

CONSUMER MEDICINE INFORMATION

METHYLPHENIDATE EXTENDED RELEASE (TEVA)

Methylphenidate Extended Release 18 mg, 27 mg, 36 mg & 54 mg, extended release tablets

What is in this leaflet

This leaflet answers some common questions about Methylphenidate Extended Release (Teva). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you or your child taking Methylphenidate Extended Release (Teva) against the benefits this medicine is expected to have for you or your child.

If you have any concerns about taking Methylphenidate Extended release (Teva), ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Methylphenidate Extended Release (Teva) is used for

Methylphenidate Extended Release (Teva) is used to treat Attention Deficit Hyperactivity Disorder (ADHD).

Methylphenidate Extended Release (Teva) is part of a comprehensive treatment program, which usually includes psychological, educational and social therapy.

Methylphenidate Extended Release (Teva) is a stimulant that increases attention and decreases impulsiveness and hyperactivity in patients with ADHD.

Methylphenidate Extended Release (Teva) should be used as part of a total treatment program for ADHD that may include counselling or other therapies.

Methylphenidate Extended Release (Teva) is not recommended for use in children less than 6 years and elderly over 65 years because it has not been studied in these age groups.

Your doctor may have prescribed Methylphenidate Extended Release (Teva) for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you/your child.

Methylphenidate Extended Release (Teva) can be abused or lead to dependence. Keep Methylphenidate Extended Release (Teva) in a safe place to prevent misuse and abuse

Before you take Methylphenidate Extended Release (Teva)

When you must not take it

Do not take Methylphenidate Extended Release (Teva) if you/your child have an allergy to:

- Methylphenidate hydrochloride (the active ingredient in Methylphenidate Extended Release (Teva) or
- any of the other ingredients in Methylphenidate Extended Release (Teva). See Product Description at the end of this leaflet for a list of ingredients.

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 Extended Release (Teva) if you/your child have any of the following medical conditions:

- overactive thyroid gland
- heart problems, including angina (chest pain), irregular heart beat that is potentially life threatening and high blood pressure (untreated or not under control)
- a problem with the blood vessels in your brain (such as an aneurysm or a stroke)
- severe depression, anorexia nervosa, suicidal tendency, bipolar disorder or other mental illness
- currently taking or have taken a 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
- phaeochromocytoma (a tumour of the adrenal gland)
- have a history of drug or alcohol abuse.

Do not use Methylphenidate Extended Release (Teva) if the packaging is torn or shows signs of tampering.

Do not use Methylphenidate Extended Release (Teva) beyond the expiry date (month and year) printed on the pack. If you/your child take it after the expiry date it may not work.

Before you/your child start to take it

You must tell your doctor if you/your child:

- are/is pregnant or planning to become pregnant
- are/is breastfeeding or wish to breastfeed.
- The active ingredient in Methylphenidate Extended Release (Teva) 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. develop severe headaches, weakness or paralysis of any body part, or develop problems with coordination, vision, speaking, finding words or with your memory
- 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 Extended Release (Teva).

- have/had thoughts about suicide or attempted suicide
- have/has high blood pressure
- have/has aggressive behavior or hostility
- have/has a narrowing or blockage in your digestive tract (stomach, small or large intestine)
- have Tourette's syndrome (tics) or a family history of this disorder
- have a problem with the blood vessels in your brain (such as an aneurysm)
- have/has eye problems such as glaucoma (increased pressure in the eye) 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 behavior 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 Extended Release (Teva).

Taking other medicines

If you/your child are taking any other medicines, including any you can buy without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

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

- Monoamine oxidase (MOA) inhibitors such as phenelzine, selegiline
- medicines that increase blood pressure
- medicines used to treat high blood pressure. Methylphenidate Extended Release (Teva) 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 Extended Release (Teva) 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 treat depression or anxiety such as venlafaxine, sertraline, amitriptyline and imipramine

- medicines used to prevent seizures such as phenytoin, phenobarbitone and primidone and valproate.
- antipsychotic medicines such as olanzapine, risperidone and quetiapine used to improve the symptoms of certain types of mental illness, eg. schizophrenia and bipolar disorder.

These medicines may be affected by Methylphenidate Extended Release (Teva) or may affect how well it works. Your doctor or pharmacist can tell you what to do if you/your child are taking any of these medicines.

How to take Methylphenidate Extended Release (Teva)

How to take it

Follow the directions given to you by your doctor and pharmacist. These directions may differ from the information contained in this leaflet.

Methylphenidate Extended Release (Teva) should be swallowed whole with a glass of liquid. It should not be chewed, broken or crushed. Methylphenidate Extended Release (Teva) may be taken with or without food.

How much to take

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

Adolescents and Children over 6 years

- The starting dose is one 18 mg tablet in the morning
- The maximum dose for children aged from 6 to 12 years is 54 mg a day and the maximum dose for adolescents aged from 13 to 18 years is 72 mg a day, taken as one dose.

Adults

- The starting dose is one Methylphenidate Extended Release (Teva) 18 mg or 36 mg extended-release tablet in the morning
- The maximum dose is 72 mg a day taken as one dose.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you/your child forget to take it

- It may be best to wait until the following morning to take the next dose. Remember the effects of Methylphenidate Extended Release (Teva) 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.

While you are taking Methylphenidate Extended Release (Teva)

Things you must do

- Always follow your doctor's instructions carefully
- Take Methylphenidate Extended Release (Teva) exactly as your doctor has prescribed. Like all stimulants, Methylphenidate Extended Release (Teva) 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
- Have your child's height and weight checked regularly as Methylphenidate Extended Release (Teva) may slow children's rate of growth
- 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 from happening
- Tell your doctor if you become pregnant while taking Methylphenidate Extended Release (Teva)
- 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 and it is not known if they were caused by methylphenidate. Contact your/your child's doctor or mental health professional straight away or seek urgent medical attention if these occur
- Tell your doctor if you or your child become aggressive, anxious or agitated, or feel more aggressive, anxious or agitated than usual
- Parents and/or caregivers should contact their/their child's doctor or seek urgent treatment if they/their child develops chest pain, tightness in chest, shortness of breath, irregular heart beat, feeling faint or loss of consciousness while taking Methylphenidate Extended Release (Teva)
- 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
- 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 have an operation as methylphenidate should not be used on the day of the operation
- If you/your child are about to start taking a new medicine, tell your doctor and pharmacist that you/your child are taking Methylphenidate Extended Release (Teva).
- If you/your child develop prolonged and painful erections, seek immediate medical attention.

Things you must not do

- Do not drink alcohol whilst you are being treated with Methylphenidate Extended Release (Teva) as it may increase the risk of side effects
- Do not use Methylphenidate Extended Release (Teva) 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.

Things to be careful of

- Methylphenidate Extended Release (Teva) 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 Extended Release (Teva) before you drive a car, operate machinery, or do anything else that could be dangerous.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You/your child may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You/your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you/your child experience any of the following and they worry you:

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, muscle tenderness or weakness, not caused by exercise
- clenching or grinding of the teeth

other changes such as:

- decreased sex drive
- feeling very tired or weak

Tell your doctor immediately if you notice any of the following:

behavioural changes such as:

- 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 being 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
- numbness and tingling feeling in fingers and toes

reproductive system changes such as:

- prolonged or painful erections

- difficulty getting and keeping an erection
- enlarged breasts in boys or men

changes in your sight, namely:

- visual disturbance
- blurred or double vision
- dilated pupils

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any Methylphenidate Extended Release (Teva) by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Take the bottle of Methylphenidate Extended Release (Teva) with you if you can.

Keep telephone numbers for these places handy.

If you/your child take too much Methylphenidate Extended Release (Teva) you/your child may experience symptoms such as vomiting, agitation, muscle twitching, hallucination, dry mouth, excessive sweating, headache, irregular heart beat, dilated pupils, convulsions/fits, breathing problems, confusion and seizures.

Storage conditions

Keep your Methylphenidate Extended Release (Teva) tablets in the bottle until it is time to take them.

Store below 30°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store Methylphenidate Extended Release (Teva), or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you/your child to stop taking Methylphenidate Extended Release (Teva) or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What Methylphenidate Extended Release (Teva) tablets look like

18 mg tablets: Capsule-shaped, biconvex, yellow coloured tablet with “2392” printed on one side in black ink.

27 mg tablets: Capsule-shaped, biconvex, grey coloured tablet with “2393” printed on one side in black ink.

36 mg tablets: Capsule-shaped, biconvex, white coloured tablet with “2394” printed on one side in black ink.

54 mg tablets: Capsule-shaped, biconvex, red-brown coloured tablet with “2395” printed on one side in black ink.

Ingredients

Tablet Core

Lactose monohydrate, hypromellose, silica (colloidal anhydrous), magnesium stearate, fumaric acid, methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methacrylate copolymer (1:2), triethyl citrate, talc.

Tablet Coating

18 mg tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide, iron oxide yellow, iron oxide red.

27 mg tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide, iron oxide yellow, indigo carmine aluminium lake, iron oxide black.

36 mg tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide.

54 mg tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide, iron oxide red.

Printing ink

Shellac glaze, iron oxide black, propylene glycol.

Who supplies this medicine

Distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

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30 August 2024

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