

## APPROVED PATIENT INFORMATION LEAFLET

Scheduling Status: **S6**

**Proprietary name and dosage form:**

**RITALIN® 10 Tablets**

**RITALIN® LA 10 Capsules**

**RITALIN® LA 20 Capsules**

**RITALIN® LA 30 Capsules**

**RITALIN® LA 40 Capsules**

**Please read this leaflet carefully before using RITALIN Tablets or Capsules**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **RITALIN** 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.

### **1. What RITALIN contains**

#### **RITALIN tablet 10 mg, divisible**

- The **active substance** of RITALIN is methylphenidate hydrochloride.

The **other ingredients** are calcium phosphate, lactose, wheat starch, gelatine, magnesium stearate and talc.

RITALIN 10 tablets contain lactose.

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### **RITALIN LA capsule 10 mg, 20 mg, 30 mg or 40 mg, extended-release capsule, hard**

- The **active substance** of RITALIN is methylphenidate hydrochloride.
- The **other ingredients** are ammonio methacrylate copolymer, black iron oxide (E172) (10 and 40 mg capsules only), gelatine, methacrylic acid copolymer, macrogol, red iron oxide (E172) (10 and 40 mg capsules only), sucrose sugar spheres, talc, titanium dioxide (E171), triethyl citrate, and yellow iron oxide (E172) (10, 30 and 40 mg capsules only).

**RITALIN LA capsules** contains sucrose.

### **2. What RITALIN is used for**

RITALIN is used for Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years and older and in adults with ADHD onset in childhood. ADHD is a medical condition where the child has difficulty in paying attention and staying focused on most tasks given to them. They also tend to move around a lot and are very fidgety (making unnecessary fuss).

*RITALIN 10 only:*

Narcolepsy in adults. Narcolepsy is a chronic sleep disorder with no known cause. The main characteristic of Narcolepsy is excessive and overwhelming daytime sleepiness, even after an adequate night's sleep.

### **3. Before you take RITALIN**

RITALIN will only be prescribed by your or your child's doctor.

#### **Do not take RITALIN if you or your child:**

- Are allergic (hypersensitive) to methylphenidate or to any of the other ingredients of RITALIN listed in the beginning of this leaflet.
- Have an overactive thyroid.
- Have glaucoma (increased eye pressure).
- Suffer from anxiety, tension or agitation.
- Have uncontrolled speech and body movements (Tourette's syndrome) or if any other family members suffer from Tourette's syndrome.

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- Have a tumour of the adrenal gland called phaeochromocytoma.
- Have heart problems – such as a heart attack, irregular heartbeat, chest pain (angina), heart failure, or heart disease or were born with a heart problem.
- Have high blood pressure (hypertension) or narrowing of the blood vessels (arterial occlusive disease) which can cause pain in the arms and legs.
- Are taking a medicine called a ‘monoamine oxidase inhibitor’ (MOI) used for depression or have taken a MAOI in the last 2 weeks.

If you think that any of these may apply to you or your child, tell the doctor without taking RITALIN.

### **Take special care with RITALIN if you or your child:**

- experience abnormally sustained or frequent and painful erections of the penis on RITALIN treatment or after treatment discontinuation. This can occur in any age group and may need urgent medical treatment. If this occurs, tell your doctor immediately.
- experience a combination of the following symptoms: restlessness, tremor, sudden muscle contractions, abnormal high temperature and nausea and vomiting while taking methylphenidate with medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine), stop treatment with methylphenidate and medicines that raise the level of serotonin in the body and tell your doctor immediately.
- Have a history of drug or alcohol abuse.
- Have had fits, epilepsy, convulsions, seizures.
- Have high blood pressure (hypertension).
- Have any heart defects (e.g. structural cardiac abnormality).
- Have any other current or previous heart problems.
- Have or have had any disorder of the blood vessels in the brain e.g. weakening of blood aneurysm, stroke, inflammation of blood vessels (vasculitis).

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- Have acute mental disorders that cause abnormal thinking and perceptions, psychosis or feeling unusually excited, over-active and uninhibited acute mania – your doctor will have told you if you have this.
- Have psychotic symptoms such as seeing or feeling things that are not really there (hallucinations).
- Have aggressive behaviour.
- Have any suicidal thoughts or behaviour.
- Have motor tics or if any other family members suffer from tics. Signs of tics are hard to control, repeated twitching of any parts of the body or repeating sounds and words.

If any of these applies to you, tell your doctor. He/she will decide if you can start/continue taking RITALIN.

There is evidence that patients with ADHD may become addicted to RITALIN, and may tend to abuse drugs later in life. RITALIN will be given to you or your child only under close medical supervision and after a proper diagnosis.

Do not drink alcohol whilst taking this medicine.

Laboratory test for amphetamines may be falsely positive.

### **RITALIN and children**

RITALIN is not recommended for children under 6 years of age.

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### Pregnancy and Breastfeeding

**Do not take RITALIN if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other healthcare professional for advice.**

If you are pregnant or think you may be pregnant, tell your doctor. You must not use RITALIN during pregnancy unless specifically prescribed by your doctor.

### Breastfeeding mothers

If you are breastfeeding, tell your doctor. You must not use RITALIN if you are breastfeeding. If you are taking RITALIN, you must not breastfeed your baby.

### Driving and using machines

RITALIN may cause dizziness, drowsiness, blurred vision, hallucination or other central nervous system side-effects, which affect concentration. If you experience such symptoms, do not drive or use machines, or do other activities that need quick reactions.

### Important information about some of the ingredients of RITALIN

If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking RITALIN 10 tablets.

RITALIN 10 tablets contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take RITALIN 10.

RITALIN LA capsules contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

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### Taking other medicines with RITALIN

**Tell your doctor or pharmacist** if you are taking or have recently taken any other medicine, including herbal or non-prescription medicines.

It may be necessary to change the dose or in some cases to stop one of the medicines.

Do not take RITALIN if you are taking

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

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

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

**Always tell your healthcare professional if you are taking any other medicine, including complementary and traditional medicines.**

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### Having an Operation

If you are going to have an operation, tell the doctor that you are on treatment with RITALIN. You should not take RITALIN on the day of your operation if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

### 4. How to use RITALIN

Do not share medicines prescribed for you with others.

The doctor will decide on the most suitable dosage according to the individual patient's medical need and response. Always take or give RITALIN exactly as the doctor has instructed you.

### How much to take

Do not change the dose without talking to your or your child's doctor.

If you have the impression that the effect of RITALIN is too strong or too weak, talk to your or your child's doctor.

### Children

The doctor will tell you how many tablets/capsules of RITALIN to give your child. The usual starting dose is 5 mg once or twice daily gradually increased until an improvement is noticed. The highest recommended total daily dose is 60 mg.

### Adults

Your doctor will tell you how many tablets/capsules to take. The usual daily dose is 20 to 30 mg but some patients may need more or less than this.

The highest recommended daily dose is 60 mg for the treatment of narcolepsy and 80 mg for the treatment of ADHD.

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

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### When and how to take RITALIN

Do not drink alcohol whilst taking RITALIN. Alcohol may make the side-effects of RITALIN worse.

Remember that some foods and medicines contain alcohol.

- **RITALIN tablet 10 mg:** Take RITALIN once or twice daily (e.g. at breakfast or/and lunch time). Swallow the tablet with water.
- **RITALIN LA capsule:** Take RITALIN LA once daily in the morning, with or without food. Swallow the capsule as a whole with water. Do not crush, chew or divide the capsule or the contents.

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

- Carefully open the capsule and sprinkle the beads over a small amount of soft food (e.g. apple-sauce).
- The granules must be swallowed whole and not chewed or crushed.
- The food should not be warm because this could affect the special properties of the beads.
- Immediately eat all of the medicine/food mixture.
- This soft food mixture **should not be chewed**; it must be swallowed only.
- Do not store any medicine/food mixture for future use.

RITALIN LA capsules taken once daily are comparable to RITALIN tablets taken twice a day. The doctor will advise you how to take RITALIN LA capsules especially if you were previously taking RITALIN tablets.

In some patients RITALIN may cause sleeplessness. To avoid difficulty in falling asleep, the last dose of RITALIN should be taken before 6 p.m. unless the doctor recommends otherwise.

### How long to take RITALIN

Use this medicine exactly as instructed by the doctor.

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Do not use more of it, do not use it more often, and do not use it for longer than instructed by the doctor. If used inappropriately, this medicine may become addictive.

Treatment for ADHD varies in length from patient to patient. It may be stopped during or after puberty.

The doctor may discontinue RITALIN periodically to see whether it is still needed.

### **If a RITALIN dose is missed**

If a dose of RITALIN is missed, you or your child should take it as soon as possible. The remaining doses for that day should be taken at regularly spaced intervals. Do not take a double dose of RITALIN to make up for missed dose. If you have any questions about this, check with your doctor.

### **If you or your child take more RITALIN than you should**

If too many RITALIN are accidentally taken, go immediately to the doctor or to the nearest hospital emergency department. Tell the doctor at what time the tablets or capsules were taken. You/your child may require medical attention.

The symptoms of overdose are vomiting, agitation, headache, tremors, muscle twitching, irregular heartbeat, flushing, fever, sweating, dilated pupils, breathing difficulties, confusion and fits; muscle spasms, fever, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

### **5. Possible Side-effects**

RITALIN can have side-effects.

Not all side-effects reported for RITALIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RITALIN, please consult your doctor, pharmacist or other healthcare professional for advice.

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**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

### ***Less frequent***

- Swelling of throat, lips or tongue, or difficulty in breathing (signs of severe allergic reaction)
- Sudden high fever, very high blood pressure and severe convulsions (Neuroleptic Malignant Syndrome)
- Severe headache or confusion, weakness or paralysis of limbs or face, difficulty speaking (signs of disorders of blood vessels in the brain)
- Fast heartbeat; chest pain; uncontrollable twitching and jerking (sign of dyskinesia)
- Bruising (sign of thrombocytopenia purpura)
- Muscle twitching or tics
- A sore throat and fever or chills (signs of a **low white blood cell count**)
- Uncontrollable writhing movements of the limb, face and/or trunk (choreoathetoid movements)
- Seeing or feeling things that are not really there (hallucinations)
- Fits (seizures, convulsions, epilepsy)
- Skin blisters or itching (sign of exfoliative dermatitis)
- Red blotches on the skin (sign of erythema multiforme)
- Prolonged erection, causing discomfort of the penis (sign of priapism)

These are all serious side-effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

### **Frequent**

- Sore throat and runny nose
- Nervousness
- Skin rash, itchy rash and hives (urticaria)
- Fever

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- Nausea, vomiting, stomach pain, dry mouth, upset stomach, indigestion, toothache
- Headache, dizziness, sleepiness
- Involuntary trembling of the body (sign of tremor)
- Changes in blood pressure (usually an increase), abnormal heart rhythm, palpitation
- Cough
- Hair loss
- Decreased appetite
- Difficulty in falling asleep
- Excessive emotional distress, troubled sleep disturbance, emotional excitement, restlessness
- Excessive sweating
- Joint pain
- Decreased weight
- Feeling jittery

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### Less frequent:

- Muscle cramps
- Blurred vision
- Depressed mood
- Slowing of growth (height and weight) during prolonged use in children
- Low red blood cell count (anaemia), low platelet count (thrombocytopenia)
- Unusually active
- Uncontrolled speech and body movements (Tourette's syndrome)
- Abnormal liver function including liver coma

### Additional side-effects that occurred with RITALIN:

- Decrease in number of blood cells (red cells, white cells and platelets)
- Swelling of the ears (a symptom of allergic reaction)
- Irritated, aggression, mood changes, abnormal behaviour or thinking, anger, thoughts or attempts of suicide (including completed suicide), excessive awareness of surroundings, feeling unusually excited, over-active and uninhibited (mania), feeling disorientated, changes 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 ischaemic neurological deficit), migraine
- Double vision, dilated pupils, trouble seeing
- Stopped heart beat, heart attack
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon')
- Sore throat, shortness of breath
- Diarrhoea, constipation

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- Swelling of face and throat, redness 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 heart

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

### 6. Storage and disposing of RITALIN

#### RITALIN® 10:

Store at or below 25 °C and protect from moisture. Do not store in bathroom.

KEEP OUT OF THE REACH OF CHILDREN.

#### RITALIN® LA capsules:

Store at or below 25 °C. Keep the container tightly closed. Protect from moisture. Do not store in bathroom.

KEEP OUT OF THE REACH OF CHILDREN.

Do not use after the expiry date stated on the label or carton.

Any unused product or waste material should be disposed of in accordance with local requirements.

Keep all medicines out of the reach and sight of children.

Return any unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### 7. Presentation

RITALIN® 10 is supplied as tablets of 10 mg in blister packs of 30.

RITALIN® LA is available in white HDPE bottles containing 30 and 100 modified-release capsules.

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### 8. Identification

#### **RITALIN® 10:**

White, round tablet, flat on both sides, with bevelled edges. Imprinted “CG” on one side, and “A/B” with a score on the other. Diameter approximately 7,0 mm; thickness approximately 2,5 mm.

#### **RITALIN® LA 10**

Size # 2, modified-release hard gelatine capsule with a light brown opaque cap and a white opaque body, imprinted with “NVR” in tan ink on the cap and “R10” in tan ink on the body, containing white to off-white beads that are roughly spherical in shape.

#### **RITALIN® LA 20**

Size # 2, modified-release white opaque hard gelatine capsule, imprinted with “NVR” in tan ink on the cap and “R20” in tan ink on the body, containing white to off-white beads that are roughly spherical in shape.

#### **RITALIN® LA 30**

Size # 2, modified-release yellow opaque hard gelatine capsule, imprinted with “NVR” in tan ink on the cap and “R30” in tan ink on the body, containing white to off-white beads that are roughly spherical in shape.

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### RITALIN® LA 40

Size # 1, modified-release light brown opaque hard gelatine capsule, imprinted with “NVR” in tan ink on the cap and “R40” in tan ink on the body, containing white to off-white beads that are roughly spherical in shape.

#### 9. Registration number:

RITALIN® 10	B/1.2/1610
RITALIN® LA 10	44/1.2/0594
RITALIN® LA 20	36/1.2/0186
RITALIN® LA 30	36/1.2/0187
RITALIN® LA 40	36/1.2/0188

#### 10. Name and address of the registration holder

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#### 11. Date of publication of the Patient Information Leaflet

29 September 2017