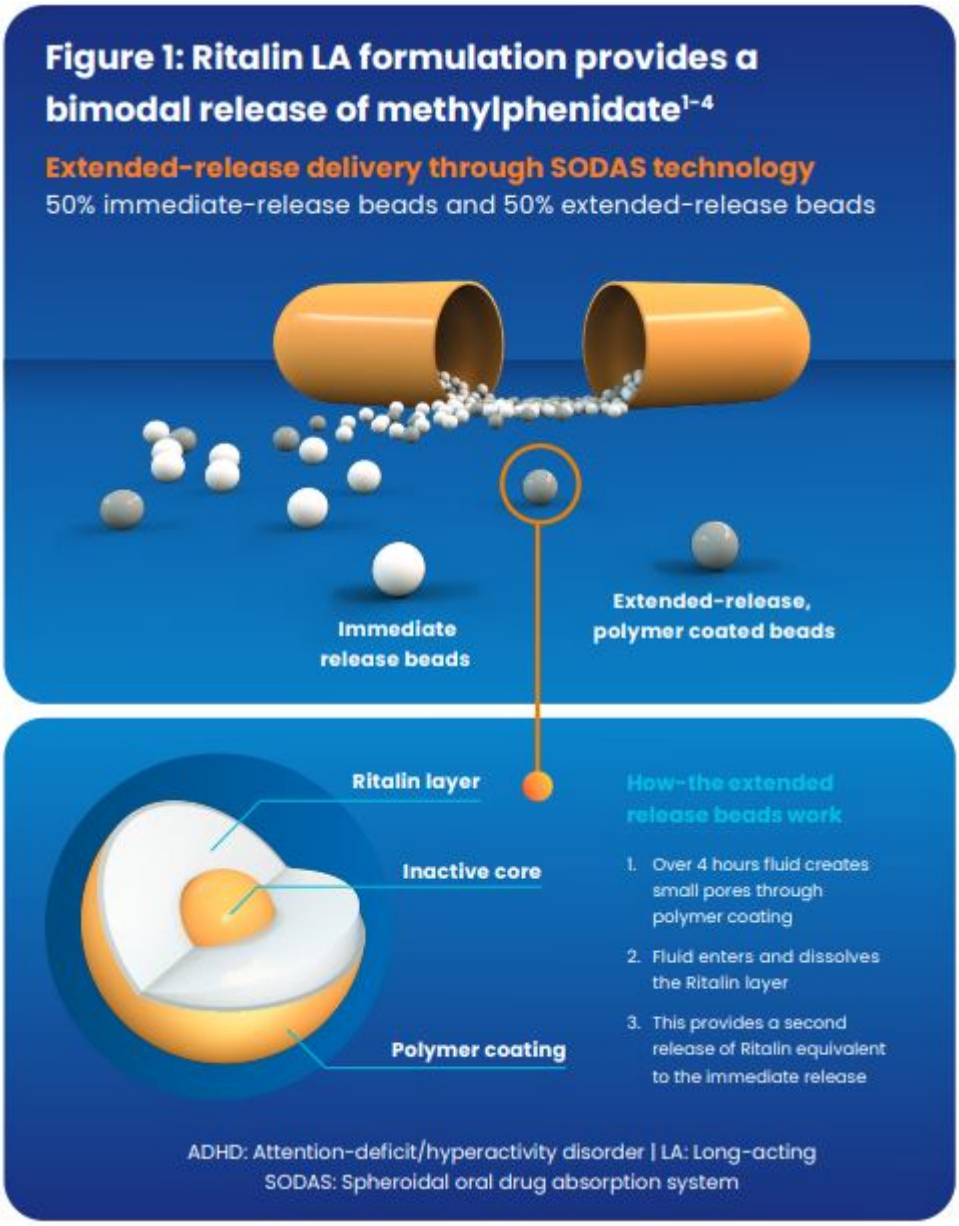
Ritalin® LA gets your ADHD patients quickly up to peak methylphenidate (MPH) levels[1-4]

SODAS® technology is based on the production of uniform beads with (1) core granules or crystals, (2) a layer with the active ingredient, (3) and subsequent coatings containing controlled release polymers and other excipients. Within the gastrointestinal tract, polymers are gradually dissolved, creating pores in the outer coating of the bead and allowing fluid to solubilise the layer of Ritalin® LA. This process provides a second release of Ritalin® LA equivalent to that achieved with the IRbeads.[2-3]

Image


50%
IMMEDIATE
RELEASE (IR) BEADS
FOR A RAPID
EARLY PEAK[2–4]
50%
EXTENDED
RELEASE (ER) BEADS
FOR A SECOND PEAK
~4 HOURS LATER[2–4]

Image



References:

1. Lopez F et al. Pediatric Drugs 2003;5(8):545-555

2. https://pharmaceuticalresearch.wordpress.com/2012/07/05/sodas-spheroidal-oral-drug-absorption-system/

3. Silva et al. J Child Adolesc Psychopharmacol 2005;15:637-54

4. John S. Markowitz et al Clin Pharmacokinet 2003; 42 (4): 393-401

Dosage and Administration

Dose and method of administration: Children and adolescents (6 years and over)

Ritalin® 10 mg Immediate Release Tablets

Start with 5 mg once or twice daily (e.g. at breakfast and at lunch) with gradual increments of 5 or 10 mg weekly. The total daily dosage should be administered in divided doses. In some children with ADHD, sleeplessness may occur as the effect of the drug wears off. On rare occasions, an additional dose at about 8.00 p.m. may help; a trial dose may help to clarify the issue in an individual case, if the symptom warrants treatment.[2]

Ritalin® tablet

- The tablet is dividable
- The tablet can, if required, be used to prolong the effect of the treatment with one capsule a day.

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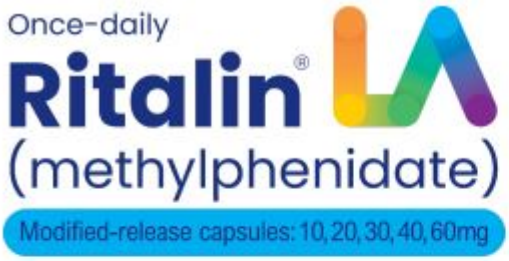

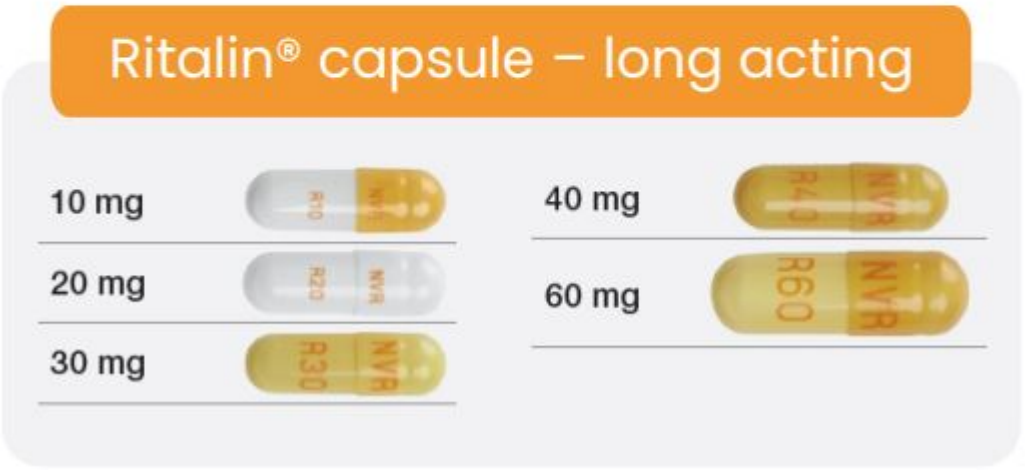

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Titration

Ritalin® capsule for adults with ADHD

Dosing is individual

Recommended start dose is 20 mg, with possibility for dose titration per week until wanted effect has been reached.

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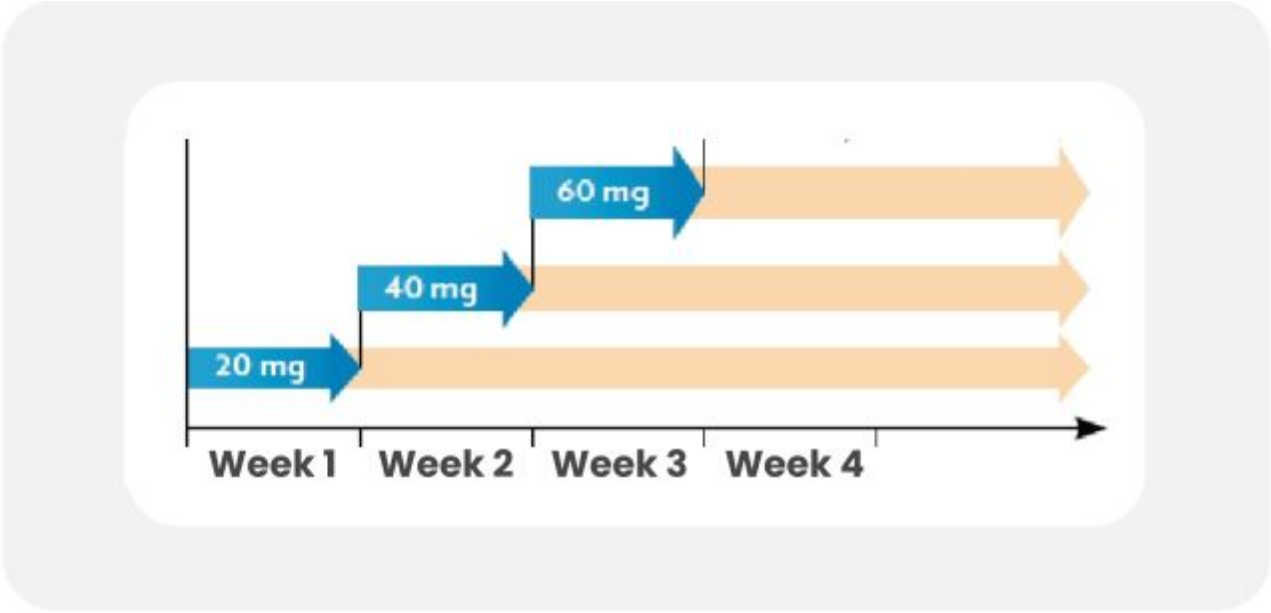

Ritalin® LA capsule contents can be sprinkled on food for easy administration[1]

Sometimes, the simple act of swallowing a capsule or tablet can be a challenge for both children and their carers.

Ritalin® LA capsules may be carefully opened and the beads sprinkled over a small amount of cold soft food.

The mixture of Ritalin® LA and food should be consumed immediately in its entirety[1]

The soft food (e.g. apple sauce, jam, spread, yoghurt) should not be warm, as it may affect the prolonged-release properties of the formulation. The drug and food mixture should not be stored for future use. Ritalin® LA capsules and or their contents should not be crushed, chewed, or divided.[1]

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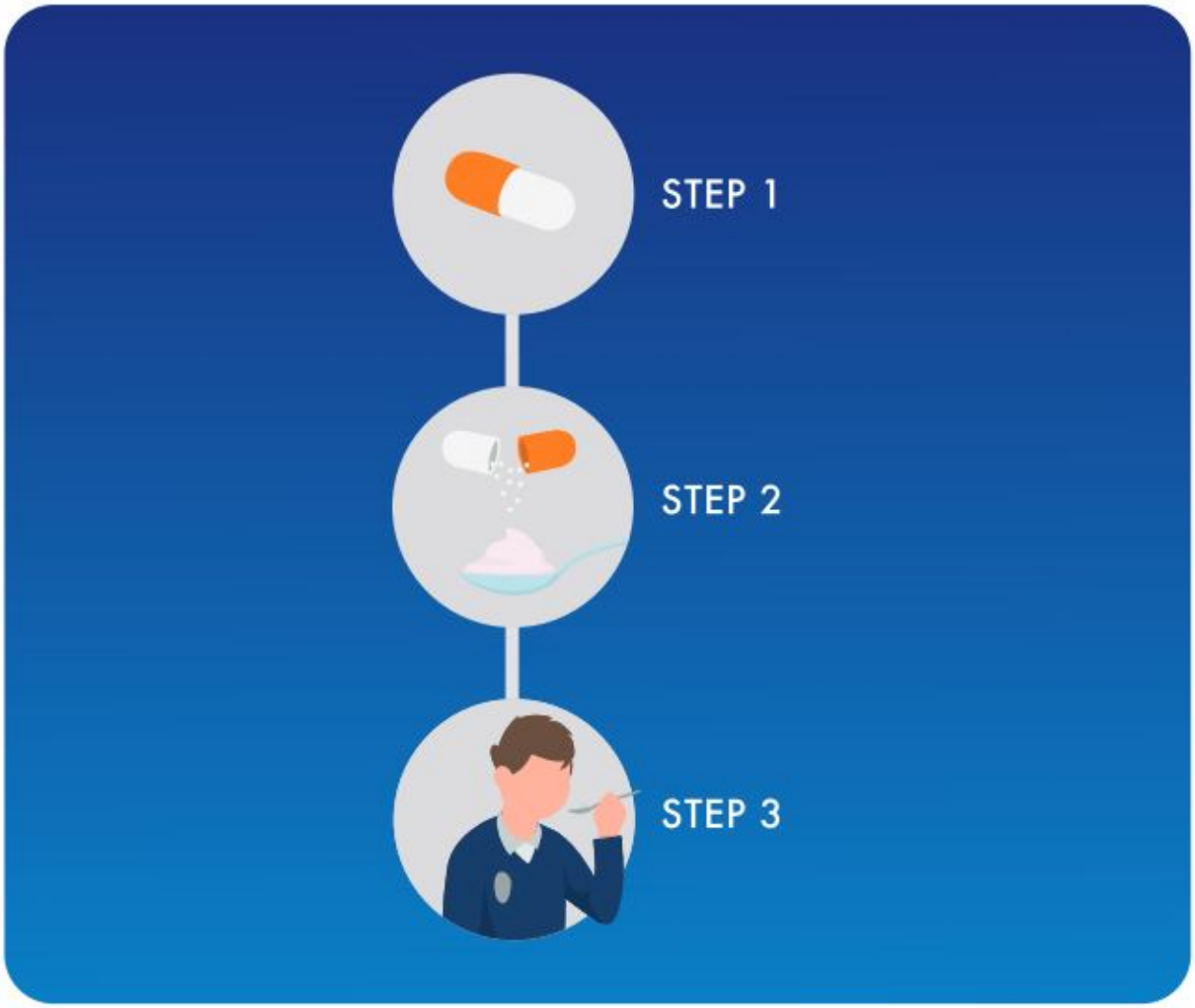

References:

1. Ritalin Australian Product Information 2020

2. Ritalin 10 PBS Information 2020

Safety

Special Warnings and Precautions for Use

General Treatment with methylphenidate is not indicated in all cases of ADHD and should be considered only after detailed history taking and evaluation of the patient. The decision to prescribe methylphenidate should depend on the physician’s assessment of the chronicity and severity of the symptoms and in paediatric patients, the appropriateness to the child’s age. Prescription should not depend solely on the presence of isolated behavioural characteristics. When the symptoms are associated with acute stress reactions, treatment with methylphenidate is usually not indicated.[1]

Image

Adverse events with an incidence ≥ 2% in all patients with Ritalin® LA in children a placebo-controlled randomised study[1]

Adverse event	Ritalin LA N = 161 (%)
Total	103 (64.0)
Headache	26 (16.1)
Insomnia	17 (10.6)
Upper abdominal pain	12 (7.5)
Anorexia	11 (6.8)
Appetite, decreased	11 (6.8)
Nasopharyngitis	11 (6.8)
Irritability	8 (5.0)
Lethargy	8 (5.0)

Adverse event	Ritalin LA N = 161 (%)
URTI	7 (4.3)
Vomiting	6 (3.7)
Cough	5 (3.1)
Dermatitis	5 (3.1)
Ear infection	5 (3.1)
Nausea	5 (3.1)
Joint sprain	4 (2.5)
Pyrexia	4 (2.5)

Source Australian PI. Adverse events, regardless of study drug relationship, reported in 2% or more subjects
A patient with multiple occurrences of an adverse event under one treatment is counted only once in the category.

Image

Adverse events with an incidence ≥ 2% in all patients with Ritalin® LA in children a placebo-controlled randomised study[1]

Preferred term	All Ritalin® LA N=314 n (%)	Placebo N=318 n (%)
Number of patients with any adverse event	132 (42.0)	112 (35.2)
Headache	37 (11.8)	32 (10.1)
Decreased appetite	30 (9.6)	5 (1.6)
Abdominal pain upper	15 (4.8)	9 (2.8)
Nasopharyngitis	13 (4.1)	15 (4.7)
Nausea	12 (3.8)	4 (1.3)
Vomiting	10 (3.2)	4 (1.3)
Insomnia	8 (2.5)	4 (1.3)
Upper respiratory tract infection	8 (2.5)	8 (2.5)
Dysmenorrhoea	7 (2.2)	0
Cough	4 (1.3)	3 (0.9)
Abdominal pain	3 (1.0)	3 (0.9)

Adapted from Ritalin® XL UKPAR.2 * Safety population of controlled multiple-dose paediatric Ritalin® XL studies (D0007, DUS02, DDE01). A patient with multiple occurrences of an adverse event under one treatment is counted only once in the category.[2]
Ritalin XL (Novartis) is registered brand name for Ritalin LA (Novartis) in UK.

References:

1. Ritalin Australian Product Information 2020

2. Ritalin® XL Public Assessment Report UKPAR Medicines &Healthcare products Regulatory Agency UK March 2018

Checklists

Image

Prescriber Checklist: Initiating Paediatric Treatment

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).

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Prescribers checklist for monitoring ongoing therapy in paediatric 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 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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Prescriber Checklist: Monitoring Ongoing Paediatric Treatment

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

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Prescribers checklist for initiating treatment of adult 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 in a patient aged 18 years or older, with attention-deficit/hyperactivity disorder (ADHD).

The use of appropriate and comprehensive assessments and diagnosis are important to minimise inappropriate use of methylphenidate.

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
- Appropriate assessment and treatment of comorbidities such as depression and anxiety should occur prior to the initiation of treatment and then monitored at every dose adjustment and then at least at every 6 months and every visit.
- Appropriate assessment and management of co-existing substance abuse disorders should occur prior to initiation of treatment and then monitored closely during treatment (at least at every dose adjustment, and then at least every 6 months and every visit).
- 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.
- Adults 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.

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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Prescriber Checklist: Initiating Adult Treatment

This checklist is designed to support you in the appropriate prescription of Ritalin 10 or Artige or Ritalin LA in a patient aged 18 years or older, with attention-deficit/hyperactivity disorder (ADHD).

PDF
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Prescriber Checklist: Monitoring Ongoing Adult Treatment

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).

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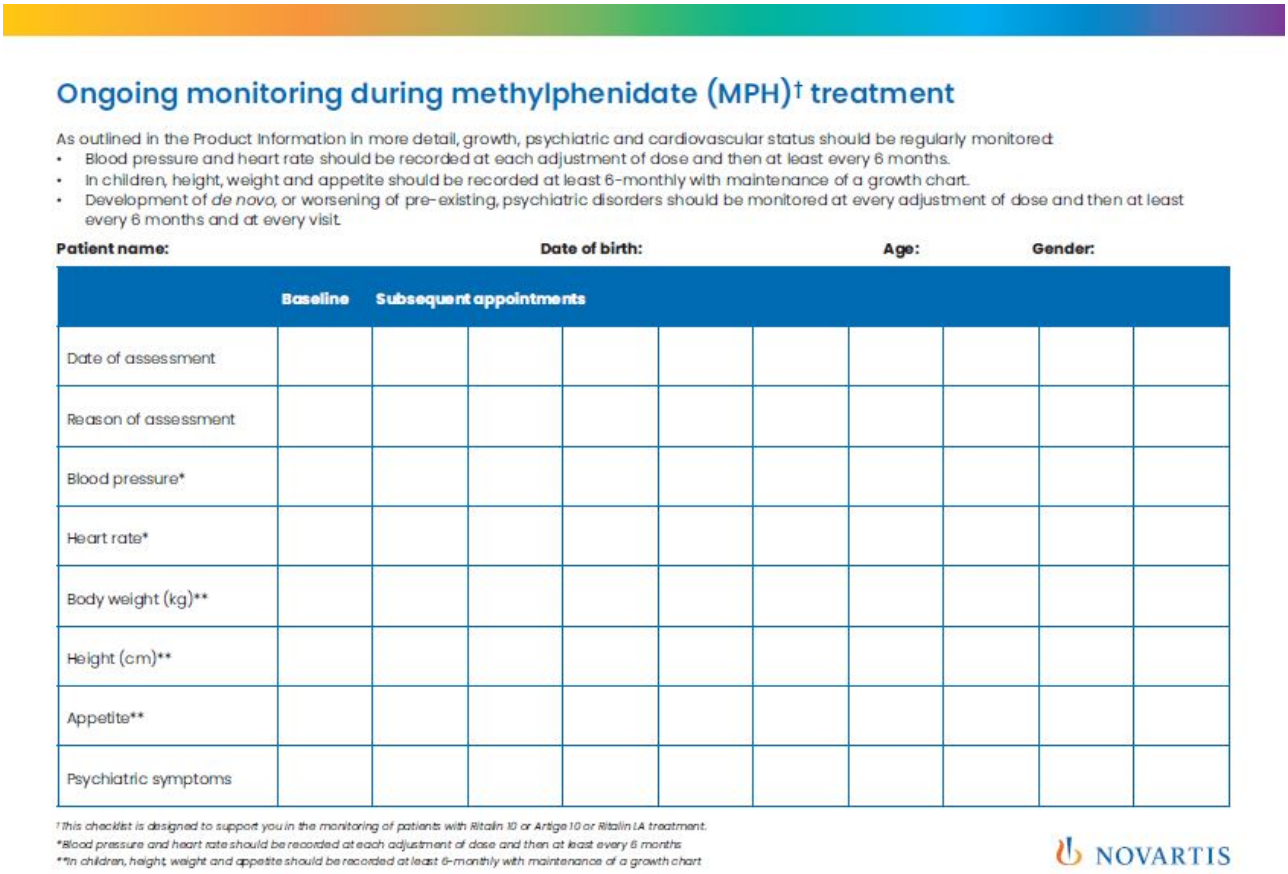

Ongoing monitoring during methylphenidate (MPH)† treatment

As outlined in the Product Information in more detail, growth, psychiatric and cardiovascular status should be regularly monitored:

- Blood pressure and heart rate should be recorded at each adjustment of dose and then at least every 6 months.
- In children, 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.

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

	Baseline	Subsequent appointments								
Date of assessment										
Reason of assessment										
Blood pressure*										
Heart rate*										
Body weight (kg)**										
Height (cm)**										
Appetite**										
Psychiatric symptoms										

† This checklist is designed to support you in the monitoring of patients with Ritalin 10 or Antige 10 or Ritalin LA treatment.
*Blood pressure and heart rate should be recorded at each adjustment of dose and then at least every 6 months.
**In children, height, weight and appetite should be recorded at least 6-monthly with maintenance of a growth chart.

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Monitoring chart during methylphenidate (MPH)† treatment

Ongoing monitoring during methylphenidate (MPH)† treatment

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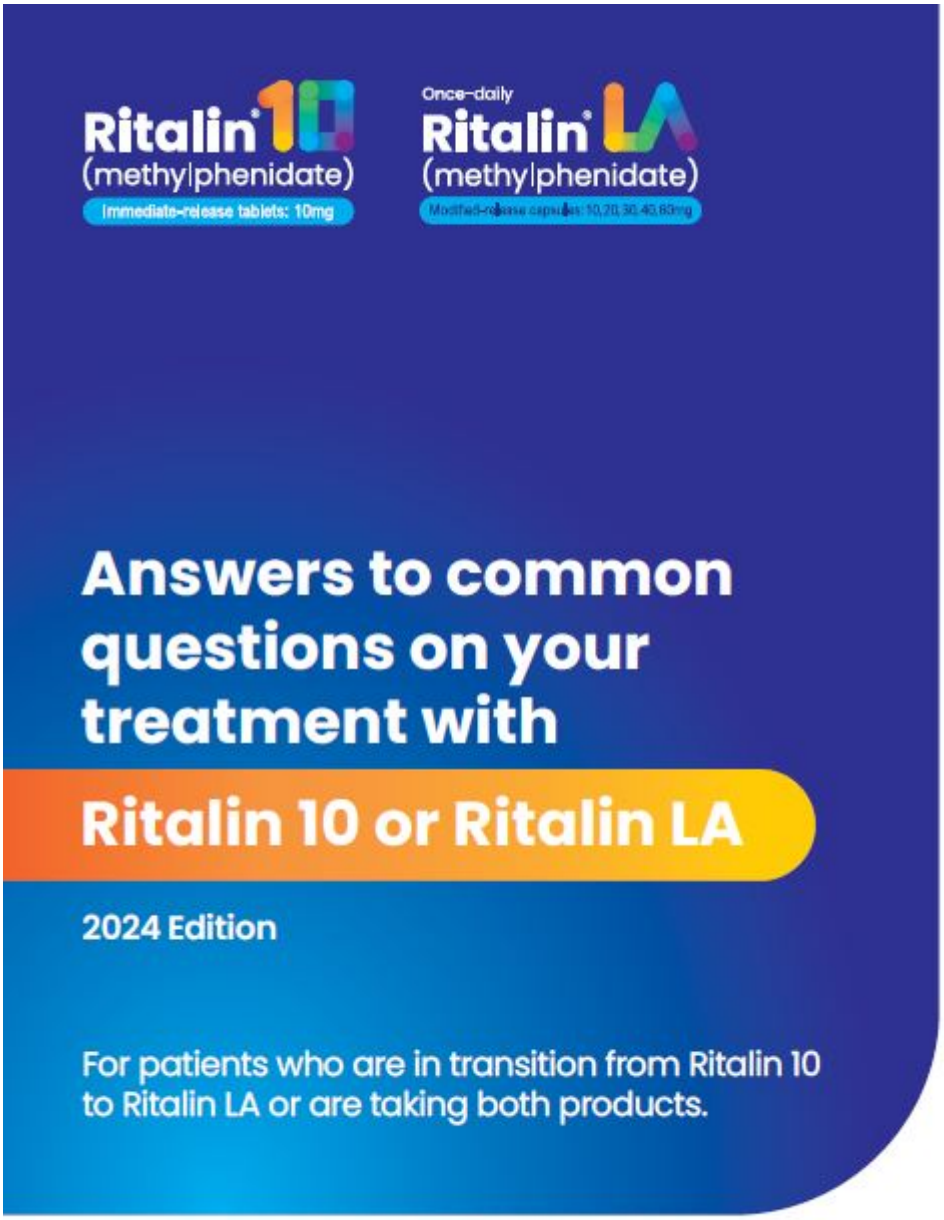

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Patient Guide to Ritalin 10 or Ritalin LA

This booklet is designed to address common questions your patients may have when starting Ritalin 10 tablets or Ritalin LA (long-acting) capsules.

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