

METHYLPHENIDATE XR ARX

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 METHYLPHENIDATE XR ARX?

METHYLPHENIDATE XR ARX contains the active ingredient Methylphenidate hydrochloride and is used to treat Attention Deficit Hyperactivity Disorder (ADHD).

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

2. What should I know before I use METHYLPHENIDATE XR ARX?

Do not use if you have ever had an allergic reaction to METHYLPHENIDATE XR ARX 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 METHYLPHENIDATE XR ARX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with METHYLPHENIDATE XR ARX 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 METHYLPHENIDATE XR ARX?

- Your doctor will tell you how much METHYLPHENIDATE XR ARX to take and how long you will need to take it.

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

5. What should I know while using METHYLPHENIDATE XR ARX?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using METHYLPHENIDATE XR ARX.Take METHYLPHENIDATE XR ARX exactly as your doctor has prescribed. Like all stimulants, METHYLPHENIDATE XR ARX 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 METHYLPHENIDATE XR ARX 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">Store METHYLPHENIDATE XR ARX in a cool dry place where the temperature is below 30°C. Keep the container tightly closed.

For more information, see Section [5. What should I know while using METHYLPHENIDATE XR ARX?](#) 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 METHYLPHENIDATE XR ARX . Like all medicines, METHYLPHENIDATE XR ARX can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. 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.

METHYLPHENIDATE XR ARX

Active ingredient(s): *methylphenidate hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using METHYLPHENIDATE XR ARX. **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 METHYLPHENIDATE XR ARX.**

Where to find information in this leaflet:

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

1. Why am I using METHYLPHENIDATE XR ARX?

METHYLPHENIDATE XR ARX contains the active ingredient methylphenidate hydrochloride.

METHYLPHENIDATE XR ARX is a stimulant that increases attention and decreases impulsiveness and hyperactivity in patients with Attention Deficit Hyperactivity Disorder (ADHD).

METHYLPHENIDATE XR ARX is used to treat ADHD. METHYLPHENIDATE XR ARX is part of a comprehensive treatment program which usually includes psychological, educational and social therapy.

METHYLPHENIDATE XR ARX should be used as part of a total treatment program for ADHD that may include counselling or other therapies.

2. What should I know before I use METHYLPHENIDATE XR ARX?

Warnings

Do not use METHYLPHENIDATE XR ARX if:

- You are allergic to methylphenidate hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- The packaging is torn or shows signs of tampering.

Symptoms of an allergic reaction may include: rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body.

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

- glaucoma (increased pressure in the eye) which is poorly controlled
- overactive thyroid gland

- heart problems, including severe angina (chest pain), irregular heartbeat, heart muscle disease, high blood pressure (untreated or not under control)
- severe depression, anorexia nervosa, suicidal tendency or other mental illness
- phaeochromocytoma (a tumour of the adrenal gland)
- have a history of drug or alcohol abuse
- currently taking or have taken a monoamine oxidase (MAO) inhibitor, medicines used to treat major depression (eg. phenelzine, tranylcypromine) or medicines used in Parkinson's disease (eg. selegiline) within the last 14 days

Check with your doctor if you:

- have any other medical conditions
 - are/is or have/has been alcohol or drug dependent
 - have/has seizures or fits
 - have/has heart problems
 - Heart-related problems including sudden death in patients who have heart problems or heart defects, stroke and heart attack in adults and increased blood pressure and heart rate have been reported with the use of methylphenidate, the active ingredient in METHYLPHENIDATE XR ARX.
 - have / had thoughts about suicide or attempted suicide
 - have/has high blood pressure
 - have/has aggressive behaviour or hostility
 - have/has a narrowing or blockage in your digestive tract (stomach, small or large intestine)
 - have tics (movements or sounds you cannot control) or Tourette's syndrome, or a family history of these conditions
 - have/has a problem with the blood vessels in your brain (such as an aneurysm)
 - have/has eye problems, such as increased pressure in the eye, a condition called "glaucoma" or long-sightedness (difficulty seeing near objects)
 - have/has liver or kidney problems
 - have/has mental problems including psychosis, mania, bipolar illness, or depression

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

Your doctor may need to adjust the dose or adapt your treatment if you/your child have any of these conditions.

If you have not told your doctor or pharmacist about any of the above, tell them before you/your child start taking METHYLPHENIDATE XR ARX.

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.

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

The active ingredient in METHYLPHENIDATE XR ARX 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.

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.

In particular, tell your doctor or pharmacist if you/your child are taking any of the following:

- Monoamine oxidase (MAO) inhibitors such as phenelzine, selegiline
- medicines that increase blood pressure
- medicines used to treat depression or anxiety such as venlafaxine, sertraline, amitriptyline and imipramine
- medicines used to prevent seizures such as phenytoin, phenobarbitone, primidone and valproate.
- antipsychotic medicines such as olanzapine, risperidone and quetiapine used to improve the symptoms of certain types of mental illness, e.g. schizophrenia and bipolar disorder.

Some medicines may interfere with METHYLPHENIDATE XR ARX 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 METHYLPHENIDATE XR ARX.

4. How do I use METHYLPHENIDATE XR ARX?

How much to take / use

If you/your child are currently taking other formulations of methylphenidate, your doctor will decide the best starting dose

- **Children and Adolescents**
 - The starting dose is one METHYLPHENIDATE XR ARX 18 mg extended- release tablet in the morning
 - The maximum dose is 54 mg a day taken as one dose.
- **Adults**
 - The starting dose is one METHYLPHENIDATE XR ARX 18 mg or 36 mg extended-release tablet in the morning
 - The maximum dose is 72 mg a day taken as one dose.

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

How to take / use METHYLPHENIDATE XR ARX

- METHYLPHENIDATE XR ARX should be swallowed whole with a glass of liquid. It should not be chewed, broken or crushed.
- METHYLPHENIDATE XR ARX may be taken with or without food.

If you/your child forget to use METHYLPHENIDATE XR ARX

METHYLPHENIDATE XR ARX should be used regularly at the same time each day. If you miss your dose at the usual time:

- **It may be best to wait until the following morning to take the next dose. Remember the effects of METHYLPHENIDATE XR ARX are designed to last approximately 12 hours from the time it is taken.**
- **Do not take or give your child a double dose to make up for the dose missed.**
- **If you/your child have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.**

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much METHYLPHENIDATE XR ARX

If you think that you have used too much METHYLPHENIDATE XR ARX, 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.

If you/your child take too much METHYLPHENIDATE XR ARX you/your child may experience symptoms such as vomiting, agitation, muscle twitching, hallucination, dry mouth, excessive sweating, fever, headache, irregular or fast heartbeat, dilated pupils, convulsions/fits, breathing problems, confusion and seizures

5. What should I know while using METHYLPHENIDATE XR ARX?

Things you/ your child should do

- Always follow your doctor's instructions carefully
- Take METHYLPHENIDATE XR ARX exactly as your doctor has prescribed. Like all stimulants, METHYLPHENIDATE XR ARX 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/your child's blood pressure and pulse and do blood test from time to time to prevent unwanted side effects
- Tell your doctor if you/your child become pregnant while taking METHYLPHENIDATE XR ARX
- Tell your doctor if you or your child become aggressive, anxious or agitated, or feel more aggressive, anxious or agitated than usual
- Tell your doctor if you or your child develop severe headaches, weakness or paralysis of any body part, or

develop problems with coordination, vision, speaking, finding words or with your memory

- Children should have their height and weight checked regularly as METHYLPHENIDATE XR ARX may slow children's rate of growth
- Tell your doctor if you/your child experience numbness, tingling and a changing colour of the fingers and toes when cold ('Raynaud's phenomenon')
- Tell your doctor if you/your child are about to start taking a new medicine, that you/your child are taking METHYLPHENIDATE XR ARX

Call you/ your child's doctor straight away if:

- Parents and/or caregivers should be alert for the development of thoughts or acts of self-harm, hallucinations, abnormal thinking (psychosis) or new or worsening hostility. These were uncommon symptoms seen in clinical studies with methylphenidate hydrochloride and it is not known if they were caused by methylphenidate hydrochloride. Contact your/your child's doctor or mental health professional straight away or seek urgent medical attention if these occur
- Parents and/or caregivers should contact their/their child's doctor or seek urgent treatment if they/their child develops chest pain, tightness in the chest, shortness of breath, irregular heartbeat, feeling faint or loss of consciousness while taking METHYLPHENIDATE XR ARX
- You or your child develop prolonged and painful erections

Remind any doctor, dentist or pharmacist you visit that you are using METHYLPHENIDATE XR ARX.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use METHYLPHENIDATE XR ARX to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar.
- **Do not stop treatment without first checking with your doctor.**

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep the tablets in the bottle until it is time to take them.
- Store METHYLPHENIDATE XR ARX in a cool dry place where the temperature is below 30°C. Keep the container tightly closed.

Keep medicines where children cannot reach them.

A locked cupboard at least one-and- a-half metres (1.5 m) above the ground is a good place to store medicines.

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?

All medicines can have side effects. If you/ your child 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.

Less serious side effects

Less serious side effects	What to do
<p>Stomach or bowel problems such as:</p> <ul style="list-style-type: none"> • loss of appetite • stomach pain • nausea • vomiting • dry mouth • indigestion • constipation • weight loss • diarrhoea <p>Difficulty thinking or working because of:</p> <ul style="list-style-type: none"> • headache • trouble sleeping • dizziness <p>Throat or lung infections such as:</p> <ul style="list-style-type: none"> • cold • cough • sore throat and hoarse/ loss of voice • feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell <p>Joints or movement changes such as:</p> <ul style="list-style-type: none"> • painful and/ or swollen joints • aching muscles, muscle tightness, spasm, tenderness or weakness, not caused by exercise • difficulty opening the mouth 	<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"> clenching or grinding the teeth <p>Other changes such as:</p> <ul style="list-style-type: none"> decreased sex drive or difficulty getting and keeping an erection feeling very tired or weak excessive thirst feeling sleepy loss of bladder control 	

Serious side effects

Serious side effects	What to do
<p>Behavioural changes</p> <ul style="list-style-type: none"> aggression confusion disorientation seeing, feeling or hearing things that are not there mood swings, overexcitement over-activity and uninhibited behaviour feeling depressed feeling tense nervousness or anxiety brief periods of acute anxiety where symptoms suddenly and usually include difficulty breathing, chest pains, fast heart rate, dizziness and lightheadedness, sweating, trembling and faintness restlessness agitation and irritability movements or sounds that you cannot control (tics) <p>Nervous system changes such as:</p> <ul style="list-style-type: none"> convulsions, fits or seizures muscle twitching or tremor numbness and tingling feeling in fingers and toes <p>Reproductive system changes such as:</p> <ul style="list-style-type: none"> prolonged and painful erections <p>Changes in your sight, namely:</p> <ul style="list-style-type: none"> visual disturbance blurred or double vision dilated pupils <p>Changes to the skin or hair such as:</p> <ul style="list-style-type: none"> unusual hair loss or thinning of the hair redness of the skin excessive sweating signs of allergy such rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body <p>Body temperature changes such as:</p>	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> fever hot flushes <p>Heart or blood problems such as:</p> <ul style="list-style-type: none"> fast or abnormal heart beat increased blood pressure chest pain chest discomfort low white blood cell count low platelet count <p>Other side effects such as:</p> <ul style="list-style-type: none"> shortness of breath slowing of growth (height and weight) in children blockage of the oesophagus, stomach, small or large intestine in patients who already have a narrowing in any of these organs increased levels of the liver enzyme ALT 	

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 METHYLPHENIDATE XR ARX contains

Active ingredient (main ingredient)	Methylphenidate hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Lactose monohydrate Hypromellose Colloidal anhydrous silica Magnesium stearate Methacrylic acid copolymer Triethyl citrate Purified talc Fumaric acid Opadry 85F220137 Yellow (ARTG PI No. 140409 – 18 mg tablets) Opadry 85F275019 Grey (ARTG PI No. 140410 – 27 mg tablets) Opadry 85F48105 White (ARTG PI No. 123056 – 36 mg tablets)

	<ul style="list-style-type: none"> • Opadry 85F15266 Red (ARTG PI No. 141465 – 54 mg tablets) • OPACODE monogramming ink S-1-17823 BLACK (PI 12108)
Potential allergens	<ul style="list-style-type: none"> • Lactose

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

What METHYLPHENIDATE XR ARX looks like

METHYLPHENIDATE XR ARX 18 mg are yellow capsule-shaped tablets, with "2392" printed in black ink on one side [AUST R 344274].

METHYLPHENIDATE XR ARX 27 mg are grey capsule-shaped tablets, with "2393" printed in black ink on one side [AUST R 344270].

METHYLPHENIDATE XR ARX 36 mg are white capsule-shaped tablets, with "2394" printed in black ink on one side [AUST R 344277].

METHYLPHENIDATE XR ARX 54 mg are brownish- red capsule-shaped tablets, with "2395" printed in black ink on one side [AUST R 344275].

Who distributes METHYLPHENIDATE XR ARX

Sponsored in Australia by:

Teva Pharma Australia Pty Ltd
 Level 1, 37 Epping Road
 Macquarie Park NSW 2113
 AUSTRALIA

Distributed in Australia by:

Arrotex Pharmaceuticals
 15 – 17 Chapel Street
 Cremorne, Victoria, 3121

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