

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

**Riavenir LA 10 mg**

**Modified-release capsules**

Each capsule contains:

methylphenidate hydrochloride 10 mg

**Riavenir LA 20 mg**

**Modified-release capsules**

Each capsule contains:

methylphenidate hydrochloride 20 mg

**Riavenir LA 30 mg**

**Modified-release capsules**

Each capsule contains:

methylphenidate hydrochloride 30 mg

**Riavenir LA 40 mg**

**Modified-release capsules**

Each capsule contains:

methylphenidate hydrochloride 40 mg

**Riavenir LA 60 mg**

**Modified-release capsules**

Each capsule contains:

methylphenidate hydrochloride 60 mg

**Inactive ingredients:** See section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

### **Abuse, misuse and addiction**

Riavenir LA has a high potential for abuse and misuse, which can lead to substance use problems, including addiction. Abuse and misuse of central nervous system (CNS) stimulants, including Riavenir LA, can lead to overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

## **1. What is this medicine intended for?**

For treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**Therapeutic group:** Central nervous system stimulant.

Riavenir LA contains the active ingredient methylphenidate hydrochloride. Methylphenidate hydrochloride is a central nervous system stimulant.

Riavenir LA capsules are used to treat Attention Deficit Hyperactivity Disorder (ADHD or hyperkinetic disorder), which is a behavioral disorder in children, adolescents and adults. About 3% of children suffer from this disorder, which makes them unable to sit still or concentrate on tasks for any length of time. Children with this disorder may have difficulty in learning and doing homework.

It may frequently be difficult to manage them both in school and at home.

Adults with ADHD often find it hard to concentrate. They often feel restless, impatient, inattentive and become bored easily. They may experience difficulty organizing their private life and work.

Riavenir LA is assumed to work by regulating specific chemicals in the brain that affect behavior. It helps focus attention, shut out distraction and allows impulsive people to think before they act. If treatment is successful, it improves the person's natural ability to be attentive.

This medicine is part of a treatment program which usually also includes psychological, educational and social therapy.

If you have any question about how Riavenir LA works or why this medicine has been prescribed for you or your child, refer to your doctor.

## **2. Before using this medicine**

### **Do not use this medicine:**

- if you are allergic (hypersensitive) to methylphenidate (the active ingredient) or to any of the other ingredients in this medicine, listed in section 6 'Additional information'. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or breathing difficulties; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

### **Do not take Riavenir LA if you have the following medical conditions:**

- periods of anxiety, tension or agitation

- Tourette's syndrome (a condition of uncontrolled body movements and speech or tics) or if you have a family history of this disorder
- increased pressure in the eye (glaucoma)
- an overactive thyroid or other thyroid problems
- heart problems such as heart attack, irregular heartbeat, chest pain (severe angina), heart failure, heart disease or a congenital heart problem
- very high blood pressure (hypertension) or narrowing of the arterial blood vessels (arterial occlusive disease, that can cause pain in the arms and legs)
- a rare tumor of the adrenal gland, known as pheochromocytoma

**If you are unsure whether you are suffering from any of the medical conditions listed above, ask the doctor.**

**Do not take Riavenir LA if you are taking a medicine from the monoamine oxidase (MAO) inhibitors group or if you took MAO inhibitors within the 14 days before starting Riavenir LA treatment.** Taking Riavenir LA together with medicines from the MAO inhibitors group may cause a severe reaction, which includes a sudden rise in body temperature, extremely high blood pressure and severe convulsions.

**If you are not sure if you took any of these medicines, ask the doctor.**

### **Special warnings about using this medicine:**

**Tell the doctor if you are allergic to any other medicine, food, dyes or preservatives.**

The doctor will want to know if you are prone to allergies.

### **Abuse, misuse and addiction**

Riavenir LA use has a high potential for abuse and misuse, which can lead to substance use problems, including addiction. Abuse and misuse of Riavenir LA, other medicines containing methylphenidate and medicines containing amphetamine, can lead to overdose and death. The risk of overdose and death increases with higher doses of Riavenir LA or when Riavenir LA is used in ways that are not approved, such as snorting or injection.

- The doctor should check you or your child's risk for abuse, misuse and addiction before starting treatment with Riavenir LA, and will monitor you or your child during the course of treatment.
- Riavenir LA may lead to physical dependence after prolonged use, even if taken in accordance with the doctor's instructions.
- Do not give Riavenir LA to anyone else: **Methylphenidate may be a target for people who abuse prescription medicines or street drugs.** Store this medicine in a safe place to protect it from theft. Never give your medicine to anyone else, as it may cause death or harm them. Selling or giving Riavenir LA to others may harm them and is against the law.
- Store this medicine in a safe place and properly dispose of any medicine that was not used (see chapter 5 'How should this medicine be stored?').
- Tell your doctor if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.

**Before treatment with Riavenir LA, tell the doctor if you are suffering from any of the listed medical conditions or behaviors:**

- heart defects (e.g., structural cardiac abnormality)
- tics (muscle twitching which is usually in the face or shoulders) or if your brothers or sisters have tics

- family history of sudden death or irregular heartbeat
- hardening of the arteries
- any other previous or current heart problem
- abnormality of the blood vessels in the brain, e.g., weakening of the blood vessel (aneurysm), stroke or inflammation of blood vessels (vasculitis)
- severe depression, bipolar disorder or other mental illnesses
- suicidal thoughts or behavior
- epilepsy (seizures, convulsions or fits)
- high blood pressure
- acute mental disorders that cause abnormal thinking and perceptions (psychosis) or an unusual feeling of excitement, hyperactivity and disinhibition (acute mania) - the doctor will tell you if you have these conditions
- psychotic symptoms such as seeing or feeling things that are not really there (hallucinations)
- Aggressive behavior
- you have or develop eye problems, including increased pressure in your eye, glaucoma or problems with your close-up vision (far-sightedness)

If you have any of the conditions listed above, the doctor may want to take special precautionary measures.

### **Additional warnings**

- Riavenir LA may give a false-positive result when testing for drug use. This includes testing used in sports
- Some children receiving long-term Riavenir LA may have slower growth, but, will usually catch up once the treatment is discontinued (also see sections 'Duration of treatment' and 'Tests and follow-up')
- In some patients, Riavenir LA may cause abdominal discomfort, loss of appetite and sleeping difficulties, especially at the beginning of treatment. The doctor can help reduce these symptoms by lowering the Riavenir LA dose or by changing the time of administration of the medicine
- If you experience abnormally sustained or frequent and painful erections of the penis on Riavenir LA treatment or after treatment discontinuation, you may need urgent medical treatment. This can occur in any age group. **If this happens, refer to a doctor immediately**
- If you are taking Riavenir LA with medicines that raise the serotonin level in the body (serotonergic medicines, e.g., sertraline and venlafaxine, used to treat depression), and you experience a combination of the following symptoms: restlessness, tremors, sudden muscle contractions, abnormally high fever, nausea and vomiting, stop treatment with Riavenir LA and these medicines and refer to your doctor immediately
- If you are due to undergo surgery, inform the doctor that you are taking Riavenir LA. Do not take Riavenir LA on the day of surgery in case a certain type of anesthetic is used, since there is a chance of a sudden increase in blood pressure during surgery

### **Children and adolescents**

This medicine is not indicated for use in children under 6 years of age.

### **Tests and follow-up**

Be sure to come to follow-up visits to the doctor so that treatment progress can be monitored. To prevent occurrence of side effects, the doctor will periodically measure your blood pressure and perform blood tests.

If your child is not growing taller or gaining weight as expected, it may be necessary to take breaks in administration of Riavenir LA.

## **Drug interactions**

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**

Some medicines and Riavenir LA that are taken together may interfere with each other. These medicines include:

- medicines that increase blood pressure
- oral anticoagulants or warfarin (medicines used to prevent blood clots)
- alpha-2 receptor agonists like clonidine (used to treat high blood pressure)
- medicines to treat depression, such as tricyclic antidepressants and monoamine oxidase (MAO) inhibitors
- certain anti-convulsants (medicines used to treat epilepsy or convulsions)
- phenylbutazone (to treat pain or fever)
- guanethidine
- anesthetics
- medicines that influence the level of dopamine in the body (dopaminergic medicines used to treat Parkinson's disease or psychosis)
- medicines that raise the serotonin level in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine)

It may be necessary to change the dosage of your medicines or you may have to take other medicines. Consult your doctor.

If you did not inform the doctor of the other medicines you are taking, consult the doctor before taking Riavenir LA.

If you are about to start treatment with a new medicine, remind your doctor, dentist, or pharmacist that you are being treated with Riavenir LA.

## **Using this medicine and food**

Riavenir capsules may be taken with or without food.

## **Using this medicine and alcohol consumption**

Do not drink alcohol while being treated with Riavenir LA. Remember that certain foods and medicines contain alcohol.

Drinking alcohol may exacerbate some of the side effects of Riavenir LA, such as dizziness and drowsiness.

## **Pregnancy and breastfeeding**

## **Pregnancy**

Do not use Riavenir LA during pregnancy, unless the doctor explicitly prescribed it. This medicine may affect the unborn baby, if you take it during pregnancy.

If you became pregnant while being treated with Riavenir LA, consult the doctor. The doctor will discuss the risks and benefit of taking the medicine during pregnancy with you.

## **Breastfeeding**

Do not breastfeed while being treated with Riavenir LA. The active ingredient in Riavenir LA can pass into breast milk.

## **Driving and using machines**

Exercise caution when driving, operating machines or performing activities that require alertness while being treated with Riavenir LA, until you know how this medicine affects you.

This medicine may cause hallucinations, dizziness, drowsiness, blurred vision or other central nervous system side effects that may impair some people's ability to concentrate. If you experience any of these symptoms, do not drive a car, operate machines or perform activities that require rapid reactions or that may be dangerous.

Children should be cautioned against riding a bicycle, playing near a road, and the like.

## **3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

### **Dosage:**

Riavenir LA is available in modified-release capsules containing 10 mg, 20 mg, 30 mg, 40 mg or 60 mg of methylphenidate hydrochloride as the active ingredient.

The dosage and treatment regimen will be determined by the doctor only, according to the patient's needs and response to treatment.

Do not change the dosage without consulting the doctor.

If you think that the effect of the medicine is too strong or too weak, consult the attending doctor.

### **Do not exceed the recommended dose.**

### **Duration of treatment:**

Continue taking Riavenir LA for the duration of time instructed by the doctor.

This medicine helps regulate the symptoms, but does not cure them. The doctor will check the improvement in your condition in order to confirm that the medicine is working properly and will discuss the question of how long to continue treatment with you.

Treatment for ADHD varies in length from patient to patient. During the course of treatment of ADHD, the doctor may tell you to stop taking Riavenir LA for certain periods of time (e.g.,

on weekends or school vacations) to see if it is still necessary to take it. These treatment breaks also help prevent a slow-down in growth that sometimes occurs when children take this medicine for a long time.

**Method of administration:**

Riavenir LA can be taken with or without food.

Swallow the capsule whole, once daily in the morning, with a full glass of water. Do not crush or chew the capsules.

If the patient is unable to swallow the capsule, the capsule can be carefully opened and its content (small beads) sprinkled on a small amount of soft food (e.g., applesauce):

- Make sure the food is not hot because this could affect the special properties of the beads inside the capsule
- Immediately eat all of the medicine/food mixture
- Do not store the mixture for future use

If the capsules cause you abdominal discomfort, they can be taken with food, but make sure to always take them the same way (i.e., always with food or always without food). In this way, the effect will always be the same.

**If you have accidentally taken a higher dose** or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Do this even if you do not experience any signs of poisoning or discomfort.

Some of the symptoms of overdose are: vomiting, agitation, headache, tremors, muscle twitching, irregular heartbeat, flushing, fever, sweating, dilated pupils, breathing difficulties, confusion, seizures and muscle spasms accompanied by fever and red-brown urine.

**If you forget to take the medicine** at the scheduled time, and you remembered before midday, take a dose as soon as you remember and go back to your usual schedule the following day.

If you did not remember to take it before midday, skip the missed dose and take the next dose the next morning, as usual. Do not take two doses together to compensate for the missed dose. If you do so, you may increase the chance of side effects.

If it is hard for you to remember when to take your medicine, consult the pharmacist.

Adhere to the treatment as recommended by your doctor.

**If you stop taking this medicine**

Even if your health improves, do not stop taking this medicine without consulting your doctor. If you stop treatment suddenly, your medical condition may return to its pretreatment state or side effects, such as depression, may appear. In order to avoid this, the doctor may tell you to reduce the daily dose gradually before stopping treatment completely. Medical supervision after stopping treatment is necessary.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

**Tell your doctor as soon as possible, if you do not feel well while you are taking Riavenir LA.**

Like with all medicines, using Riavenir may cause side effects in some users. Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

**Report to the doctor immediately or proceed to an emergency room in the following cases:**

- signs of an allergy, such as: swelling of the face and throat, lips or tongue, shortness of breath, wheezing or breathing difficulties. These are signs of a severe allergic reaction
- weakness or paralysis of the limbs or face, difficulty speaking or unexplained fainting
- skin rash, itching, red blotches on the skin, blisters or peeling of the skin
- sudden increase in body temperature, sweating, fast heartbeat, chest pain, muscle stiffness and blood pressure fluctuations, which may lead to coma
- constant “flu-like” symptoms such as chills, fever, sore throat and runny nose, swollen glands, aching muscles or joints
- unusual bleeding or skin bruising
- unusual tiredness, shortness of breath when exercising, dizziness, pale skin
- involuntary shaking of the body (signs of tremor), such as uncontrollable twitching, jerking or writhing movements
- seizures (fits) or unexplained fainting
- pain or tightness in the chest
- fast or irregular heartbeat
- yellowing of the skin or eyes, dark-colored urine or light-colored stools
- confusion, hallucinations or delusions (seeing or feeling things that are not really there)
- excitement, hyperactivity and uninhibited behavior
- severe or persistent headache
- uncontrolled speech and body movements (Tourette’s syndrome)
- prolonged erection, causing discomfort of the penis (sign of priapism)
- thoughts or attempts of killing yourself (suicidal ideation or attempt, including completed suicide)
- Fingers and toes feeling numb, feeling cold, tingling and changing color (from white to blue, and then red) when cold (Raynaud’s phenomenon, peripheral coldness)
- seizures and uncontrolled writhing (dyskinesia)
- abnormal reduction in the levels of blood cells of all types. This is associated with anemia, reduced platelets and reduced white blood cells. This can lead to tiredness, increased risk of bleeding and/or increased chance of infection. This can be severe or lifethreatening (pancytopenia)

The side effects listed above may be serious. Urgent medical attention may be necessary.

**Additional side effects:**

Tell the doctor if you notice any of the following effects and it worries you:

Very common side effects (effects that occur in more than 1 in 10 users):

- nausea
- loss of appetite
- sore throat and runny nose
- nervousness
- inability to sleep
- dry mouth

Common side effects (effects that occur in 1-10 in 100 users):

- vomiting or abdominal pain
- upset stomach or indigestion
- feeling nervous, anxious or agitated
- feeling jittery
- restlessness
- sleep disorders
- headache
- cough
- drowsiness
- dizziness
- irritability
- hair loss
- hives (urticaria)
- joint pain
- toothache
- excessive sweating
- abnormal heart rhythm
- palpitations
- sensation of excessive emotional distress or excitement
- decreased weight
- feeling depressed
- feeling aggressive
- excessive teeth grinding

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- trismus - spasm of the jaw muscles that makes it difficult to open the mouth

Rare side effects (effects that occur in 1-10 in 10,000 users):

- weight loss and slowed growth in children
- blurred vision or visual focus disturbances

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- transient depressed mood
- muscle cramps
- anemia (a reduction in the number of red blood cells), leukopenia (a reduction in the number of white blood cells), thrombocytopenia (a reduction in the number of platelets)

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- stuttering
- bedwetting in children at night

- chest pain, tiredness
- inability to develop or maintain an erection, swelling of the breasts in men
- inflammation of the nasopharyngeal airways
- swelling of the ears (sign of an allergic reaction)
- irritability, aggressiveness, mood changes, abnormal behavior or thinking, anger, excessive awareness of surroundings, unusually excited feeling, hyperactivity and uninhibited behavior (mania), disorientation, libido changes, lack of emotion or feeling, doing things over and over again, obsession with one thing, confusion, addiction
- temporary muscle weakness, loss of skin sensation or of other functions of the body due to a temporary lack of blood supply to the brain (reversible ischemic neurological deficit), migraine
- double vision, dilated pupils, vision difficulty
- absence of a pulse, heart attack
- sore throat, shortness of breath
- diarrhea, constipation
- skin reddening, large red patches on the skin that appear within a few hours of taking the medicine
- muscle pains, muscle twitching
- increased eye pressure (increased intraocular pressure)

Additional side effects that occurred with other medicines that contain the same active ingredient as Riavenir LA:

- blood in the urine
- sudden death
- 
- abnormal sounds from the heart

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

Reporting side effects:

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.

## **6. Additional information**

**In addition to the active ingredient, this medicine also contains:**

methacrylic acid-methyl methacrylate copolymer (1:1), triethyl citrate, talc, cellulose spheres, ethylcellulose, hydroxypropylcellulose, hypromellose, diluted hydrochloric acid.

Capsule shell: gelatin, titanium dioxide, iron oxide yellow (10, 30, 40 and 60 mg capsules only).

Printing ink: shellac glaze, iron oxide black, propylene glycol.

**What the medicine looks like and contents of the pack:**

Riavenir LA 10 mg, 20 mg, 30 mg, 40 mg and 60 mg capsules contain beads in a shade of white to cream with a spherical shape.

Riavenir LA 10 mg is marketed as hard capsules for modified release. The capsules have a yellow cap with a white opaque body. The cap and the body of the capsules are imprinted with "10" in black.

Riavenir LA 20 mg is marketed as hard, opaque white capsules for modified release. The cap and the body of the capsules are imprinted with "20" in black.

Riavenir LA 30 mg is marketed as hard, opaque ivory capsules for modified release. The cap and the body of the capsules are imprinted with "30" in black.

Riavenir LA 40 mg is marketed as hard, opaque yellow capsules for modified release. The cap and the body of the capsules are imprinted with "40" in black.

Riavenir LA 60 mg is marketed as hard capsules for modified release. The capsules have an ivory cap with a white opaque body. The cap and the body of the capsules are imprinted with "60" in black.

Each Riavenir LA package contains 30 or 100 capsules in a bottle with a child-resistant cap. Not all pack sizes may be marketed.

**Registration holder's name and address:** BioAvenir Ltd., 1 David Hamelech Street, Herzliya Pituach 4666101.

**Manufacturer's name and address:**

Develco Pharma GmbH, Grienmatt 27,79650 Schopfheim, Germany

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**Registration number of the medicine in the Ministry of Health's National Drug Registry:**

Riavenir LA 10 mg: 167-43-36188-00

Riavenir LA 20 mg: 167-44-36189-00

Riavenir LA 30 mg: 167-45-36190-00

Riavenir LA 40 mg: 167-46-36191-00

Riavenir LA 60 mg: 167-47-36664-99

