APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

METHYCAP 10 mg LA Modified release capsules

METHYCAP 20 mg LA Modified release capsules

METHYCAP 30 mg LA Modified release capsules

METHYCAP 40 mg LA Modified release capsules

Methylphenidate hydrochloride

METHYCAP 10/20/30/40 mg LA contains sugar (sucrose: 10 mg: 59,7 mg; 20 mg: 119,5 mg; 30 mg: 179,2 mg; and 40 mg: 238,9 mg respectively)

Read all of this leaflet carefully before you start taking METHYCAP LA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- METHYCAP LA 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 METHYCAP LA is and what it is used for

METHYCAP LA 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.
METHYCAP LA is used for Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years and older and in adults with ADHD onset in childhood.

ADHD is a medical condition where the child or adult 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).

METHYCAP LA is prescribed only by a specialist in behavioural disorders. This specialist will follow up your further treatment. A thorough examination is necessary. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had ADHD since childhood. Using treatment programmes as well as medicine helps to manage ADHD.

2. What you need to know before you take/use METHYCAP LA

Do not take METHYCAP LA:

- if you are hypersensitive (allergic) to methylphenidate, or to any of the ingredients of METHYCAP LA (see section 6)
- if you suffer from anxiety, tension or agitation
- if you have uncontrolled speech and body movements (Tourette's syndrome) or if any other family members suffer from Tourette's syndrome
- if you have a thyroid problem
- 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 feeling like killing yourself, severe depression (where you feel very sad, worthless and hopeless), mania (where you feel excitable, over-active and uninhibited), anorexia
- if you have increased pressure in your eye (glaucoma)
- if you have a tumour of your adrenal gland (phaeochromocytoma)
- 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
- If you have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- 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 taking a medicine called a 'monoamine oxidase inhibitor' (MOI) used for depression or have taken a MAOI in the last 2 weeks

- if you are pregnant or breastfeeding your baby.

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

Warnings and precautions

Take special care with METHYCAP LA if you or your child:

- unexpectedly experience prolonged erections during treatment, in both children and adults. 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.
- experience a combination of the following symptoms: mental status changes (e.g. agitation, hallucinations, delirium, and coma) a dysfunction of the nerves that regulate non-voluntary body functions, such as heart rate, blood pressure and sweating (irregular heartbeat, temporary high blood pressure, dizziness, excessive sweating, flushing, overheating), muscular problems (e.g. tremor, rigidity, muscle jerks, overactive or overresponsive bodily reflexes, incoordination), seizures/fits and gastrointestinal problems (e.g. nausea, vomiting, diarrhoea) while taking METHYCAP LA with medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine), stop treatment with METHYCAP LA and medicines that raise the level of serotonin in the body and tell your doctor immediately
- have a history of drug or alcohol abuse
- have had fits, epilepsy, convulsions, seizures

- have high blood pressure (hypertension)
- have any heart defects (e.g. structural cardiac abnormality) or any other current or previous heart problems
- have or have had any disorder of the blood vessels in the brain e.g. weakening of blood aneurysm, stroke, inflammation of blood vessels (vasculitis) - symptoms of vasculitis include severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory
- have acute mental disorders that cause abnormal thinking and perceptions, psychosis or feeling unusually excited, over-active and uninhibited acute mania – your doctor will have told you if you have this
- if you have depression, anorexia nervosa/anorexic disorders (an eating disorder causing people to obsess about weight and what they eat), suicidal tendencies, psychotic symptoms, severe mood disorders, mania (extremely elevated and excitable mood), schizophrenia (a disorder that affects a person's ability to think, feel and behave clearly), psychopathic/borderline personality disorder (a mental disorder characterised by unstable moods, behaviour and relationships)
- experience psychotic symptoms such as seeing or feeling things that are not really there (hallucinations)
- already have, or start to experience aggressive behaviour
- experience any suicidal thoughts or behaviour
- already have or start to experience hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words, or if any other family members suffer from tics

- have been diagnosed with any form of bipolar disorder (see Do not take METHYCAP LA)
- experience slower weight gain and slightly slower growth when using METHYCAP LA for a long time.

There is evidence that patients with ADHD may become addicted to METHYCAP LA, especially in patients who have a history of drug or alcohol abuse. METHYCAP LA will be given to you or your child only under close medical supervision and after a proper diagnosis.

METHYCAP LA is not indicated for use in children under the age of 6 years.

Other medicines and METHYCAP LA

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

Do not take METHYCAP LA if you are taking:

- a medicine called a monoamine oxidase inhibitor (MAOI), used to treat depression or have taken an MAOI in the last 2 weeks. Taking an MAOI with METHYCAP LA may cause a sudden increase in your blood pressure.

It is particularly important that you tell your doctor or pharmacist if you or your child are taking any of the following medicines:

- medicine used to treat high blood pressure
- medicines that increase blood pressure
- tricyclic antidepressants and DOPA (used to treat depression)

- medicines that influence the level of dopamine in the body (dopaminergic medicines used to treat Parkinson's disease or psychosis e.g. haloperidol)
- warfarin (anticoagulant used to prevent blood clots)
- alpha-2 agonists e.g. clonidine and dexmedetomidine (used to treat high blood pressure)
- some anticonvulsants (used to treat seizures e.g. phenobarbital, phenytoin, primidone)
- medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression, like sertraline and venlafaxine).

If you are going to have an operation, tell the doctor that you are taking METHYCAP LA. You should not take METHYCAP LA on the day of your operation 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.

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

METHYCAP LA with food and drink

METHYCAP LA can be taken with or without food.

Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Alcohol can also affect the coating of the capsule contents causing accelerated release, rather than slow release, of METHYCAP LA which could lead to toxicity.

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 using METHYCAP LA.

Do not take METHYCAP LA if you are pregnant or breastfeeding you baby (see Do not take METHYCAP LA).

Fertility

No human data on the effect of methylphenidate on fertility are available.

Driving and using machines

METHYCAP LA may cause dizziness, drowsiness, blurred vision, hallucination 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.

It is not always possible to predict to what extent METHYCAP LA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which METHYCAP LA affects you.

METHYCAP LA contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take METHYCAP LA

Do not share medicines prescribed for you with any other person. Always use METHYCAP LA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults

Your doctor will tell you how many capsules to take. The usual starting dose in patients taking METHYCAP LA for the first time is 20 mg daily.

If you have previously been treated with an immediate-release medicine containing methylphenidate for ADHD, your doctor will inform you of the relevant dosage to take.

Your doctor will monitor your progress and may increase your dose at weekly intervals in 20 mg increments.

The highest recommended daily dose in adults is 80 mg.

Children and adolescents (6 years and older):

The doctor will tell you how many capsules of METHYCAP LA to give your child. The usual starting dose is 20 mg once daily, gradually increased until an improvement is noticed. A lower dose starting at 10 mg may be recommended by your doctor. The highest recommended total daily dose is 60 mg.

When and how to take METHYCAP LA

Take METHYCAP LA once daily in the morning, with or without food. Swallow the capsule as a whole with water. Do not crush, chew or divide the capsule or the contents.

If you or your child are unable to swallow a METHYCAP LA capsule, you can sprinkle the contents on a small amount of food, as follows:

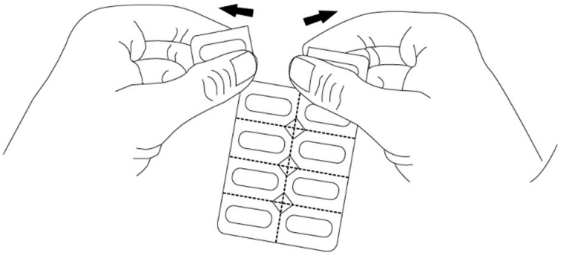
- carefully open the capsule and sprinkle the beads over a small amount of soft food (e.g. apple-sauce)
- the food should not be warm because this could affect the special properties of the beads
- immediately swallow all of the medicine/food mixture.
- this soft food mixture should not be chewed; it must be swallowed only
- do not store any medicine/food mixture for future use.

Opening instruction for the blister

This medicine is available in peelable, child resistant blisters. Please observe the following opening instruction for the blister:

1. Do not push the capsule out of the blister, as this will crush it.
2. Take the blister with the printed foil up and bend it backwards along the perforated line,

bend the blister in the opposite direction and repeat several times. Tear along the cross-perforation to pull off a single dose.



3. To take out the capsule carefully peel off the lidding foil, starting in the corner indicated by the arrow and peel it back.

If you do not feel better, tell your doctor. They may decide you need a different treatment. Your doctor will tell you how long your treatment with METHYCAP LA will last. Do not stop treatment early because stopping treatment immediately can cause unwanted side effects. If used inappropriately, this medicine may become addictive. Treatment for ADHD varies in length from patient to patient. The doctor may discontinue METHYCAP LA periodically to see whether it is still needed.

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

If you take more METHYCAP LA 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, agitation, tremors, hyperreflexia (overactive or overresponsive bodily reflexes), muscle twitching, convulsions (may be followed by coma), euphoria (a feeling or state of intense excitement and happiness), confusion, hallucinations, delirium (a serious change in mental abilities), sweating, flushing, headache, fever, irregular heartbeats, high blood pressure, mydriasis (diluted pupils), dryness of mucous membranes and red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you forget to take METHYCAP LA

METHYCAP LA capsules should not be taken too late in the morning as it may cause disturbances in sleep. If you miss your morning dose, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking METHYCAP LA

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 medicine taken each day, before stopping it completely. Talk to your doctor before stopping METHYCAP LA.

4. Possible side effects

METHYCAP LA can have side effects.

Not all side effects reported for METHYCAP LA are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using METHYCAP LA, please consult your healthcare provider for advice.

If any of the following happens, stop using METHYCAP LA 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
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to METHYCAP LA. 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)
- changes in personality, anxiety, restlessness, depression, disorientation, abnormal thinking
- excessive teeth grinding (bruxism)
- thinking about or feeling like killing yourself

- feeling, or hearing things that are not real, these are signs of psychosis or hallucinations
- uncontrolled speech and body movements (Tourette's), fits (seizures, convulsions epilepsy), fast heartbeat, chest pain, uncontrollable twitching and jerking (sign of dyskinesia)
- mood changes/mood swings, feeling unusually excited, over-active and un-inhibited (mania), disorientation, hypervigilance, confusion, dependence, delusions, thought disturbances, excessive and often incoherent talkativeness or wordiness
- tightness or pain in the chest, neck, back or arms, as well as fatigue, lightheadedness, abnormal heartbeat and anxiety (symptoms of a heart attack)
- severe headache or confusion, weakness or paralysis of limbs or face, difficulty speaking (signs of disorders of blood vessels in the brain)
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system -due to a temporary lack of blood supply to the brain
- skin peeling or purplish red patches (sign of erythema multiforme)
- skin blisters or itching (sign of exfoliative dermatitis)
- prolonged erection, causing discomfort of the penis (sign of priapism)
- 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 (thrombocytopenia)
- fatigue, weakness, dizziness, trouble breathing, fast heartbeat, fever, pale skin, purple or red spots on the skin, rash, easy bruising, and abnormal bleeding (pancytopenia).

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:

- sore throat and runny nose
- decreased appetite
- nervousness, insomnia (sleeplessness), uncontrollable outburst of laughter or crying, aggression, irritability, abnormal behaviour, lower sex drive, panic attack, stress, anxiety, restlessness, sleep disorder, agitation
- uncontrolled, involuntary muscle movement. tremors, headache, drowsiness, dizziness, restlessness or an inability to sit still, sleepiness
- high blood pressure, coldness of hands and feet
- cough, pain in your throat, difficulty breathing
- nausea, dry mouth, stomach pain and discomfort, diarrhoea, vomiting, indigestion, toothache
- rash, itching, hives, fever, hair loss, excessive sweating
- joint pain, swelling and stiffness
- feeling jittery, fever, thirst, growth retardation, fatigue
- weight loss, blood pressure and heart rate changes (increased).

Less frequent side effects:

- stomach flu
- anaemia, easy bruising, bleeding and pinpoint-sized reddish-purple spots on the lower legs, abnormal blood test results, a problem with the blood-forming stem cells in the bone marrow (symptoms include fatigue, weakness, dizziness, trouble

breathing, fast heartbeat, fever, pale skin, purple or red spots on the skin, rash, easy bruising, and abnormal bleeding)(leucopenia)

- anorexia (no appetite), reduced weight and height gain during prolonged use in children
- hyperactivity, anger, tearfulness, mood swings, apathy, tension, disorientation, repetitive behaviour, over-focusing, sex drive disorder, abuse, and dependence
- temporary muscle weakness, sedation, movement disorder, speech impediment, loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain (reversible ischaemic neurological deficit)
- blurred vision, difficulties in visual accommodation, dilated pupils, visual disturbances
- chest pain
- inflammation and/or blocking of central nervous system arteries, cold hands and feet, fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud’s phenomenon)
- constipation
- abnormal liver function including liver coma
- easy bruising, bleeding and pinpoint-sized reddish-purple spots on the lower legs, painless swelling under the skin, itchy, hive-like welts or fluid-filled blisters, peeling skin, skin rash with red bumps on a flat, red patch of skin
- muscle cramps, muscle tightness, muscle twitching, muscle pain
- blood in urine
- breast enlargement in males
- decrease in number of blood cells (red cells, white cells and platelets), blood test for

alkaline phospatase increased, heart murmur, liver enzyme increased (as per blood test).

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

- nosebleeds
- delusions, thought disturbances, lack of feeling or emotion
- migraine, convulsions/fits, inflammation and/or blocking of central nervous system arteries
- double vision
- abnormal heartbeats
- swelling of face and throat, redness of the skin, large red blotches on the skin appearing within a few hours of taking the medicine
- lockjaw
- incontinence (loss of bladder control)
- erectile dysfunction
- chest discomfort, extreme fever.

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 or 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 METHYCAP LA. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store METHYCAP LA

Store all medicines out of reach of children.

Store at or below 30 °C and protect from moisture.

Keep blisters in carton until required for use.

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 METHYCAP LA contains

The active ingredient is methylphenidate hydrochloride.

The other ingredients are:

Capsule content:

Ammonio methacrylate copolymer, methacrylic acid-methyl methacrylate copolymer, povidone, sugar spheres (sucrose and maize starch), talc, triethyl citrate.

Hard gelatin capsule size 2 (10 mg, 30 mg and 40 mg):

Gelatin, titanium dioxide, yellow iron oxide

Hard gelatin capsule size 2 (20 mg):

Gelatin, titanium dioxide

Red printing ink

Potassium hydroxide, propylene glycol, red iron oxide, shellac glaze, strong ammonia solution

What METHYCAP LA looks like and contents of the pack

METHYCAP 10 mg LA: Hard gelatin capsule size 2, with a dark yellow opaque cap and a white opaque body, imprinted with “RUB” in red ink on the cap and “M10” in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.

METHYCAP 20 mg LA: Hard gelatin capsule size 2, white opaque capsule, imprinted with “RUB” in red ink on the cap and “M20” in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.

METHYCAP 30 mg LA: Hard gelatin capsule size 2, ivory opaque capsule, imprinted with “RUB” in red ink on the cap and “M30” in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.

METHYCAP 40 mg LA: Hard gelatin capsule size 1, dark yellow opaque, imprinted with “RUB” in red ink on the cap and “M40” in red ink on the body, containing white and whitish pellets. Capsule length: 20 mm.

APPROVED PATIENT INFORMATION LEAFLET

Peelable child-resistant blisters (Aclar/PVC/Al/PET) cross-perforated

Each blister contains 10 capsules, 3 blister strips per outer carton (30 capsules).

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, 7945, Cape Town

South Africa

Tel: + 27 21 707 7000

or 0860-PHARMA (742 762)

This leaflet was last revised in

23 March 2026

Registration numbers

METHYCAP 10 mg LA: A57/1.2/0792

METHYCAP 20 mg LA: A57/1.2/0793

METHYCAP 30 mg LA: A57/1.2/0794

METHYCAP 40 mg LA: A57/1.2/0795