



PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Ritalin® 10 mg Tablets

Each tablet contains:
Methylphenidate Hydrochloride 10 mg

Ritalin® SR 20 mg Tablets

Each tablet contains:
Methylphenidate Hydrochloride 20 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) and for treatment of narcolepsy.

Therapeutic group: Central nervous system stimulant.

Ritalin tablets contain the active ingredient methylphenidate hydrochloride. Methylphenidate hydrochloride is a central nervous system stimulant.

Attention Deficit Hyperactivity Disorder (ADHD or hyperkinetic disorder) 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 is assumed to work by regulating specific chemicals in the brain that affect behavior. It helps to focus attention, shut out distraction and allows impulsive people to think before they act. If treatment is successful, it improves the natural ability of the person to be attentive.

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

Narcolepsy is a sleep-attack disorder. It is not a normal state of fatigue. Patients with narcolepsy experience recurring attacks of irresistible day-time sleep, despite adequate night-time sleep. Narcolepsy must be diagnosed by a doctor by recording wake-sleep patterns.

Ritalin relieves excessive day-time sleepiness in patients suffering from narcolepsy.

Do not use this medicine to prevent or treat normal fatigue.

If you have any question about how Ritalin 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 this medicine:

- if you are allergic (hypersensitive) to the active ingredient methylphenidate, or to any of the other ingredients the medicine contains listed in section 6 'Further Information'. Some of the symptoms of 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 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 (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 if you are suffering from any of the medical conditions listed above, ask the doctor.

Do not take Ritalin 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 treatment. Taking Ritalin 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.

Tell the doctor if you have an intolerance to lactose or gluten (also see section: 'Important information regarding some of the ingredients of the medicine').

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

- heart defects (e.g., structural cardiac abnormality)
- a family history of sudden death or irregular heartbeat
- hardening of the arteries
- any other current or previous heart problem
- abnormality of blood vessels in the brain e.g., weakening of the blood vessels (aneurysm), stroke or inflammation of blood vessels (vasculitis)
- severe depression, bipolar disorder or other mental illnesses
- epilepsy (seizures, convulsions or fits)
- high blood pressure
- history of addiction to alcohol, drugs or drug dependence
- tics (muscle twitching, usually in the face or shoulders) or if your brothers or sisters have tics
- acute mental disorders that cause abnormal thinking and perception (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
- suicidal thoughts or behavior

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

Additional warnings

Ritalin may give a false-positive result when testing for drug use. This includes testing used in sports.

Some children receiving Ritalin for a long time may have a slowdown in growth, however, they will usually catch up once the treatment is stopped (also see sections: 'Duration of treatment' and 'Tests and follow-up')

In some patients, Ritalin may cause upset stomach, loss of appetite and sleeping difficulties, especially at the beginning of treatment. The doctor can help reduce these symptoms by lowering the Ritalin dose or by changing the dosing times of the tablets

Use of the medicine and alcohol consumption

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

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

Use of the medicine and food

Ritalin 10 mg tablets: may be taken with or without food (e.g. at breakfast or lunch).

Ritalin SR 20 mg tablets: take immediately after a meal and preferably after a substantial breakfast.

Swallow the tablet whole with water.

Do not chew or crush the tablet.

Ritalin SR 20 mg tablets can not be halved.

If the tablets 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.

When and how to take Ritalin SR 20 mg tablets:

Take Ritalin SR 20 mg tablets immediately after a meal and preferably after a substantial breakfast.

Swallow the tablet whole with water.

Do not chew or crush the tablet.

Ritalin SR 20 mg tablets can not be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

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 this medicine, consult a doctor or pharmacist.

If you are about to begin treatment with a new medicine, remind your doctor and pharmacist that you are being treated with Ritalin.

Tell every doctor, dentist or pharmacist treating you that you are taking Ritalin.

Swallow the tablet with a full glass of water.

Ritalin 10 mg tablets can be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

Additional warnings

Ritalin may give a false-positive result when testing for drug use. This includes testing used in sports

Some children receiving Ritalin for a long time may have a slowdown in growth, however, they will usually catch up once the treatment is stopped (also see sections: 'Duration of treatment' and 'Tests and follow-up')

In some patients, Ritalin may cause upset stomach, loss of appetite and sleeping difficulties, especially at the beginning of treatment. The doctor can help reduce these symptoms by lowering the Ritalin dose or by changing the dosing times of the tablets

Use of the medicine and alcohol consumption

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

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

Use of the medicine and food

Ritalin 10 mg tablets: may be taken with or without food (e.g. at breakfast or lunch).

Ritalin SR 20 mg tablets: take immediately after a meal and preferably after a substantial breakfast.

Swallow the tablet whole with water.

Do not chew or crush the tablet.

Ritalin SR 20 mg tablets can not be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

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 this medicine, consult a doctor or pharmacist.

3. SIDE EFFECTS

As with any medicine, use of Ritalin 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.

Ritalin SR 20 mg tablets can not be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

Additional warnings

Ritalin may give a false-positive result when testing for drug use. This includes testing used in sports

Some children receiving Ritalin for a long time may have a slowdown in growth, however, they will usually catch up once the treatment is stopped (also see sections: 'Duration of treatment' and 'Tests and follow-up')

In some patients, Ritalin may cause upset stomach, loss of appetite and sleeping difficulties, especially at the beginning of treatment. The doctor can help reduce these symptoms by lowering the Ritalin dose or by changing the dosing times of the tablets

Use of the medicine and alcohol consumption

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

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

Use of the medicine and food

Ritalin 10 mg tablets: may be taken with or without food (e.g. at breakfast or lunch).

Ritalin SR 20 mg tablets: take immediately after a meal and preferably after a substantial breakfast.

Swallow the tablet whole with water.

Do not chew or crush the tablet.

Ritalin SR 20 mg tablets can not be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

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 this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ritalin 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.

Ritalin SR 20 mg tablets can not be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

Additional warnings

Ritalin may give a false-positive result when testing for drug use. This includes testing used in sports

Some children receiving Ritalin for a long time may have a slowdown in growth, however, they will usually catch up once the treatment is stopped (also see sections: 'Duration of treatment' and 'Tests and follow-up')

In some patients, Ritalin may cause upset stomach, loss of appetite and sleeping difficulties, especially at the beginning of treatment. The doctor can help reduce these symptoms by lowering the Ritalin dose or by changing the dosing times of the tablets

Use of the medicine and alcohol consumption

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

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

Use of the medicine and food

Ritalin 10 mg tablets: may be taken with or without food (e.g. at breakfast or lunch).

Ritalin SR 20 mg tablets: take immediately after a meal and preferably after a substantial breakfast.

Swallow the tablet whole with water.

Do not chew or crush the tablet.

Ritalin SR 20 mg tablets can not be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

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 this medicine, consult a doctor or pharmacist.

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 that appears on the package. The expiry date refers to the last day of that month.

Storage conditions: Store below 25°C. Store in the original packaging in order to protect from moisture.

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:

Ritalin 10 mg tablets:

Wheat starch, lactose crystal, calcium phosphate tribasic, talc, gelatin, magnesium stearate.

Each tablet of Ritalin 10 mg tablets contains 40 mg lactose as well as 48 mg wheat starch (contains gluten).

Ritalin SR 20 mg tablets:

Lactose monohydrate, cetylstearyl alcohol, hypromellose, talc, magnesium stearate, titanium dioxide, polyoxyl hydrogenated castor oil, carnauba wax and fine black ink.

Each tablet of Ritalin SR 20 mg tablets contains 90 mg lactose monohydrate.

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

Ritalin 10 mg tablets:

Marketed in tablet form. The package contains 30 tablets.

Ritalin 10 mg tablets are white, round, flat with beveled edges, with "CG" stamped on one side and "A/B" and a score line on the other side.

Ritalin SR 20 mg tablets:

Marketed in tablet form. The package contains 30 tablets.

Ritalin SR 20 mg tablets are white to cream colored, round, biconvex, with beveled edges and film-coated. The tablets are marked with the wording "CIBA" in black on one side, and "16" on the other.

Ritalin SR 20 mg tablets can not be halved.

Side effects of unknown frequency:

- stuttering
- bedwetting in children at night

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

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 that are taken together, may interfere with each other. These medicines include:

- medicines that increase blood pressure
- alpha-2 receptor agonists like clonidine (used to treat high blood pressure)
- oral anticoagulants or warfarin (medicines used to prevent blood clots)
- certain anticonvulsants (to treat epilepsy or fits)
- medicines to treat depression, such as tricyclic antidepressants and monoamine oxidase (MAO) inhibitors
- severe depression, bipolar disorder or other mental illnesses
- epilepsy (seizures, convulsions or fits)
- high blood pressure
- history of addiction to alcohol, drugs or drug dependence
- tics (muscle twitching, usually in the face or shoulders) or if your brothers or sisters have tics
- acute mental disorders that cause abnormal thinking and perception (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
- suicidal thoughts or behavior

If you accidentally took a higher dosage or if a child accidentally swallowed the medicine, refer immediately to