PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

Methylphenidate 10 LA Biotech, 10 mg modified-release hard capsules

Methylphenidate 20 LA Biotech, 20 mg modified-release hard capsules

Methylphenidate 30 LA Biotech, 30 mg modified-release hard capsules

Methylphenidate 40 LA Biotech, 40 mg modified-release hard capsules

Methylphenidate 60 LA Biotech, 60 mg modified-release hard capsules

Methylphenidate hydrochloride

Contains sugar (sucrose):

Each capsule of 10 mg contains 59,7 mg sucrose.

Each capsule of 20 mg contains 119,5 mg sucrose.

Each capsule of 30 mg contains 179,2 mg sucrose.

Each capsule of 40 mg contains 238,9 mg sucrose.

Each capsule of 60 mg contains 358,4 mg sucrose.

Read all of this leaflet carefully before you start taking Methylphenidate LA Biotech

- 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.
- Methylphenidate LA Biotech 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 LA Biotech is and what it is used for

2. What you need to know before you take Methylphenidate LA Biotech

3. How to take Methylphenidate LA Biotech

4. Possible side effects

5. How to store Methylphenidate LA Biotech

6. Contents of the pack and other information

1. What Methylphenidate LA Biotech is and what it is used for

What it is used for

Methylphenidate LA Biotech is used to treat 'attention deficit hyperactivity disorder' (ADHD).

- it is used in children aged 6 years and over and in adults who had ADHD onset in childhood.
- it is used only after other treatments which do not involve medication have been tried and have been insufficient. e. g. counselling and behavioural therapy.

Methylphenidate LA Biotech is not for use as a treatment for ADHD in children under 6 years of age.

How it works

Methylphenidate LA Biotech improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention span and concentration and reduce impulsive behaviour.
The medicine is given as part of a treatment programme, which usually includes psychological, educational and social therapy.

Methylphenidate LA Biotech treatment must only be initiated by, and used under the supervision of a doctor, specialised in the treatment of ADHD, such as an expert paediatrician, a child and adolescent psychiatrist or a psychiatrist. A careful examination by this doctor is required. If you as an adult have not been treated before, the doctor will perform tests to confirm that you have been affected by ADHD since childhood.

Although there is no cure for ADHD, it can be managed using treatment programmes.

About ADHD

Children and young people with ADHD find it:

- hard to sit still and
- hard to concentrate.

It is not their fault that they cannot do these things.

Patients can have ADHD in varying degrees with symptoms including:

- lack of concentration
- restlessness
- hyperactivity
- impulsivity
- emotional instability
- disorganised thinking

This is shown by, for example:

- difficulty concentrating
- forgetfulness
- talking too much
- difficulties in planning and carrying out tasks to completion
- blindfold actions

- impatience

ADHD does not affect the intelligence of a child or young person.

2. What you need to know before you take Methylphenidate LA Biotech

Do not take Methylphenidate LA Biotech

- if you are hypersensitive (allergic) to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- if you have a thyroid problem
- if you have increased pressure in the eye (glaucoma)
- if you have a tumour of the adrenal gland (phaeochromocytoma)
- if you have an eating problem when you do not feel hungry or want to eat - such as 'anorexia nervosa'
- 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 was born with a heart problem
- if you have had a problem with the blood vessels in the 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 currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) – see 'Other medicines and Methylphenidate LA Biotech"
- 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 like:
  - feeling like killing yourself
  - severe depression, where you feel very sad, worthless and hopeless
  - mania, where you feel unusually excitable, over-active, and un-inhibited
- if you have a history of pronounced lack of gastric acid (anacidity of the stomach) with a pH value above 5,5
- if you are taking medicines to reduce secretion of gastric acid or to treat excessive acidity of the stomach (H2 receptor blocker, proton pump inhibitor or antacid treatment)
- if you are pregnant or breastfeeding your baby

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

Warnings and precautions

You or your child will undergo a thorough assessment of your/his/her condition prior to starting treatment with Methylphenidate LA Biotech.

Methylphenidate LA Biotech treatment should not and need not, be indefinite.

Your doctor will assess your heart condition (family history and physical exam) prior to initiating treatment with Methylphenidate LA Biotech.

Take special care with Methylphenidate LA Biotech:

- if you develop heart palpitations, chest pain or difficulty breathing

- if you develop severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory during treatment
- if you have liver or kidney problems
- if you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- if you have hard-to-control, repeated twitching of any parts of the body or repeats sounds and words
- if you have a mental health problem which is not in the 'Do not take' section above. Other mental health problems include:
  - mood swings (from being manic to being depressed - called 'bipolar disorder')
  - starting to be aggressive or hostile, or 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
- if you or your child develops blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Methylphenidate LA Biotech.

Methylphenidate LA Biotech must not be used in the elderly (older than 60 years).

Your heart and blood vessel status should be monitored carefully.

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

Methylphenidate LA Biotech can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child.

Checks that your doctor will make before you start taking Methylphenidate LA Biotech

These checks are to decide if Methylphenidate LA Biotech is the correct medicine for you or your child. Your doctor will talk to you about:

- any other medicines you or your child is taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how you or your child is feeling, such as feeling high or low, having strange thoughts and if you or your child has had any of these feelings in the past
- whether there is a family history of 'tics' (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words)
- any mental health or behavioural problems you or your child or other family members have ever had.

Your doctor will discuss whether you or your child is 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.

It is important that you provide as much information as you can. This will help your doctor decide if Methylphenidate LA Biotech is the correct medicine for you or your child. Your doctor may decide that other medical tests are needed before you or your child start taking this medicine.

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.

Drug testing

Methylphenidate LA Biotech may give a positive result when testing for drug use.

Athletes must be aware that this medicine may cause a positive reaction to 'antidoping' tests.

Other medicines and Methylphenidate LA Biotech

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

Do not take Methylphenidate LA Biotech if you or your child:

- is taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression or has taken an MAOI in the last 14 days. Taking an MAOI with Methylphenidate LA Biotech may cause a sudden increase in blood pressure.

If you or your child is taking other medicines, Methylphenidate LA Biotech may affect how well they work or may cause side effects. Tell your doctor if you or your child is taking medicines to treat:

- depression
- mental health problems
- epilepsy
- blood pressure problems, especially a medicine called clonidine
- cough and colds. Some remedies contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products

- medicines that thin the blood to prevent blood clots

Methylphenidate LA Biotech must not be taken together with H2 receptor blockers, proton pump inhibitors or antacids which are used to reduce gastric acid secretion or to counteract excessive acidity in the stomach, as this could lead to a faster release of the total amount of active substance.

If you are in any doubt about whether any medicines you or your child is taking are included in the list above, ask your doctor or pharmacist for advice before taking Methylphenidate LA Biotech.

Having an operation

Tell your doctor if you or your child is going to have an operation. Methylphenidate LA Biotech should not be taken on the day of 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.

Methylphenidate LA Biotech with alcohol

Do not drink alcohol while taking Methylphenidate LA Biotech. 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, 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 this medicine.

Methylphenidate LA Biotech should not be taken during pregnancy or when breast-feeding. Tell your doctor or pharmacist before using Methylphenidate LA Biotech if you or your daughter:

- is having sex. Your doctor will discuss contraception.
- is pregnant or think she might be pregnant.
- is breastfeeding or planning to breastfeed. It is possible that methylphenidate is passed into human breast milk.

Driving and using machines

You or your child may feel dizzy, have problems focussing or have blurred vision when taking Methylphenidate LA Biotech. If these happen, you should not drive, use machines, ride a bike or horse or climb trees.

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

Methylphenidate LA Biotech contains sucrose

If you or your child has been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this Methylphenidate LA Biotech.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium free'.

3. How to take Methylphenidate LA Biotech

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

Always take Methylphenidate LA Biotech exactly as your doctor or pharmacist has told you. Check with

your doctor or pharmacist if you are not sure.

Use in children

The maximum daily dose is 60 mg.

- your doctor will usually start treatment with a low dose and increase it gradually as required.
- your doctor will tell you what strength of capsule to take each day.
- do not split the dose of a capsule; take the entire contents.
- Methylphenidate LA Biotech should not be taken too late in the morning as it may cause disturbances in sleep.

Use in adults

For adults who have taken Methylphenidate LA Biotech before

- if you have already taken Methylphenidate LA Biotech as a child or adolescent, the same daily dosage (mg/day) can be used; your doctor will check regularly to see if any adjustment is required
- adult patients may require a higher daily dosage, but the doctor will aim to give you the lowest dose that is effective
- the maximum daily dose is based among other things on your body weight (see below)

For adults who have not taken Methylphenidate LA Biotech before

The recommended starting dose is 10 mg daily.

- your doctor will increase your dose in increments of 10 mg daily, depending on how well you tolerate the medicine and how effective it is
- the aim should be the lowest dose that is effective for you

- your doctor will decide the maximum daily dose for you
- the daily dose is 1 mg per kg body weight, up to a maximum of 80 mg of methylphenidate daily

Things your doctor will do when you or your child is undergoing treatment

Your doctor will do some tests

- before you or your child starts - to make sure that Methylphenidate LA Biotech is safe and will be of benefit.
- after you or your child starts - 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 LA Biotech.

Method of administration

Methylphenidate LA Biotech is intended for oral use.

Children take Methylphenidate LA Biotech in the morning with or without food.

Adults take Methylphenidate LA Biotech in the morning and at lunchtime with or without food.

Methylphenidate LA Biotech is a form of methylphenidate with “controlled release“ action which releases

the medicine gradually over a prolonged period of time. Taking the capsule with or after meals is very important in order for their action to be delayed.

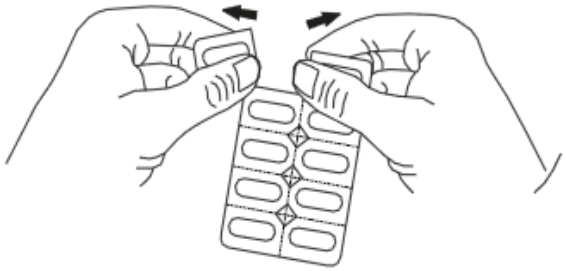
The capsules may be swallowed whole with a drink of water. Alternatively, you can open the capsules, sprinkle the contents onto a small amount (tablespoon) of applesauce or yoghurt and take it immediately. Do not store for future use.

The capsules and the capsule contents must not be crushed or chewed.

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 or your child does not feel better after 1 month of treatment

If you or your child does not feel better, tell your doctor. They may decide a different treatment is needed.

Long-term treatment

Methylphenidate LA Biotech does not need to be taken for ever. If you or your child takes Methylphenidate LA Biotech for more than a year, your doctor should stop treatment at least once per year for a short time. In case of children this may happen during a school holiday. This will show if the medicine is still needed.

Not using Methylphenidate LA Biotech properly

If Methylphenidate LA Biotech is not used properly, this may cause abnormal behaviour. It may also mean that you or your child starts to depend on the medicine. Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.

If you take more Methylphenidate LA Biotech than you should

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

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 heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

If you forget to take Methylphenidate LA Biotech

Do not take a double dose to make up for forgotten individual doses.

If you stop taking Methylphenidate LA Biotech

If you or your child suddenly stops taking this medicine, 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 Methylphenidate LA Biotech.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Methylphenidate LA Biotech can have side effects.

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

If any of the following happens, stop taking Methylphenidate LA Biotech 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 LA Biotech. 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:

Frequent side effects

- uneven heartbeat (palpitations)
- mood changes

Less frequent side effects

- 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
- changes in personality
- seeing, feeling or hearing things that are not real- these are signs of psychosis
- uncontrolled speech and body movements (Tourette's) or worsening of it
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome').
- paralysis or problems with movement and vision, temporary lack of adequate blood and oxygen (ischemia) to the brain
- chest pain

- thinking about or feeling like killing yourself
- feeling unusually excited, over-active and un-inhibited (mania)
- heart attack
- fits (seizures, convulsions, epilepsy)
- 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

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:

- cold
- decreased appetite
- weight loss
- not being able to sleep
- feeling agitated, feeling nervous
- feeling aggressive, emotional unstable, anxious, stressed, irritable
- excessive teeth grinding (bruxism)
- panic attack
- feeling depressed or lack of feeling or emotion or showing much interest
- decreased sex drive
- headache
- feeling unusually sleepy or drowsy
- feeling dizzy

- movements which you cannot control
- being unusually active
- fast heart beat (tachycardia) or irregular heart beat (dysrhythmia)
- high blood pressure or other changes of blood pressure
- cough, sore throat or nose and throat irritation
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst, feeling sick vomiting
- dry mouth
- tooth ache
- unusual hair loss or thinning
- itching, rash or raised red itchy rashes (hives)
- excessive sweating
- joint pain
- high temperature (fever)
- shaking, tired
- thirsty

Less frequent side effects

- shaking or trembling
- inflammation of the mucous membranes of stomach and small intestine
- feeling tearful, excessive awareness of surroundings, tension
- abnormal thinking
- lack of energy
- obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking,

having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

- a movement disorder that makes it hard for you to stay still
- feeling very calm or sleepy
- double or blurred vision
- dilated pupils, trouble seeing
- difficulty in focusing of eye
- dry eye
- pain resulting from not enough blood flow to the heart
- inflammation or blocked arteries in the brain
- fingers and toes feeling numb, tingling and changing colour from white to blue, then red when cold ('Raynaud's phenomenon')
- constipation
- abnormal liver function which could lead to altered level of consciousness as a result of liver failure
- painless swelling under the skin, triggered by an allergy to animal dander, pollen, drugs, venom, food or medication
- muscle pain twitching tightness, muscle cramps
- blood in the urine
- swelling of the breasts in men
- problems/changes in the menses
- changes in sex drive
- sudden death
- extra sound during heart beat (based on investigation findings)

Not known: frequency cannot be estimated from available data

- pancytopenia (abnormal decrease in the levels of all type of blood cells)
- believing things that are not true
- confusion
- excessive uncontrolled talking
- abuse
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- a major fit (‘grand mal convulsions’)
- migraine
- tingling sensation
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)
- higher pressure inside the eye than normal
- slow, fast or extra heart beats
- hot flush / flushing
- pain in the area of mouth and throat
- nose bleeding
- retching
- dry skin
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- inability to control the excretion of urine (incontinence)
- erectile dysfunction

- prolonged erections, sometimes painful, or an increased number of erections
- breast pain
- very high fever
- disturbance in attention
- influenza like illness
- increases in blood thyroid stimulating hormone levels
- stress with partner / family
- ringing in the ears (tinnitus)
- stuttering or stammering (dysphemia)

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

Effects on growth

When used for more than a year, Methylphenidate LA Biotech may cause reduced growth in some children.

- There may be lack of weight gain or height.
- Your doctor will carefully watch you or your child's height and weight, and how well you or your child is eating.
- If you or your child is not growing as expected, then treatment with Methylphenidate LA Biotech may be stopped.

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 Methylphenidate LA Biotech.

5. How to store Methylphenidate LA Biotech

Store all medicines out of reach of children.

Store at or below 30 °C.

If the capsules are removed from the blister, it should be used within 4 months.

Do not use this medicine after the expiry date which is stated on the carton box and blister after {EXP}. The expiry date refers to the last day of that month.

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 Methylphenidate LA Biotech contains

- The active substance is methylphenidate hydrochloride.

Methylphenidate 10 LA Biotech: Each modified-release hard capsule contains 10 mg methylphenidate hydrochloride (equivalent to 8,65 mg methylphenidate).

Methylphenidate 20 LA Biotech: Each modified-release hard capsule contains 20 mg methylphenidate hydrochloride (equivalent to 17,3 mg methylphenidate).

Methylphenidate 30 LA Biotech: Each modified-release hard capsule contains 30 mg methylphenidate hydrochloride (equivalent to 25,95 mg methylphenidate).

Methylphenidate 40 LA Biotech: Each modified-release hard capsule contains 40 mg methylphenidate hydrochloride (equivalent to 34,6 mg methylphenidate).

Methylphenidate 60 LA Biotech: Each modified-release hard capsule contains 60 mg methylphenidate

hydrochloride (equivalent to 51,9 mg methylphenidate).

- The other ingredients are:

Capsule contents: ammonio methacrylate copolymer (type B), methacrylic acid-methyl methacrylate copolymer (1:1), povidone 30, sugar spheres, talc, triethyl citrate.

Capsule shell: gelatin, titanium dioxide (E171).

Additionally in Methylphenidate 10 LA Biotech, Methylphenidate 30 LA Biotech, Methylphenidate 40 LA Biotech and Methylphenidate 60 LA Biotech: Iron oxide yellow (E172).

Printing ink

Potassium hydroxide

Propylene glycol

Red iron oxide (E 172)

Shellac glaze

Strong ammonia solution

What Methylphenidate LA Biotech looks like and contents of the pack

Methylphenidate 10 LA Biotech modified-release hard capsules:

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.

Methylphenidate 20 LA Biotech modified-release hard capsules:

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.

Methylphenidate 30 LA Biotech modified-release hard capsules:

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.

Methylphenidate 40 LA Biotech modified-release hard capsules:

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.

Methylphenidate 60 LA Biotech modified-release hard capsules:

Hard gelatin capsule size 0, with a dark yellow opaque cap and an ivory opaque body, imprinted with “RUB” in red ink on the cap and “M60” in red ink on the body, containing white and whitish pellets. Capsule length: 22 mm.

Child resistant unit-dose blisters (white opaque Aclar/PVC//Al/PET) boxed in cardboard cartons.

10 mg: 28, 30, 50, 56, 60, 100 capsules.

20 mg: 28, 30, 50, 56, 60, 84, 100 capsules.

30 mg: 28, 30, 50, 56, 60, 100 capsules.

40 mg: 28, 30, 50, 56, 60, 100 capsules.

60 mg: 28, 30, 50, 56, 60, 100 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Methylphenidate 30 LA Biotech: 57/1.2/0760

Methylphenidate 40 LA Biotech: 57/1.2/0761

Methylphenidate 60 LA Biotech: 57/1.2/0762

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.