METHYLPHENIDATE-TEVA XR

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-TEVA XR?

METHYLPHENIDATE-TEVA XR 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-TEVA XR? in the full CMI.

2. What should I know before I use METHYLPHENIDATE-TEVA XR?

Do not use if you have ever had an allergic reaction to METHYLPHENIDATE-TEVA XR 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-TEVA XR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with METHYLPHENIDATE-TEVA XR 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-TEVA XR?

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

More instructions can be found in Section 4. How do I use METHYLPHENIDATE-TEVA XR? in the full CMI.

5. What should I know while using METHYLPHENIDATE-TEVA XR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using METHYLPHENIDATE-TEVA XR. • Take METHYLPHENIDATE-TEVA XR exactly as your doctor has prescribed. Like all stimulants, METHYLPHENIDATE-TEVA XR 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	• 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	• Be careful before you drive or use any machines or tools until you know how METHYLPHENIDATE-TEVA XR affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Store METHYLPHENIDATE-TEVA XR 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-TEVA XR? 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-TEVA XR. Like all medicines, METHYLPHENIDATE-TEVA XR 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-TEVA XR

Active ingredient(s): *methylphenidate hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using METHYLPHENIDATE-TEVA XR. **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-TEVA XR.**

Where to find information in this leaflet:

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

1. Why am I using METHYLPHENIDATE-TEVA XR?

METHYLPHENIDATE-TEVA XR contains the active ingredient methylphenidate hydrochloride. METHYLPHENIDATE-TEVA XR is a stimulant that increases attention and decreases impulsiveness and hyperactivity in patients with Attention Deficit Hyperactivity Disorder (ADHD).

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

METHYLPHENIDATE-TEVA XR 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-TEVA XR?

Warnings

Do not use METHYLPHENIDATE-TEVA XR 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-TEVA XR 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)
- 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-TEVA XR.
    - 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-TEVA XR.

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-TEVA XR 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.

Use in elderly patients

METHYLPHENIDATE-TEVA XR is not recommended for use in the elderly over 65 years because it has not been studied in these age groups.

Use in children

METHYLPHENIDATE-TEVA XR is not recommended for use in children less than 6 years because it has not been studied in these age groups.

Abuse and dependence

METHYLPHENIDATE-TEVA XR can be abused or lead to dependence.

Keep METHYLPHENIDATE-TEVA XR 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.

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 treat high blood pressure. METHYLPHENIDATE-TEVA XR may decrease the effectiveness of these medicines and your doctor may check your blood pressure and change your dose of antihypertensive medicine.
- medicines used for anaesthesia. METHYLPHENIDATE-TEVA XR should not be taken with certain anaesthetics on the day of the operation, as there is a chance of a sudden rise in blood pressure and heart rate during the operation. Tell your doctor if you are going to have an operation.
- 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-TEVA XR 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-TEVA XR.

4. How do I use METHYLPHENIDATE-TEVA XR?

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-TEVA XR 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-TEVA XR 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-TEVA XR you take until it is right for you.

How to take / use METHYLPHENIDATE-TEVA XR

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

If you/your child forget to use METHYLPHENIDATE-TEVA XR

METHYLPHENIDATE-TEVA XR 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-TEVA XR 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-TEVA XR

If you think that you have used too much METHYLPHENIDATE-TEVA XR, 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-TEVA XR 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-TEVA XR?

Things you/ your child should do

- Always follow your doctor's instructions carefully
- Take METHYLPHENIDATE-TEVA XR exactly as your doctor has prescribed. Like all stimulants, METHYLPHENIDATE-TEVA XR 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-TEVA XR
- 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-TEVA XR 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-TEVA XR

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-TEVA XR
- You or your child develop prolonged and painful erections

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

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use METHYLPHENIDATE-TEVA XR 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-TEVA XR 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-TEVA XR 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-TEVA XR 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
Stomach or bowel problems such as: • loss of appetite • stomach pain • nausea • vomiting • dry mouth • indigestion • constipation • weight loss • diarrhoea **Difficulty thinking or working because of:** • headache • trouble sleeping • dizziness **Throat or lung infections such as:** • 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 **Joints or movement changes such as:** • painful and/ or swollen joints • aching muscles, muscle tightness, spasm, tenderness or weakness, not caused by exercise • difficulty opening the mouth • clenching or grinding the teeth **Other changes such as:** • decreased sex drive or difficulty getting and keeping an erection • feeling very tired or weak • excessive thirst • feeling sleepy • loss of bladder control	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Behavioural changes • 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) • obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, having repeated unwanted thoughts, feelings, images, or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions)) **Nervous system changes such as:** • convulsions, fits or seizures • muscle twitching or tremor	**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.**

Serious side effects	What to do
• numbness and tingling feeling in fingers and toes **Reproductive system changes such as:** • prolonged and painful erections • enlarged breasts in boys or men **Changes in your sight, namely:** • visual disturbance • blurred or double vision • dilated pupils • high pressure in the eye, which may cause blindness (glaucoma) • increased pressure in the eye **Changes to the skin or hair such as:** • 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 **Body temperature changes such as:** • fever • hot flushes **Heart or blood problems such as:** • fast or abnormal heart beat • increased blood pressure • chest pain • chest discomfort • low white blood cell count • low platelet count **Other side effects such as:** • shortness of breath • nose bleeds • 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-TEVA XR contains

Active ingredient (main ingredient)	Methylphenidate hydrochloride
Other ingredients (inactive ingredients)	• 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) • Opadry 85F15266 Red (ARTG PI No. 141465 – 54 mg tablets) • OPACODE monogramming ink S-1-17823 BLACK (PI 12108)
Potential allergens	• Lactose

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

What METHYLPHENIDATE-TEVA XR looks like

METHYLPHENIDATE-TEVA XR 18 mg are yellow capsule-shaped tablets, with "2392" printed in black ink on one side [AUST R 370912].

METHYLPHENIDATE-TEVA XR 27 mg are grey capsule-shaped tablets, with "2393" printed in black ink on one side [AUST R 370911].

METHYLPHENIDATE-TEVA XR 36 mg are white capsule-shaped tablets, with "2394" printed in black ink on one side [AUST R 370900].

METHYLPHENIDATE-TEVA XR 54 mg are brownish- red capsule-shaped tablets, with "2395" printed in black ink on one side [AUST R 370899].

Who distributes METHYLPHENIDATE-TEVA XR

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

AUSTRALIA

This leaflet was prepared in June 2026