

**Approved Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
METHYLPHENIDATE 18/27/36/54 DRL (prolonged-release tablets)**

SCHEDULING STATUS:

S6

METHYLPHENIDATE 18 DRL, 18 mg, prolonged-release tablets

METHYLPHENIDATE 27 DRL, 27 mg, prolonged-release tablets

METHYLPHENIDATE 36 DRL, 36 mg, prolonged-release tablets

METHYLPHENIDATE 54 DRL, 54 mg, prolonged-release tablets

Methylphenidate hydrochloride

Contains sugar (lactose monohydrate)

Contains sugar: Lactose monohydrate

METHYLPHENIDATE 18 DRL contains sugar (4 mg lactose monohydrate per tablet).

METHYLPHENIDATE 27 DRL contains sugar (3,4 mg lactose monohydrate per tablet).

METHYLPHENIDATE 36 DRL contains sugar (6,6 mg lactose monohydrate per tablet).

METHYLPHENIDATE 54 DRL contains sugar (6,8 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking METHYLPHENIDATE DRL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- METHYLPHENIDATE DRL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What METHYLPHENIDATE DRL is and what it is used for

2. What you need to know before you take METHYLPHENIDATE DRL
3. How to take METHYLPHENIDATE DRL
4. Possible side effects
5. How to store METHYLPHENIDATE DRL
6. Contents of the pack and other information

1. What METHYLPHENIDATE DRL is and what it is used for

METHYLPHENIDATE DRL contains the active substance methylphenidate and is used to treat:

- Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents aged 6 to 17 years and adults aged 18 to 65 years who meet specific criteria for ADHD. ADHD is a medical condition where the child has difficulty concentrating, staying focused and sitting still.

How it works:

- METHYLPHENIDATE DRL improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour.

2. What you need to know before you take METHYLPHENIDATE DRL

Do not take METHYLPHENIDATE DRL if:

- You are allergic to methylphenidate or any of the other ingredients of METHYLPHENIDATE DRL (listed in section 6)
- You have a thyroid problem

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- You have an eating problem when you do not feel hungry or want to eat - such as “anorexia nervosa”
- You have mental health problems such as:
 - a “psychopathic” or “borderline personality” problem,
 - abnormal thoughts or visions or an illness called “schizophrenia”
 - signs of a severe mood problem like:
 - o feeling like killing yourself
 - o severe depression, where you feel very sad, worthless and hopeless
 - o mania, where you feel unusually excitable, over-active, and uninhibited
- You have been diagnosed with Bipolar disorder and the symptoms are not properly controlled
- You have increased pressure in your eye (glaucoma)
- You have a tumour of your adrenal gland (pheochromocytoma)
- You have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs.
- You have ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or were born with a heart problem.
- You have had a problem with the blood vessels in your brain - such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)

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- You are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) (see 'Other medicines and METHYLPHENIDATE DRL')
- You suffer from anxiety, tension or agitation
- You or a family member suffers from Tourette's syndrome (a condition characterised by uncontrolled speech and body movements)
- You are pregnant or breastfeeding.

Do not take METHYLPHENIDATE DRL if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions

METHYLPHENIDATE DRL treatment is not indicated in all children with ADHD. Your doctor will decide if your child should use this medicine, based on a very thorough assessment of the severity and how long your child's symptoms are in relation to their age.

- METHYLPHENIDATE DRL is not for use in children under 6 years of age and in elderly patients
- METHYLPHENIDATE DRL does not have to be taken forever. Treatment will generally stop after puberty

Talk to your doctor before taking METHYLPHENIDATE DRL if:

- You have thoughts about killing or trying to kill yourself
- You have problems with your heart (including heart defects) or an increased heartbeat. METHYLPHENIDATE DRL can increase your heart rate (pulse).

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Sudden death has been reported in patients with heart defects

- You have high blood pressure. METHYLPHENIDATE DRL can increase blood pressure
- You have low blood pressure. METHYLPHENIDATE DRL can cause dizziness or fainting in people with low blood pressure
- You have problems with sudden changes in your blood pressure or your heart rate
- You have cardiovascular disease or past medical history of stroke
- You have liver problems. You may need a lower dose.
- You have psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious
- You have mania (feeling elated or over-excited, which causes unusual behaviour) and agitation
- You have aggressive feelings
- You have unfriendly and angry (hostility) feelings
- You have a history of epilepsy or have had seizures for any other reason.
METHYLPHENIDATE DRL might lead to an increase in seizure frequency
- You have different moods than usual (mood swings) or feel very unhappy
- You have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- You have kidney problems
- You have a problem with swallowing or swallowing whole tablets
- You have a narrowing or blockage of your gut or food-pipe

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- You have had any abnormal brain scans (EEGs)
- You have ever abused or been dependent on alcohol, prescription medicines or street drugs
- You are a girl and have started your periods. See section “Pregnancy and Breastfeeding”.

Other mental health problems include:

- Feeling anxious or tense
- Feeling depressed or guilty.

Tell your doctor or pharmacist if any of the above apply to you before starting treatment.

This is because METHYLPHENIDATE DRL can make these problems worse. Your doctor will want to monitor how the medicine affects you.

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.

Children and adolescents

- If your child is not growing or gaining height or weight as expected as METHYLPHENIDATE DRL treatment may need to be interrupted.
- If your child is on long-term treatment (longer than 12 months), your doctor will monitor their weight and height.

Other medicines and METHYLPHENIDATE DRL

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Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Do not take METHYLPHENIDATE DRL with medicines called MAOIs (monoamine oxidase inhibitors) used for depression, or if you have taken an MAOI in the last 14 days. See section 2 "Do not take METHYLPHENIDATE DRL".

Tell your doctor or pharmacist if you are taking any of the following medicines for depression or anxiety:

- Tricyclic antidepressant.
- Selective serotonin reuptake inhibitor (SSRI).
- Serotonin and norepinephrine reuptake inhibitor (SNRI).

Taking METHYLPHENIDATE DRL with these type of medicines could cause a life threatening increase of serotonin in the brain (serotonin syndrome), which may lead to feeling confused or restless, sweating, shivering muscle jerks or fast heartbeat. If you develop these side effects, see a doctor straight away.

If you are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you are taking any of the following medicines, check with your doctor or pharmacist before taking METHYLPHENIDATE DRL:

- Medicines for severe mental health problems.
- Medicines for Parkinson's disease (such as levodopa).
- Medicines for epilepsy.
- Medicines used to reduce or increase blood pressure.
- Some cough and cold remedies, which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of

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these products.

- Medicines that prevents the blood from clotting.

Having an operation

Tell your doctor if you are going to have an operation. You should not take METHYLPHENIDATE DRL on the day of your surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

Drug testing

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

METHYLPHENIDATE DRL with food and drink

- METHYLPHENIDATE DRL can be taken with or without food.
- Alcohol should be avoided while taking METHYLPHENIDATE DRL. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take METHYLPHENIDATE DRL if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other health care provider for advice.

Driving and using machines

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METHYLPHENIDATE DRL may cause dizziness, drowsiness, blurred vision, hallucinations or other central nervous system side-effects, which affect concentration. If you experience such symptoms, do not drive or use machines, or do other activities that need quick reactions.

METHYLPHENIDATE DRL contains sugar (lactose monohydrate)

METHYLPHENIDATE DRL contains sugar (lactose monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking METHYLPHENIDATE DRL.

3. HOW TO TAKE METHYLPHENIDATE DRL

Do not share medicines prescribed for you with any other person.

Always take METHYLPHENIDATE DRL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

METHYLPHENIDATE DRL should not be used in children under the age of 6 years.

You should take METHYLPHENIDATE DRL once each day in the morning with a glass of water. The tablet should be swallowed whole and not chewed, broken, or crushed.

The tablet may be taken with or without food.

Your doctor will usually start treatment with a low dose and increase it gradually as required.

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The maximum daily dosage of METHYLPHENIDATE DRL is 54 mg in children aged 6 to 12 years, 72 mg in adolescents aged 13 to 18 years and 108 mg in adults.

The usual dose is:

Patients new to METHYLPHENIDATE DRL:

The recommended starting dose of METHYLPHENIDATE DRL for patients who are not currently taking METHYLPHENIDATE DRL is 18 mg once daily for children, and adolescents, and 18 or 36 mg once daily for adults.

Patients currently taking another medicine containing Methylphenidate hydrochloride, twice or three times daily:

If you are changing from your current ADHD medicine (that you take two or three times a day) to METHYLPHENIDATE DRL, your doctor will prescribe a starting dose suitable to you and gradually increase the dose if required.

Long-term treatment:

If you are undergoing long-term treatment (longer than 12 months), your doctor will discontinue your treatment from time to time to monitor your progress.

Your doctor will tell you how long your treatment with METHYLPHENIDATE DRL will last.

If you have the impression that the effect of METHYLPHENIDATE DRL is too strong or too weak, tell your doctor or pharmacist.

If you take more METHYLPHENIDATE DRL than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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Signs of overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing, headache, high fever, changes in heartbeat (slow, fast or uneven), high blood pressure, dilated pupils and dry mouth, muscle spasms, fever, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you forget to take METHYLPHENIDATE DRL

Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

If you stop taking METHYLPHENIDATE DRL

If you suddenly stop taking METHYLPHENIDATE DRL, the ADHD symptoms may come back or unwanted effects such as depression may appear. Talk to your doctor before stopping METHYLPHENIDATE DRL.

4. Possible side effects

METHYLPHENIDATE DRL can have side effects.

Not all side effects reported for METHYLPHENIDATE DRL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking METHYLPHENIDATE DRL, please consult your health care provider for advice.

If any of the following happens, stop taking METHYLPHENIDATE DRL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may

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cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to METHYLPHENIDATE DRL. You may need urgent medical attention.

Some side effects could be serious. If you have any of the side effects below, see a doctor straight away:

Frequent:

- Uneven heartbeat (palpitations)
- Mood changes or mood swings or changes in personality
- Muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system
- Reduced growth in some children when used for more than a year.

Less frequent:

- Thinking about or feeling like hurting or killing yourself
- Seeing, feeling or hearing things that are not real (these are signs of psychosis)
- Uncontrolled speech and body movements (Tourette's syndrome)
- Signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- Feeling unusually excited, overactive and uninhibited (mania)
- Heart attack
- Sudden death
- Suicidal attempt
- Fits (seizures, convulsions, epilepsy)

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- Skin peeling or purplish red patches
- Inflammation or blocked arteries in the brain
- Temporary paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain)
- Decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily
- Unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- A sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other drugs that may be taken in combination with methylphenidate.

Frequency unknown:

- Drug dependence
- Unwanted thoughts that keep coming back
- Prolonged erections, sometimes painful or an increased number of erections

If you have any of the side effects above, see a doctor straight away.

Other side effects include the following, if they get serious; please tell your doctor or pharmacist:

Frequent:

- Headache
- Feeling nervous

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- Not being able to sleep
- Joint pain
- Tension headache
- Dry mouth, thirst
- Trouble falling asleep
- Problems with sex drive
- Unusual hair loss or thinning
- Muscle tightness
- Loss of appetite or decreased appetite
- Inability to develop or maintain an erection
- Itching, rash or raised red itchy rashes (hives)
- Feeling unusually sleepy or drowsy, feeling tired
- Excessive teeth grinding (bruxism)
- Feeling of panic
- Tingling feeling, prickling, or numbness of the skin
- Increased alanine aminotransferase (liver enzyme) level in your blood
- Cough, sore throat or nose and throat irritation, upper respiratory tract infection, sinus infection
- High blood pressure, fast heart beat (tachycardia)
- Dizziness (vertigo), feeling weak, movements which you cannot control, being unusually active
- Feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour

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- High temperature (fever)
- Upset stomach or indigestion, stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick.

Less Frequent:

- Blurred vision
- Dry eyes
- Constipation
- Blood in the urine
- Listlessness
- Shaking or trembling
- Increased need to pass urine
- Muscle pain, muscle twitching, muscle cramps
- Shortness of breath or chest pain
- Feeling hot
- Increases in liver test results (seen in a blood test)
- Anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping
- Feeling disorientated or confused
- Trouble seeing or double vision
- Swelling of the breasts in men
- Excessive sweating, redness of the skin, red raised skin rash
- Muscle cramps
- Small red marks on the skin

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- Abnormal liver function including sudden liver failure and coma
- Changes in test results – including liver and blood tests
- Abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon').

Unknown frequency:

- Migraine
- Dilated pupils
- Very high fever
- Slow, fast or extra heart beats
- A major fit ('grand mal convulsions')
- Believing things that are not true
- Inability to control the excretion of urine (incontinence)
- Spasm of the jaw muscles that makes it difficult to open the mouth (Trismus)
- Chest discomfort
- Stuttering.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or your pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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By reporting side effects, you can help provide more information on the safety of METHYLPHENIDATE DRL.

5. How to store METHYLPHENIDATE DRL

Store at or below 25 °C.

Keep the bottle tightly closed in order to protect from moisture.

Do not store in a bathroom.

Do not dispose medicines in drains or sewerage systems (e.g. toilets).

Do not use after the expiry date stated on the carton.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What METHYLPHENIDATE DRL contains

The active substance is methylphenidate hydrochloride.

METHYLPHENIDATE 18 DRL:

Each prolonged-release tablet contains 18 mg methylphenidate hydrochloride.

METHYLPHENIDATE 27 DRL:

Each prolonged-release tablet contains 27 mg methylphenidate hydrochloride.

METHYLPHENIDATE 36 DRL:

Each prolonged-release tablet contains 36 mg methylphenidate hydrochloride.

METHYLPHENIDATE 54 DRL:

Each prolonged-release tablet contains 54 mg methylphenidate hydrochloride.

The other ingredients are:

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- *Tablet core:* hypromellose, macrogol, succinic acid, magnesium stearate, sodium chloride, silica colloidal anhydrous, black iron oxide (E172).
- *Film coating:* cellulose acetate, macrogol.
- *Clear coating:* hypromellose, macrogol, phosphoric acid (for pH adjustments).
- *Colour coating:* lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), yellow iron oxide (E172) (18 mg), red iron oxide (E172) (18 mg, 27 mg, 54 mg), black iron oxide (E172) (27 mg).

What METHYLPHENIDATE DRL looks like and contents of the pack

METHYLPHENIDATE 18 DRL:

Round, biconvex, yellow and homogeneous aspect film-coated tablets of approximately 8.5 mm of diameter with a hole in one side of the tablet.

METHYLPHENIDATE 27 DRL:

Round, biconvex, grey and homogeneous aspect film-coated tablets of approximately 8.5 mm of diameter with a hole in one side of the tablet.

METHYLPHENIDATE 36 DRL:

Round, biconvex, white and homogeneous aspect film-coated tablets of approximately 10 mm of diameter with a hole in one side of the tablet.

METHYLPHENIDATE 54 DRL:

Round, biconvex, pink and homogeneous aspect film-coated tablets of approximately 10 mm of diameter with a hole in one side of the tablet.

METHYLPHENIDATE DRL tablets are available in a plastic bottle, including 2 desiccant canisters, with plastic child resistant cap. The desiccant canisters are used to keep the tablets dry and should not be eaten.

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Pack size: 30 tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd

Block B, 204 Rivonia Road

Morningside

Sandton

2057

South Africa

This leaflet was last revised in

To be allocated

Registration numbers

METHYLPHENIDATE 18 DRL: 57/1.2/0036

METHYLPHENIDATE 27 DRL: 57/1.2/0037

METHYLPHENIDATE 36 DRL: 57/1.2/0038

METHYLPHENIDATE 54 DRL: 57/1.2/0039

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

<http://www.drreddys.co.za>

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2600