

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor’s prescription only

RITALIN® LA 10 mg Modified-release capsules

Each capsule contains: Methylphenidate Hydrochloride 10 mg

RITALIN® LA 20 mg Modified-release capsules

Each capsule contains: Methylphenidate Hydrochloride 20 mg

RITALIN® LA 30 mg Modified-release capsules

Each capsule contains: Methylphenidate Hydrochloride 30 mg

RITALIN® LA 40 mg Modified-release capsules

Each capsule contains: Methylphenidate Hydrochloride 40 mg

Inactive ingredients: See section ‘Important information regarding some of the ingredients of the medicine’ and section 6 ‘Further Information’.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Therapeutic group: Central nervous system stimulant.

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

Ritalin 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.

Ritalin 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 Ritalin LA works or why this medicine has been prescribed for you or your child, refer to your doctor.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are allergic (hypersensitive) to Methylphenidate (the active ingredient) or to any of the other ingredients contained in the medicine, listed in section 6 “Further 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 Ritalin LA if you are suffering from 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 are suffering from any of the medical conditions listed above, ask the doctor.

Do not take Ritalin 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 Ritalin LA treatment. Taking Ritalin 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 regarding use of the 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.

Before treatment with Ritalin 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
- history of alcohol addiction, drug abuse or drug dependence

- 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

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

Additional warnings

- Ritalin LA may give a false-positive result when testing for drug use. This includes testing used in sports
- Some children receiving long-term Ritalin 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, Ritalin 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 Ritalin 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 Ritalin 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 Ritalin 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 Ritalin LA and these medicines and refer to your doctor immediately.
- If you are due to undergo surgery, inform the doctor that you are taking Ritalin LA. Do not take Ritalin 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 intended for 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 in height or gaining weight as expected, breaks in the Ritalin LA administration may be necessary.

Drug interactions

If you are taking or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist.

Some medicines and Ritalin 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 the doctor.

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

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

Use of the medicine and food

Ritalin LA capsules may be taken with or without food.

Use of the medicine and alcohol consumption

Do not consume alcohol during the course of treatment with Ritalin LA. Remember that certain foods and medicines contain alcohol.

Alcohol consumption may exacerbate some of the side effects of Ritalin LA, such as dizziness and drowsiness.

Pregnancy and breast-feeding

Pregnancy

Do not use Ritalin 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 Ritalin LA, consult the doctor. The doctor will discuss with you the risks and benefit of taking the medicine during pregnancy.

Breast-feeding

Do not breast-feed during the course of treatment with Ritalin LA. The active ingredient in Ritalin LA can pass into breast milk.

Driving and using machines

Exercise caution when driving, operating machines or performing activities that require alertness during the course of treatment with Ritalin 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 or playing near the road, and the like.

Important information regarding some of the ingredients of the medicine

The preparation contains sugar. 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 SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Dosage:

Ritalin LA is available in modified-release capsules containing 10 mg, 20 mg, 30 mg or 40 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.

When and how to take Ritalin LA:

Ritalin 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.

Duration of treatment:

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

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

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 Ritalin 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.

If you accidentally took a higher dosage or if a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine 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 forgot to take the medicine at the designated time, and you remembered before mid-day, 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 mid-day, 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 the doctor.

As with all stimulants, **this medicine can be addictive and abused by certain people**. If you take it properly, as instructed by the doctor, abuse or dependence should not be a problem, neither now nor in the future.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If you stop treatment suddenly, your medical condition may return to its pretreatment state or side effects, such as depression, may occur. 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 the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

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

As with any medicine, use of Ritalin LA may cause side effects in some users. Do not be alarmed by 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 face, 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)

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:

- stuttering
- bedwetting in children at night

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

- Inflammation of the nasal passages and throat
- A reduction in the number of blood cells (red blood cells, white blood cells and platelets) at once
- Swelling of the ears (a sign of an allergic reaction)
- Irritability, aggression, mood changes, abnormal behavior or thinking, anger, excessive awareness of surroundings, feeling unusually excited, over-active and uninhibited (mania), disorientation, change in sex drive, lack of feeling or emotion, doing things over and over again, being obsessed with one thing, confusion, addiction
- Temporary muscle weakness, loss of skin sensation or 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, trouble seeing
- Stopped heartbeat, heart attack
- Sore throat, shortness of breath
- Diarrhea, constipation
- Swelling of face and throat, reddening of the skin, large red blotches on the skin appearing within a few hours of taking the medicine
- Muscle pain, muscle twitching
- Blood in the urine
- Swelling of the breasts in men
- Chest pain, tiredness, sudden death
- Abnormal sounds from the heart

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 30°C. Keep the container tightly closed in order to protect from moisture. After first opening the bottle, use within 6 months.
- Do not use if the package is damaged or shows signs of tampering.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Sugar spheres, ammonio methacrylate copolymer type B, methacrylic acid copolymer type A, talc, triethyl citrate, polyethylene glycol 6000, titanium dioxide, gelatin, iron oxide yellow (10 mg, 30 mg and 40 mg capsules only), iron oxide black (10 mg and 40 mg capsules only), iron oxide red (10 mg and 40 mg capsules only) and tan-colored printing ink.

Each Ritalin LA 10 mg capsule contains about 61 mg sugar.

Each Ritalin LA 20 mg capsule contains about 123 mg sugar. Each Ritalin LA 30 mg capsule contains about 184 mg sugar. Each Ritalin LA 40 mg capsule contains about 246 mg sugar.

What the medicine looks like and the contents of the package:

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

Ritalin LA 10 mg is marketed as hard gelatin capsules for modified release. The capsules have a light brown opaque cap with a white opaque body. The cap and the body of the capsules are imprinted with “NVR” and “R10” in yellowish brown, respectively.

Ritalin LA 20 mg is marketed as hard gelatin, opaque white capsules for modified release. The cap and the body of the capsules are imprinted with “NVR” and “R20” in yellowish brown, respectively.

Ritalin LA 30 mg is marketed as hard gelatin, opaque yellow capsules for modified release. The cap and the body of the capsules are imprinted with “NVR” and “R30” in yellowish brown, respectively.

Ritalin LA 40 mg is marketed as hard gelatin, opaque light brown capsules for modified release. The cap and the body of the capsules are imprinted with “NVR” and “R40” in yellowish brown, respectively.

Each Ritalin LA package contains 30 or 100 capsules. Not all package sizes may be marketed.

Registration holder and address:

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Name of manufacturer and address: Recro Gainesville LLC, Gainesville, USA **for** Novartis Pharma AG, Basel, Switzerland.

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

Ritalin LA 10 mg: 146 50 33288

Ritalin LA 20 mg: 130 61 30935

Ritalin LA 30 mg: 130 60 30936

Ritalin LA 40 mg: 130 59 30937

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