

RINIDATE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using RINIDATE?

RINIDATE contains the active ingredient methylphenidate hydrochloride and is used to treat Attention Deficit Hyperactivity Disorder (ADHD) and narcolepsy.

For more information, see Section [1. Why am I using RINIDATE?](#) in the full CMI.

2. What should I know before I use RINIDATE?

Do not use if you have ever had an allergic reaction to methylphenidate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RINIDATE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RINIDATE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RINIDATE?

- Your doctor will tell you how much RINIDATE to use and how long you need to take it.

More instructions can be found in Section [4. How do I use RINIDATE?](#) in the full CMI.

5. What should I know while using RINIDATE?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using RINIDATE.Take RINIDATE exactly as your doctor has prescribed. Like all stimulants, RINIDATE may become habit-forming and can be abused by some people. If you/your child take it correctly as instructed by your doctor, abuse or dependence should not be a problem, either now or later in life.
Things you should not do	<ul style="list-style-type: none">If you/your child suddenly stop taking this medicine, you/your child's condition may reappear or you/your child may get unwanted effects such as depression. Your doctor may want to gradually reduce the amount of medicine taken each day before stopping it completely.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how RINIDATE affects you.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">in a cool dry place where the temperature is below 25°C.

For more information, see Section [5. What should I know while using RINIDATE?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RINIDATE. Common side effects include: nervousness, insomnia, irritability, headache, drowsiness, tremor, uncontrollable body movements, loss of appetite, abdominal pain, allergic reactions, nausea, dry mouth, cough, joint pain, weight loss, increase in heart rate and blood pressure. Serious side effects include: swelling of the face, lips or tongue, sudden high fever, severe convulsions, severe headache or confusion, weakness or paralysis, chest pain, uncontrollable twitching, jerking, bruising, hallucination, fits, suicidal ideation or attempt, prolonged erection, causing discomfort of the penis, fingers and toes feeling numb, cold, tingling and changing colour and skin blisters, blotching or itching.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RINIDATE

Active ingredient(s): [methylphenidate hydrochloride]

Consumer Medicine Information (CMI)

This leaflet provides important information about using RINIDATE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RINIDATE.**

Where to find information in this leaflet:

- [1. Why am I using RINIDATE?](#)
- [2. What should I know before I use RINIDATE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RINIDATE?](#)
- [5. What should I know while using RINIDATE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RINIDATE?

RINIDATE contains the active ingredient **methylphenidate**. RINIDATE is a central nervous system stimulant used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and narcolepsy, a sleep-attack disorder.

This medicine should not be used to prevent or treat normal fatigue.

ADHD

About 3% of children suffer from ADHD. It makes them unable to sit still or concentrate on tasks for any length of time. They may have trouble learning and doing schoolwork. They frequently become difficult to manage, both in school and at home.

RINIDATE is thought to work by regulating specific chemicals in the brain that affect behaviour. It helps to focus attention, shut out distraction and allows impulsive people to think before they act. If successful, it will enhance an inattentive person's natural ability.

This medicine is part of a treatment program that usually includes psychological, educational and social therapy.

Narcolepsy

People with narcolepsy have recurring attacks of irresistible day- time sleepiness in spite of having enough sleep at night. Narcolepsy can be diagnosed by a doctor by recording wake-sleep patterns.

Narcolepsy is not a normal fatigue state.

Ask your doctor if you have any questions about why this medicine has been prescribed for you/your child.

RINIDATE, like all medicines containing central nervous system stimulants, will be given to you/your child only under close medical supervision and after diagnosis.

2. What should I know before I use RINIDATE?

Warnings

Do not use RINIDATE if:

- You/your child are allergic (hypersensitive) to methylphenidate, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.
- Always check the ingredients to make sure you can use this medicine.
- The expiry date printed on the pack has passed.
- The packaging is torn or shows signs of tampering.

Do not take RINIDATE if you/your child have any of the following medical conditions:

- periods of severe anxiety, tension or agitation
- Tourette's syndrome or you have a family history of this disorder.
- glaucoma.
- an overactive thyroid or other thyroid problems.
- heart problems such as:
 - heart attack,
 - irregular heartbeat,
 - chest pain (angina),
 - heart failure,
 - heart disease
 - if you were born with a heart problem.
- very high blood pressure (hypertension).
- narrowing of the blood vessels (arterial occlusive disease, which can cause pain in the arms and legs).
- severe depression or other mental illness.
- pheochromocytoma.
- if you/your child are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the past 14 days.**

Check with your doctor if you/your child:

Are allergic to any other medicines, foods, dyes or preservatives.

Have intolerance to lactose or gluten. This medicine contains lactose and maize starch.

Have any of the following medical conditions or behaviours:

- any heart defects (e.g. structural cardiac abnormality).

- a family history of sudden death or irregular heartbeat.
- hardening of the arteries.
- any other current or previous heart problems.
- any disorders of the blood vessels in the brain, e.g. weakening of the blood vessel (aneurysm), stroke, or inflammation of blood vessels (vasculitis).
- severe depression, bipolar disorder or other mental illness.
- epilepsy (seizures, convulsions, or fits).
- high blood pressure.
- history of alcohol or drug abuse or dependence.
- tics (muscle twitching which is usually in the face or shoulders) or a family history of this condition.
- acute mental disorders including acute psychosis and mania.
- hallucinations.
- aggressive behaviour.
- suicidal thoughts or behaviour.
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon').
- have or develop eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (longsightedness).

Mental (psychiatric) problems may develop or get worse, including behaviour and thought problems, bipolar illness, aggressive behaviour or hostility.

Your doctor may want to take special precautions if you/your child have any of the above conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

RINIDATE is not to be used during pregnancy unless specifically prescribed by your doctor. This medicine may affect your developing baby if you take it while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in RINIDATE passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

This medicine is only available with a doctor's prescription and your doctor has special permission to prescribe it.

There is not enough information to recommend its use in children under 6 years old.

RINIDATE can be abused or lead to dependence.

Keep RINIDATE in a safe place to prevent misuse and abuse.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and RINIDATE may interfere with each other. These include:

- Monoamine oxidase (MAO) inhibitors such as phenelzine and selegiline. Taking RINIDATE together with MAOI medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.
- medicines that increase blood pressure.
- alpha 2 agonists like clonidine (used to treat high blood pressure).
- oral anticoagulants or warfarin (medicines used to prevent blood clots).
- medicines used to prevent seizures such as phenytoin, phenobarbitone, primidone and valproate.
- medicines used to treat depression, such as desvenlafaxine, venlafaxine, sertraline, citalopram, amitriptyline and imipramine.
- Anaesthetics. There is a chance of a sudden rise in blood pressure during the operation if an anaesthetic is used. Your doctor will advise if you/your child should take RINIDATE on the day of the operation.
- medicines that influence the level of dopamine in the body (dopaminergic medicines, used to treat Parkinson's disease or psychosis).
- medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine).

If you experience a combination of the following symptoms while taking RINIDATE with a serotonergic medicine, STOP treatment with RINIDATE and these medicines and tell your doctor immediately:

- restlessness
- tremor
- sudden muscle contractions
- abnormal high temperature
- nausea
- vomiting

Some medicines may interfere with RINIDATE and affect how it works. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RINIDATE.

4. How do I use RINIDATE?

How much to take

Your doctor will decide on the most suitable dosage according to you/your child's medical need and response.

Follow your doctor's instructions carefully and do not change or stop your dosage without speaking to your doctor first. Your doctor may adjust the amount of RINIDATE you take until it is right for you.

How to take RINIDATE

Take the tablet(s) with a full glass of water.

You can take RINIDATE tablets with or without food.

If they upset you or your child's stomach, take them with food.

Always take the tablets in the same way (e.g. always with food or always without food) to ensure the effect is always the same.

Take the tablets in 2 or 3 doses over the day unless your doctor tells you otherwise.

If you find that you or your child have trouble sleeping, talk to your doctor about the best time to take the last dose of the day.

Take each dose 1 or 2 hours before the greatest effect is needed. For example, a child may take a dose at 7:00 a.m. so that improved concentration begins when school starts.

How long to take RINIDATE

Continue taking RINIDATE for as long as your doctor tells you.

This medicine helps to control your or your child's symptoms but does not cure your condition. Your doctor will check your/your child's progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Treatment for ADHD varies in length from patient to patient. During treatment for ADHD, your doctor may stop RINIDATE every so often (e.g. over weekends or school holidays) to see whether it is still needed. Breaks from treatment also help to prevent a slow-down in growth that sometimes happens when children take this medicine for a long time.

If you forget to take RINIDATE

If you/your child forget to take a dose of RINIDATE, take the dose as soon as you remember. Then make sure to wait the same amount of time as usual before you/your child take the next dose.

For example, if there are usually 4 hours between doses, wait 4 hours before taking the next dose and so on for the rest of that day. On the next day go back to your usual times.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the one that you/your child missed.

If you use too much RINIDATE

If you think that you have used too much RINIDATE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Some of the symptoms of an overdose may include:

- vomiting
- agitation
- headache
- tremors
- muscle twitching
- irregular heartbeat
- flushing
- fever
- sweating
- dilated pupils
- breathing problems
- confusion
- seizures
- muscle spasms, fever, red-brown urine.

5. What should I know while using RINIDATE?

Things you should do

Take RINIDATE exactly as your doctor has prescribed.

- Like all stimulants, this medicine may become habit-forming and can be abused by some people. If you/your child take it correctly as instructed by your doctor, abuse or dependence should not be a problem, either now or later in life.
- Be sure to keep all of your doctor's appointments so that your/ your child's progress can be checked. Your doctor will want to check your or your child's blood pressure, height, weight and do blood tests from time to time to prevent unwanted side effects from happening.
- If your child is not growing or gaining height or weight as expected treatment with RINIDATE may need to be interrupted.
- Tell your doctor if you are going to have an operation.
- Tell any doctor, dentist or pharmacist who treats you or your child that you are taking RINIDATE.

If you/your child are about to be started on any new medicine, remind your doctor and pharmacist that you/your child are taking RINIDATE.

Things you should not do

- Do not stop your treatment without first checking with your doctor.
- If you suddenly stop taking this medicine, your condition may reappear, or you may get unwanted effects such as depression. To prevent this, your doctor may want to gradually reduce the amount of medicine you take each day before stopping it completely.
- Do not change the dose without talking to the doctor.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- Do not give it to anyone else, even if their condition seems similar to yours.

Things to be careful of

RINIDATE may give a false positive result when testing for drug use. This includes testing used in sport.

Driving or using machines

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking RINIDATE.

RINIDATE may impair your ability to operate potentially hazardous machinery or vehicles. You should exercise caution until you are reasonably certain how you react to RINIDATE before you drive a car, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while you are taking RINIDATE. Remember that some foods and medicines contain alcohol.

Alcohol can worsen some of the unwanted effects of this medicine, such as dizziness and drowsiness.

Looking after your medicine

- Keep your medicine in the original container until it is time to take a dose.
- Store Store below 25 °C. Protect from moisture.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RINIDATE.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

In some patients RINIDATE may cause stomach upset, loss of appetite and difficulty sleeping, especially at the start of treatment. Your doctor can usually help to reduce these symptoms by lowering the dose of RINIDATE or changing the times when the tablets are taken.

Less serious side effects

Less serious side effects	What to do
<p><i>Psychiatric disorders</i></p> <ul style="list-style-type: none"> • excessive emotional distress or excitement • nervousness • feeling anxious, agitated • feeling jittery • feeling depressed • feeling aggressive • feeling irritated • unusually active • sleep disturbance • sleepiness • troubled sleep or restlessness • difficulty falling asleep • bedwetting in children during the night • mood changes • abnormal behaviour or thinking • excessive awareness of surroundings • feeling over-active and un-inhibited (mania) • changes in sex drive • lack of feeling or emotion • doing things over and over again • being obsessed with one thing • confusion • addiction <p><i>Nervous system disorders</i></p> <ul style="list-style-type: none"> • uncontrolled speech and body movements (Tourette's syndrome) • dizziness • headache • involuntary shaking of the body (sign of tremor) • stuttering • feeling disorientated • migraine • tiredness <p><i>Gastrointestinal disorders</i></p> <ul style="list-style-type: none"> • vomiting 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> stomach pain upset stomach Indigestion nausea (feeling sick) dry mouth toothache diarrhoea constipation <p><i>Metabolism disorders</i></p> <ul style="list-style-type: none"> loss of appetite decreased weight loss of weight and slower growth in children <p><i>Infections and Infestations</i></p> <ul style="list-style-type: none"> sore throat and runny nose cough fever <p><i>Eye disorders</i></p> <ul style="list-style-type: none"> blurred vision or problems focussing your eyes double vision dilated pupils trouble seeing increased eye pressure <p><i>Musculoskeletal and tissue disorders</i></p> <ul style="list-style-type: none"> muscle cramps joint pain excessive teeth grinding spasm of the jaw muscles that makes it difficult to open the mouth temporary muscle weakness muscle pain muscle twitching <p><i>Cardiac disorders</i></p> <ul style="list-style-type: none"> palpitations <p><i>Skin and tissue disorders</i></p> <ul style="list-style-type: none"> skin rash itchy rash hives hair loss skin blisters or itching red blotches on the skin excessive sweating bruising <p><i>Respiratory disorders</i></p> <ul style="list-style-type: none"> shortness of breath nosebleed <p><i>Reproductive system disorders</i></p> <ul style="list-style-type: none"> inability to develop or maintain an erection swelling of the breasts in men <p><i>Vascular disorders</i></p> <ul style="list-style-type: none"> fingers and toes feeling numb, cold, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon, peripheral coldness) 	

Serious side effects

Serious side effects	What to do
<p><i>Allergy</i></p> <ul style="list-style-type: none"> swelling of the face, lips or tongue, throat swelling of the ears <p><i>Infections and Infestations</i></p> <ul style="list-style-type: none"> sudden high fever severe convulsions a sore throat and fever or chills <p><i>Nervous system disorders</i></p> <ul style="list-style-type: none"> severe headache or confusion weakness or paralysis of limbs or face difficulty speaking uncontrollable twitching, jerking muscle twitching or tics uncontrollable writhing movements of the limb, face and/ or trunk fits (seizures, convulsions, epilepsy) loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain (reversible ischemic neurological deficit) <p><i>Cardiac disorders</i></p> <ul style="list-style-type: none"> fast heartbeat chest pain stopped heartbeat heart attack abnormal sounds from heart abnormal heart rhythm sudden death of heart origin <p><i>Psychiatric disorders</i></p> <ul style="list-style-type: none"> seeing or feeling things that are not really there (hallucination) thoughts or attempts of killing yourself. <p><i>Reproductive system disorders</i></p> <ul style="list-style-type: none"> prolonged erection, causing discomfort of the penis (sign of priapism) <p><i>Blood and the lymphatic system disorders</i></p> <ul style="list-style-type: none"> abnormal decrease in the levels of all type of blood cells. This is associated with anaemia, decreased platelets, and decreased white blood cells. This can lead to fatigue, increased risk of bleeding, and/or increased risk of infection. This may be serious or life threatening (pancytopenia). Blood in the urine 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What RINIDATE contains

Active ingredient (main ingredient)	Methylphenidate hydrochloride
Other ingredients (inactive ingredients)	Lactose monohydrate Maize starch Sodium starch glycolate Type A Hypromellose Citric acid monohydrate Colloidal anhydrous silica Magnesium stearate
Potential allergens	Not applicable

Do not take this medicine if you are allergic to any of these ingredients.

What RINIDATE looks like

RINIDATE 10 mg tablets are white to off-white, circular, flat, bevelled edged immediate release tablets with a break line and marked with "10" on one side and "73" on the other.

AUST R: 446651

Who distributes RINIDATE

Nova Pharmaceuticals Australasia Pty Ltd

Suite 305, 10 Norbrik Drive

Bella Vista, NSW 2153

Australia

www.novapharm.com.au

Toll free: 1800 002 171

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