APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S6

RADD 18 mg (prolonged-release tablets)

Methylphenidate hydrochloride

Contains sugar (lactose monohydrate 193,50 mg)

RADD 27 mg (prolonged-release tablets)

Methylphenidate hydrochloride

Contains sugar (lactose monohydrate 194,25 mg)

RADD 36 mg (prolonged-release tablets)

Methylphenidate hydrochloride

Contains sugar (lactose monohydrate 187,50 mg)

RADD 54 mg (prolonged-release tablets)

Methylphenidate hydrochloride

Contains sugar (lactose monohydrate 174,00 mg)

Read all of this leaflet carefully before you start taking RADD

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- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- RADD 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 RADD is and what it is used for
2. What you need to know before you take RADD
3. How to take RADD
4. Possible side effects
5. How to store RADD
6. Contents of the pack and other information

1. What RADD is and what it is used for

RADD contains methylphenidate hydrochloride, one of a group of medicines called centrally acting sympathomimetics.

RADD is used:

- in children over the age of 6 years and adults in the treatment of Attention Deficit Hyperactivity Disorder (ADHD)

- only after trying treatments which do not involve medicines, such as counselling and behavioural therapy.

RADD 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 RADD

Do not take RADD:

- if you are hypersensitive (allergic) to methylphenidate hydrochloride or any of the other ingredients of RADD (see section 6)
- if you currently suffer from anxiety, tension and agitation as RADD may make these symptoms worse
- if you have poorly controlled open-angle or angle-closure glaucoma (increased pressure in your eye)
- if you have a tumour of your adrenal gland (phaeochromocytoma)
- if you are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) - (see Other medicines)
- if you or anyone in your family has been diagnosed with Tourette's syndrome (sudden, brief, intermittent movements or sounds that you have no control over)
- if you have a thyroid problem

- if you have an eating problem where you do not feel hungry or want to eat - such as anorexia nervosa
- if 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 such as feeling like killing yourself, severe depression, where you feel very sad, worthless and hopeless or mania, where you feel unusually excitable, over-active, and uninhibited
- if you have been diagnosed with Bipolar disorder and the symptoms are not properly controlled
- if you have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- if 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)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

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- RADD 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 has been experiencing these symptoms in relation to their age.
- RADD is not for use in children under 6 years of age and in elderly patients (over 65 years)
- RADD does not have to be taken forever. Treatment will generally stop after puberty

Take special care with RADD:

- if you have high blood pressure as RADD could worsen this condition
- if you have a heart problem as RADD could worsen the condition and result in unwanted side effects
- if you are at risk of any condition that may affect the blood vessels of the brain (stroke or mini-stroke, are taking medicine to increase your blood pressure) your doctor will request to see you on a frequent basis for a check-up
- if you have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words as RADD may make these conditions worse
- if you currently suffer from depression or fatigue (extreme tiredness/weakness) as RADD may worsen these conditions
- if you have a mental health problem as RADD may increase the symptoms

- if you suffer from any of the following whilst taking RADD as your dosage may need to be adjusted or discontinued: mood swings (from being manic to being depressed - called bipolar disorder); starting to be aggressive or hostile, or your aggression gets worse - seeing, hearing or feeling things that are not there (hallucinations); believing things that are not true (delusions); feeling unusually suspicious (paranoia); feeling agitated, anxious or tense; feeling depressed or guilty
- if you have ever abused or been dependent on alcohol, prescription medicines or street drugs as this could result in serious heart adverse effects
- if you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs) as RADD may make these conditions worse
- if you have thoughts about killing yourself or harming yourself whilst taking RADD it is imperative you contact your doctor immediately
- if you experience problems with your vision (blurred vision, distortion)
- if you have open-angle glaucoma or are at risk for acute angle-closure glaucoma (an eye disease)
- if you are taking antidepressants or medicines for anxiety as they may affect the way RADD works
- if you have a problem with swallowing in general, or swallowing whole tablets as RADD tablets have to be swallowed whole
- if you have a narrowing or blockage of your gut or food-pipe
- if you need to have blood screening tests for drug use, as RADD may give a positive result

- When taking RADD**,** adolescent and adult males may unexpectedly experience prolonged erections. This may be painful and can occur at any time, contact your doctor if this occurs.

Your doctor will request tests before and during your treatment with RADD, this is to monitor how RADD affects you.

RADD should be taken in the morning, before or after a meal.

Children and adolescents

- if your child is not growing or gaining height or weight as expected RADD treatment may need to be interrupted

Children and adolescents on long-term treatment (longer than 12 months) will have their weight and growth monitored by the doctor.

Other medicines and RADD

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- medicines used to reduce or increase blood pressure, as RADD may affect the way these medicines work (see Take special care with RADD).
- medicines to thin the blood (warfarin), as RADD may affect the way these medicines work

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- alcohol or medicines containing alcohol, as this may affect the way RADD works and result in unwanted side effects
- certain types of anaesthetic - you should not take RADD 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
- clonidine (used to treat high blood pressure, ADHD, anxiety and pain), as this may result in serious side effects
- medicines for depression (such as chlorpromazine, haloperidol and lithium), as these medicines may affect the way RADD works and could result in unwanted side effects
- disulfiram (used in the treatment of alcoholism) may affect the way RADD works
- medicines for severe mental health problems, as this may result in serious side effects
- medicines for epilepsy (such as ethosuximide, phenobarbital, phenytoin, primidone), as RADD may affect the way these medicines work
- edicines used to control the acidity of the urine, as they may affect the way RADD works
- medicines to increase blood pressure may affect the way these medicines work
- medicines for diarrhoea that contain furazolidone, procarbazine (used together with other chemotherapy medicines), selegiline (used in the treatment of Parkinson’s disease)

- medicines for depression or anxiety called a serotonin reuptake inhibitor (SSRI) or a serotonin and norepinephrine reuptake inhibitor' (SNRI). Taking RADD 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.

RADD with food, drink and alcohol

RADD should be taken in the morning, and can be taken with or without food.
Do not drink alcohol while taking RADD. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy, breastfeeding and fertility

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

Do not take RADD if you are pregnant or breastfeeding your baby as it is not known if RADD will harm your baby.

Driving and using machines

RADD may have a moderate influence on the ability to drive and use machines.

Since RADD may cause vision changes including blurred vision, drowsiness and dizziness you should use caution before driving or operating machinery until you know how RADD affects you. It is not always possible to predict to what extent RADD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RADD affects them.

RADD contains lactose monohydrate

RADD contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RADD.

RADD contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take RADD

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

Always take RADD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

RADD, being a prolonged-release tablet, is taken once daily, in the morning, with or without food.

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RADD must be swallowed whole with adequate liquid and must not be chewed, divided or crushed.

Your doctor will prescribe a dose suitable to you, starting you on the lowest dose and increasing the dose slowly (once a week) should this be required.

The maximum daily dosage of RADD is 54 mg in children aged 6 - 13 years; 72 mg in adolescents aged 13 - 18 years and 108 mg in adults.

The usual dose is

Patients new to RADD:

The recommended starting dose of RADD for patients who are not currently taking RADD 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 RADD, your doctor will prescribe a starting dose suitable to you and gradually increase the dose if required.

Long-term treatment:

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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 RADD will last. Do not stop treatment early because the ADHD symptoms may come back or unwanted effects such as depression may appear..

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

If you take more RADD than you should

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

Symptoms of overdose may include:

Vomiting, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), depression, confusion, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

If you forget to take RADD

If you forget to take RADD, take a dose as soon as you remember, then continue to take RADD at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking RADD

It is important that you continue the course of treatment even if you begin to feel better after a few days. If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear.

Your doctor may want to gradually reduce the amount of RADD taken each day, before stopping it completely.

4. Possible side effects

RADD can have side effects.

Not all side effects reported for RADD are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using RADD, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- seizures

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- uneven heartbeat (palpitations), increased, irregular or fast heartbeat (tachycardia), slower than normal heartbeat (bradycardia)
- mood changes or mood swings or changes in personality, confusion, depression, anxiety, aggression, delusions, abnormal behaviour, mood-swings
- thinking about or feeling like killing yourself
- hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious
- uncontrolled speech and body movements (Tourette's), seizures (fits), tremors
- feeling unusually excited, over-active and un-inhibited (mania)
- chest pain, swelling of the face, fluid accumulation in the lungs
- severe heart rhythm problems that may be life threatening (ventricular fibrillation),
- abnormal or deterioration of brain function, the occurrence of confusion, altered level of consciousness, coma
- 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

- sudden increase in body temperature, very high blood pressure and severe convulsions (Neuroleptic Malignant Syndrome)
- medicine dependence
- prolonged erections, sometimes painful or an increased number of erections
- Blood in the urine, passing more urine than is normal.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- lack of interest or concern, feeling nervous, sleep disturbances (insomnia)
- headache, dizziness, drowsiness
- joint pain, muscle tightness, muscle cramps
- vision disorder, loss of balance (vertigo)
- problems with sex drive, inability to develop or maintain an erection
- skin conditions ranging from a rash, hair loss, hives, itchy skin
- loss of appetite or decreased appetite, weight loss, anorexia
- feeling unusually sleepy or drowsy, feeling tired, tingling feeling, prickling, or numbness of the skin (pins and needles)
- cough, sore throat or nose and throat irritation, inflammation of sinuses
- high blood pressure

- feeling weak, movements which you cannot control, being unusually active, feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour, clenching or grinding your teeth, feeling of panic
- Upset stomach or indigestion, stomach pain, diarrhoea, nausea, stomach discomfort and vomiting, dry mouth, thirst.

Less frequent side effects:

- bruising, and slow blood clotting after injury, excessive bleeding
- anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, repetitive actions
- blurred vision dry eye, vision changes, double vision
- chest pain and discomfort, hot flush
- difficulty breathing, cold
- constipation
- abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, yellow eyes or skin)
- skin conditions causing blisters and peeling
- muscle pain, muscle twitching, muscle cramps
- Enlarged breast tissue in males.

The following side effects have been reported but the frequency for them to occur is not known:

- diliation of the pupil of the eye
- cold and discoloured fingers and toes (Raynaud's syndrome)
- high fever
- nosebleed
- migraine
- liver failure
- inability to control the excretion of urine (incontinence)
- A reduction in the desirable and beneficial effects of treatment.

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

By reporting side effects, you can help provide more information on the safety of RADD. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store RADD

Store all medicines out of reach of children.

Store at or below 30 °C in original container.

Keep the container tightly closed.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RADD contains

The active substance is methylphenidate hydrochloride.

RADD 18: Each prolonged-release tablet contains 18 mg methylphenidate hydrochloride.

Contains sugar (lactose monohydrate 193,50 mg).

RADD 27: Each prolonged-release tablet contains 27 mg methylphenidate hydrochloride.

Contains sugar (lactose monohydrate 194,25 mg).

RADD 36: Each prolonged-release tablet contains 36 mg methylphenidate hydrochloride.

Contains sugar (lactose monohydrate 187,50 mg).

RADD 54: Each prolonged-release tablet contains 54 mg methylphenidate hydrochloride.

Contains sugar (lactose monohydrate 174,00 mg).

The other ingredients are

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Colloidal anhydrous silica, fumaric acid, hypromellose, indigo carmine aluminium lake, iron oxide black (E172), iron oxide red (E172)[1,3], iron oxide yellow (E172)[1,2], lactose monohydrate, macrogol 3350, magnesium stearate, methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methyl methacrylate copolymer (1:2), Opacode Black S-1-17823, partially hydrolysed polyvinyl alcohol, talc, titanium dioxide (E171), triethyl citrate.

RADD contains sugar in the form of lactose monohydrate.

[1] Applicable to the 18 mg strength only.

[2] Applicable to the 27 mg strength only.

[3] Applicable to the 54 mg strength only.

What RADD looks like and contents of the pack

RADD 18 mg: Yellow, capsule-shaped, biconvex film-coated tablet with 2392 printed in black ink on one side.

RADD 27 mg: Grey, capsule-shaped, biconvex film-coated tablet with 2393 printed in black ink on one side.

RADD 36 mg: White, capsule-shaped, biconvex film-coated tablet with 2394 printed in black ink on one side.

RADD 54 mg: Red-brown, capsule-shaped, biconvex film-coated tablet with 2395 printed in black ink on one side.

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RADD tablets are packed into white, round HDPE bottles with round, white plastic child-resistant screw cap with three break-points, ring and integrated desiccant. Bottles, containing 30 tablets are packed into printed outer cartons.

Holder of Certificate of Registration

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Registration number(s)

RADD 18 mg: A51/1.2/0289

RADD 27 mg: A51/1.2/0290

RADD 36 mg: A51/1.2/0291

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RADD 54 mg: A51/1.2/0292

Radd 18 mg: NAM NS4 22/1.2/0052
Radd 27 mg: NAM NS4 22/1.2/0053
Radd 36 mg: NAM NS4 22/1.2/0054
Radd 54 mg: NAM NS4 22/1.2/0055

For access to the Professional Information, please visit

https://www.mydynamics.co.za/products-healthcare-professionals/