

PATIENT INFORMATION LEAFLET

METHYLPHENIDATE BIOTECH 10

SCHEDULING STATUS:

S6

METHYLPHENIDATE BIOTECH 10 tablets

Methylphenidate

Sugar free.

Read all of this leaflet carefully before you start taking METHYLPHENIDATE BIOTECH 10.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or healthcare provider.
- METHYLPHENIDATE BIOTECH 10 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 BIOTECH 10 is and what it is used for
2. What you need to know before you take METHYLPHENIDATE BIOTECH 10
3. How to take METHYLPHENIDATE BIOTECH 10
4. Possible side effects
5. How to store METHYLPHENIDATE BIOTECH 10
6. Contents of the pack and other information.

1. What METHYLPHENIDATE BIOTECH 10 is and what it is used for

Sign:



METHYLPHENIDATE BIOTECH 10 tablets contain the active ingredient methylphenidate.

METHYLPHENIDATE BIOTECH 10 is used for attention deficit hyperactivity disorder (ADHD) in children aged 6 years and older.

ADHD is a medical condition where the child has difficulty in paying attention and staying focused on most tasks given to them. They also tend to move around a lot and are very fidgety (making unnecessary fuss).

METHYLPHENIDATE BIOTECH 10 is also used to treat narcolepsy in adults. Narcolepsy is a chronic sleep disorder with no known cause. The main characteristic of narcolepsy is excessive and overwhelming daytime sleepiness, even after an adequate night's sleep.

2. What you need to know before you take METHYLPHENIDATE BIOTECH 10

METHYLPHENIDATE BIOTECH 10 will only be prescribed by your or your child's doctor.

Do not take METHYLPHENIDATE BIOTECH 10 if you or your child:

- are hypersensitive (allergic) to methylphenidate or any of the other ingredients of METHYLPHENIDATE BIOTECH 10 (see section 6 for other ingredients)
- suffer from anxiety, tension or agitation
- have uncontrolled speech and body movements (Tourette's syndrome) or if any other family members suffer from Tourette's syndrome
- high levels of thyroid hormone in your blood, usually caused by an overactive thyroid
- have glaucoma (increased eye pressure)
- have a tumour of the adrenal gland called phaeochromocytoma
- signs of a severe mood problem like:
 - feeling like killing yourself
 - severe depression, where you feel very sad, worthless and hopeless
 - mania, where you feel unusually excitable, over-active, and uninhibited
 - mood changes from depression to mania
- have heart problems – such as a heart attack, irregular heartbeat, chest pain (angina), heart

failure, heart disease or was born with a heart problem

- are taking a medicine called a monoamine oxidase (MAO) inhibitor used for depression or has taken an MAO inhibitor in the last 2 weeks
- are pregnant or breastfeeding your baby
- have had a problem with the blood vessels in your brain - such as a stroke (caused by a burst blood vessel or blocked blood supply to the brain), swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis).

Warnings and precautions

METHYLPHENIDATE BIOTECH 10 treatment is not indicated in all children with ADHD. Your doctor will decide if your child should use METHYLPHENIDATE BIOTECH 10, based on a very thorough assessment of the severity and how long-lasting your child's symptoms are in relation to your child's age.

Long-term use (more than 12 months)

METHYLPHENIDATE BIOTECH 10 does not need to be taken forever. If you or your child takes METHYLPHENIDATE BIOTECH 10 for more than a year, your doctor may stop treatment for a short time, this may happen during a school holiday. This will show if METHYLPHENIDATE BIOTECH 10 is still needed.

Use in adults, the elderly or children under 6 years of age

METHYLPHENIDATE BIOTECH 10 is not intended for use as a treatment for ADHD in adults or children under 6 years of age. It is not known if it is safe or of benefit in these people. Safety and efficacy have not been established in patients over 60 years of age. METHYLPHENIDATE BIOTECH 10 should not be used in patients over the age of 60 years.

Take special care with METHYLPHENIDATE BIOTECH 10 if you or your child:

- have a heart condition (including a family history of heart conditions or sudden death due to heart conditions). Contact your doctor immediately if you or your child experience fast,

irregular heartbeats, chest pain, fainting, difficulty breathing or any other symptoms suggestive of a heart disorder.

- develop any of these symptoms: severe headache, numbness, weakness, paralysis, impairment of coordination, vision, speech, language or memory.
- have mental health problems, including:
 - mood swings (from being manic to being depressed - called “bipolar disorder”)
 - starting to be aggressive or hostile, or aggression worsens
 - starting to withdraw from situations, being irritated, loss of spontaneity
 - 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, suicidal thoughts.

Contact your doctor immediately if any of the abovementioned mental health problems develop or worsen in you or your child.

- unexpectedly experience prolonged erections during treatment. This may be painful and can occur at any time. It is important to contact your doctor immediately if your or your child's erection lasts for longer than 2 hours, particularly if this is painful.
- is not growing as expected, then the treatment with METHYLPHENIDATE BIOTECH 10 may be stopped for a short time or the dose may be adjusted. When used for more than a year, METHYLPHENIDATE BIOTECH 10 may cause reduced growth in some children. Your doctor will carefully watch your or your child's height and weight, as well as how well you or your child is eating.
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs).
- have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- feel weak or tired fatigue. METHYLPHENIDATE BIOTECH 10 should not be used to prevent or treat tiredness.

- have any blood disorder (e.g. leucopenia, thrombocytopenia or anaemia).
- motor or vocal tics (involuntary, repetitive sounds or movements).

Children younger than 6 years of age

METHYLPHENIDATE BIOTECH 10 is not indicated for children under the age of 6 years.

Other medicines and METHYLPHENIDATE BIOTECH 10:

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

If you are taking other medicines, METHYLPHENIDATE BIOTECH 10 may affect how well they work or may cause side effects and vice versa. If you are taking any of the following medicines, check with your doctor or pharmacist before taking METHYLPHENIDATE BIOTECH 10:

- coumarin anticoagulants (e.g. warfarin, used to thin the blood and prevent blood clots from forming).
- anticonvulsants (e.g. phenobarbital, phenytoin and primidone, used to treat epilepsy).
- antidepressants (tricyclic or selective serotonin reuptake inhibitors used to treat depression).
- monoamine oxidase (MAO) inhibitor (used to treat depression) or have taken an MAO inhibitor in the last 2 weeks. Taking an MAO inhibitor with METHYLPHENIDATE BIOTECH 10 may cause a sudden increase in blood pressure (see **Do not take METHYLPHENIDATE BIOTECH 10** above).
- antihypertensives (medicines used in the treatment of high blood pressure).
- medicines used to elevate blood pressure (used in low blood pressure).
- anaesthetics (used before an operation). Tell your doctor if you are going to have an operation. You should not take METHYLPHENIDATE BIOTECH 10 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 and heart rate during the operation.
- alpha-2 agonists e.g. clonidine or dexmedetomidine (used to treat high blood pressure).
- medicines that influence the level of dopamine in the body (dopaminergic medicines used to

treat Parkinson's disease or psychosis).

METHYLPHENIDATE BIOTECH 10 with food, drink and alcohol:

METHYLPHENIDATE BIOTECH 10 can be taken with or without food.

Do not drink alcohol while taking METHYLPHENIDATE BIOTECH 10.

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 METHYLPHENIDATE BIOTECH 10.

Do not take METHYLPHENIDATE BIOTECH 10 if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other health care provider for advice.

Driving and using machines:

METHYLPHENIDATE BIOTECH 10 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 a vehicle, use machines, or do other activities that requires your attention.

3. How to take METHYLPHENIDATE BIOTECH 10

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

Always take METHYLPHENIDATE BIOTECH 10 exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Adults:

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The usual dose in adults is 20 mg to 30 mg daily given in divided doses 2 or 3 times daily.

Some patients may require 40 mg to 60 mg daily. In others, 10 mg to 15 mg daily will be adequate.

Patients suffering from sleeplessness when the medication is taken late in the day should take the last dose before 6 p.m. (18:00).

Daily dosage above 60 mg is not recommended.

Children and adolescents (6 years and older):

Your doctor will tell you how many tablets to give your child. The usual starting dose is 5 mg once or twice daily, gradually increased until an improvement is noticed. The highest recommended total daily dose is 60 mg.

Checks that your doctor will make before you or your child start taking METHYLPHENIDATE BIOTECH 10.

These checks are to decide if METHYLPHENIDATE BIOTECH 10 is the correct medicine for you or your child. Your doctor will talk to you about:

- Whether there any other medical problems (such as heart problems) you or your family may have.
- If there is any family history of sudden unexplained death.
- Any mental health or behaviour problems you or your child or other family members have ever had. Your doctor will discuss whether you or your child are at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check you or your child's mental health history, and check if any of your family have a history of suicide, bipolar disorder or depression.

Things your doctor will do when you or your child are on treatment

Your doctor will do some tests:

- Before you or your child start - to make sure that METHYLPHENIDATE BIOTECH 10 is safe and will be of benefit.

- After you or your child start - they will be done at least every 6 months, but possibly more often. They will also be done when the dose is changed.
- These tests will include:
 - checking appetite
 - measuring height and weight for children
 - measuring weight for adults
 - measuring blood pressure and heart rate
 - checking problems with mood, state of mind or any other unusual feelings, or if these have got worse while taking METHYLPHENIDATE BIOTECH 10.

Your doctor will tell you how long your treatment with METHYLPHENIDATE BIOTECH 10 will last. If you have the impression that the effect of METHYLPHENIDATE BIOTECH 10 is too strong or too weak, tell your doctor or pharmacist.

If you take more METHYLPHENIDATE BIOTECH 10 than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any METHYLPHENIDATE BIOTECH 10 tablets left or not.

Symptoms of overdosing include vomiting, agitation, tremors, overactive reflexes (hyperreflexia), muscle twitching, convulsions or fits (may be followed by coma), intense feeling of wellbeing (euphoria), confusion, hallucinations, acute confusional state (delirium), sweating, flushing, headache, extreme fever (hyperpyrexia), abnormally fast heartbeat (tachycardia), abnormal heartbeats (palpitation), irregular heartbeats (cardiac dysrhythmias), high blood pressure (hypertension), pupil dilatation (mydriasis), and dryness of mucous membranes.

If you forget to take METHYLPHENIDATE BIOTECH 10:

If you forget to take a dose, take it as soon as you remember. The remaining dose(s) for that day should be taken at regularly spaced intervals. Do not take a double dose to make up for forgotten

individual doses.

If you stop taking METHYLPHENIDATE BIOTECH 10:

Do not stop taking METHYLPHENIDATE BIOTECH 10 unless your doctor tells you to. Should you need to stop taking METHYLPHENIDATE BIOTECH 10, your doctor will decide which is the best method for you.

If you have any further questions on the use of METHYLPHENIDATE BIOTECH 10, ask your doctor or pharmacist.

4. Possible side effects

METHYLPHENIDATE BIOTECH 10 can have side effects.

Not all side effects reported for METHYLPHENIDATE BIOTECH 10 are included in this leaflet.

Should your or your child's general health worsen or if you or your child experience any untoward effects while taking METHYLPHENIDATE BIOTECH 10, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking METHYLPHENIDATE BIOTECH 10 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 cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to METHYLPHENIDATE BIOTECH 10. 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:

Frequently occurring side effects:

Sign: 

- Abnormal fast heart rate (tachycardia), abnormal heartbeats (palpitations), irregular heartbeats (dysrhythmias).
- Changes in blood pressure and heart rate (usually an increase).

Less frequently occurring side effects:

- Purple bruises, as well as tiny reddish-purple dots that look like a rash (thrombocytopenic purpura).
- Fits (convulsions), occurrence of involuntary movements (choreo-athetoid movements).
- Neuroleptic malignant syndrome (characterised by fever, muscular rigidity, altered mental status and autonomic dysfunction).
- Tics (involuntary, repetitive sounds or movements), exacerbation of existing tics.
- Abnormal activity (hyperactivity), loss of contact with reality (psychosis), seeing, hearing or imagining things that do not exist (hallucinations), mood changes, mood swings, or changes in personality.
- Suicidal thoughts (thinking about or feeling like killing yourself).
- Uncontrolled speech and body movements (Tourette's syndrome).
- Feeling unusually excited, overactive and uninhibited (mania).
- Chest pain (angina), heart attack.
- Fits (seizures, convulsions, epilepsy).
- Double vision (diplopia), blurred vision, inability to focus on near or far objects (visual accommodation), or other changes in vision.
- Inflammatory skin disease with redness and scaling (exfoliative dermatitis), skin rash or hives (erythema multiforme).
- Pain in your muscles (myalgia), involuntary contractions of groups of muscle (muscle twitching), muscle cramps.
- Blood in your urine (haematuria).
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon').

Side effects with an unknown frequency:

- Abnormally fast heart rhythm arising from improper electrical activity in the upper part of your heart (supraventricular tachycardia), abnormally slow heart action (bradycardia) or a heartbeat outside the normal rhythm (extrasystoles).
- Fever, feeling sick (nausea), loss in body mass, skin rash or discolouration, severe headache, fits, weakness in part of your face, difficulty speaking or difficulty walking.

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

Tell your doctor if you notice any of the following:

Frequently occurring side effects:

- Runny or stuffy nose (nasopharyngitis).
- Lack or loss of appetite for food (anorexia), moderately reduced weight gain during prolonged use in children.
- Sleeping problems, including sleeplessness (insomnia).
- Restlessness, panic attacks, stress.
- Decrease in libido (sex drive).
- Excessive teeth grinding (bruxism).
- Headache, dizziness or sleepiness, abnormal, uncontrollable, involuntary movements (dyskinesia), unintentional and purposeless motions and restlessness (psychomotor hyperactivity).
- Feeling nervous.
- Pain in joints (arthralgia).
- Exaggerated changes in mood (affect lability), feeling aggressive, agitated, anxious, depressed or irritated, abnormal behaviour
- Coughing, pain in the back of your throat (pharyngolaryngeal pain).
- Stomach pain/discomfort, diarrhoea, nausea (feeling sick), dry mouth, thirst.

- Hair loss (alopecia).
- Fever, growth failure in children.
- Shaking movement (tremor).
- Cold hands and feet.
- Shortness of breath.
- Excessive sweating.
- Feeling tired.

Less frequently occurring side effects:

- Obsessive behaviour patterns, including difficulties with social interaction and relationships (hypervigilance).
- Disorientation.
- Sexual dysfunction which is characterised as a lack of desire for sexual activity (libido disorder).
- Abnormal thinking, lack of interest (apathy), repetitive behaviours, over-focusing.
- Feeling relaxed or sleepy (sedation), reversible ischaemic neurological deficit (a type of stroke which lasts more than 24 hours and settles within a week).
- Dilatation of the pupil of your eye (mydriasis).
- Constipation.
- Breast enlargement in men (gynaecomastia).
- Inflammation of your digestive system causing an upset stomach.
- Muscle tension.

Side effects with an unknown frequency:

- Delusions, disturbed thoughts, feeling confused, relying on or being controlled by someone or something else (dependence), excessive, uncontrollable talkativeness (logorrhoea).
- Cluster headache (migraine).
- Prolonged erection, causing discomfort of the penis (sign of priapism).

- Nosebleed.
- Spasm of your jaw muscles that makes it difficult to open your mouth (lockjaw).
- Inability to control the excretion of urine (incontinence).

Laboratory test results:

Decrease in the number of white blood cells (leucopenia), decrease in blood platelets

(thrombocytopenia), decrease in number of red blood cells (anaemia).

Decreased blood cells (red and white) and platelets (pancytopenia).

Increased liver enzymes, abnormal liver function (including liver coma).

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 via the 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 METHYLPHENIDATE BIOTECH 10.

5. How to store METHYLPHENIDATE BIOTECH 10

- Store at or below 25 °C. Protect from moisture.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

Sign: 

What METHYLPHENIDATE BIOTECH 10 contains:

The active substance is methylphenidate hydrochloride.

Other ingredients are calcium hydrogen phosphate dihydrate, magnesium stearate, maize starch and microcrystalline cellulose.

What METHYLPHENIDATE BIOTECH 10 looks like and contents of the pack:

White, round, flat scored tablet marked with "RU 10" on one side. Diameter 7 mm.

PVC/aluminium blister strip, containing ten tablets. Three blister strips are packed in an outer carton.

Pack size: 30 tablets.

Holder of Certificate of Registration:

Biotech Laboratories (Pty) Ltd

Ground Floor Block K West Central Park

400 16th Road, Randjespark

Halfway House

Midrand 1685

Tel. no.: 011 848 3050

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Methylphenidate 10 Biotech: 49/1.2/1000

Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.

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