

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S6

### METHYLPHENIDATE HCL-DOUGLAS 10 mg, tablets

**Methylphenidate Hydrochloride**

**Contains sugar: Lactose 53 mg**

**Read all of this leaflet carefully before you start taking METHYLPHENIDATE HCL-DOUGLAS 10 mg**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- METHYLPHENIDATE HCL-DOUGLAS 10 mg 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 HCL-DOUGLAS 10 mg is and what it is used for
2. What you need to know before you take METHYLPHENIDATE HCL-DOUGLAS 10 mg
3. How to take METHYLPHENIDATE HCL-DOUGLAS 10 mg
4. Possible side effects
5. How to store METHYLPHENIDATE HCL-DOUGLAS 10 mg
6. Contents of the pack and other information

## **1. What METHYLPHENIDATE HCL-DOUGLAS 10 mg is and what it is used for**

METHYLPHENIDATE HCL-DOUGLAS 10 mg is used for Attention-Deficit Hyperactivity Disorder (ADHD) in children that are aged 6 years and older. ADHD is a medical condition where the child experiences difficulty in staying focused and paying attention and have a tendency to move around a lot and fidget.

Narcolepsy in adults. Narcolepsy is a chronic sleep disorder characterised by excessive daytime sleepiness.

## **2. What you need to know before you take METHYLPHENIDATE HCL-DOUGLAS 10 mg**

METHYLPHENIDATE HCL-DOUGLAS 10 mg will be prescribed by your or your child's doctor.

### **Do not use METHYLPHENIDATE HCL-DOUGLAS 10 mg if you or your child:**

- Are hypersensitive (allergic) to methylphenidate or any of the other ingredients of METHYLPHENIDATE HCL-DOUGLAS 10 mg (listed in section 6).
- Suffer from anxiety, tension or agitation.
- Have been diagnosed with or have family history of uncontrolled speech and body movements (Tourette's syndrome).
- Have heart problems such as a high blood pressure, chest pain (angina) heart failure, narrowing of the blood vessels (arterial occlusive disease), were born with a heart problem, heart attack, disease of the heart muscle (cardiomyopathy), irregular heartbeat, disorders caused by the dysfunction of ion channels (channelopathies), and have been diagnosed with QT prolongation which is an irregularity of the electrical activity of the heart.
- Have increased eye pressure (glaucoma).
- Have an overactive thyroid.

- Have a tumor of the adrenal gland called pheochromocytoma.
- Are taking a medicine used for depression called a monoamine oxidase inhibitor (MAOI), or have taken a MAOI in the last 2 weeks.
- If you are pregnant or breastfeeding your baby.

### **Warnings and precautions**

Take special care with METHYLPHENIDATE HCL-DOUGLAS 10 mg if you or your child:

- Have any heart defects (e.g. structural cardiac abnormalities).
- Have any other pre-existing heart problems.
- Have high blood pressure (hypertension).
- Have or have previously had any disorder of the blood vessels in the brain e.g. weakening of blood vessels, aneurysm, inflammation of blood vessels (vasculitis) or stroke.
- Have existing or a family history of mental disorders that can cause abnormal thinking and perceptions, acute psychosis, mania, or suicidal thoughts or behaviour, mood swings (bipolar disorder).
- Have psychotic symptoms such as seeing or feeling things that are not really there (hallucinations).
- Start having aggressive or hostile behaviour, or your aggression gets worse.
- Have motor tics, which are involuntary movements caused by spasm-like contractions of muscles, most commonly involving the face, mouth, eyes, head, neck or shoulders, or vocal tics, which are sounds uttered unintentionally, or if any family members suffer from tics (Tourette's syndrome).
- Experience a combination of the following symptoms: agitation, hallucinations, delusion, coma, increased heart rate, unexpected changes in blood pressure, dizziness, flushing, abnormal high

temperature, tremor, sudden muscle contractions and/or stiffness, lack of coordination, seizures, and nausea, diarrhoea 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.

- Suffer from anxiety, agitation or tension.
- Experience abnormally sustained or frequent and painful erections of the penis while receiving treatment with METHYLPHENIDATE HCL-DOUGLAS 10 mg or after treatment discontinuation. This can occur in any age group and may need urgent medical treatment, sometimes including surgery. If this occurs, tell your doctor immediately.
- Show reduced weight gain and slight delay in growth. Growth, weight and appetite should be monitored.
- Have kidney or liver problems.
- Have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs).
- If you have ever abused or been dependent on alcohol, prescription medicines or illicit drugs.

Tell your doctor if any of the above apply to you, as taking METHYLPHENIDATE HCL-DOUGLAS 10 mg can make these problems worse.

Laboratory tests for amphetamines may produce falsely positive results.

### **Other medicines and METHYLPHENIDATE HCL-DOUGLAS 10 mg**

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

Do not take METHYLPHENIDATE HCL-DOUGLAS 10 mg if you or your child:

- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI), which is used to treat depression, or if you have taken an MAOI in the last 14 days as taking an MAOI with METHYLPHENIDATE HCL-DOUGLAS 10 mg can cause a sudden increase in your blood pressure.

If you or your child are taking any of the following medicines, check with your doctor or pharmacist before taking METHYLPHENIDATE HCL-DOUGLAS 10 mg:

- warfarin (anticoagulant medicine used to prevent blood clots)
- some anticonvulsants e.g. phenytoin, primidone (used to treat seizures)
- tricyclic antidepressants e.g. imipramine, desipramine (used to treat depression)
- medicines used to treat high blood pressure, e.g. alpha-2 agonists such as clonidine, as well as pressor agents including beta blockers.
- medicines used to increase blood pressure
- medicines that influence the level of dopamine in the body (used to treat Parkinson's disease or severe mental health problems)
- medicines that can raise the level of serotonin in the body (used to treat depression such as sertraline and venlafaxine).

### **Having an operation**

If you will be having an operation, tell your doctor. You should not take METHYLPHENIDATE HCL-DOUGLAS 10 mg on the day of your surgery if a certain type of anaesthetic is used, as there is a chance of a sudden rise in blood pressure and heart rate during the operation.

### **METHYLPHENIDATE HCL-DOUGLAS 10 mg with food, drink and alcohol**

Taking METHYLPHENIDATE HCL-DOUGLAS 10 mg with food may help to prevent stomach pain, feeling sick or being sick.

Do not drink alcohol while taking METHYLPHENIDATE HCL-DOUGLAS 10 mg. Alcohol may make the side effects worse.

### **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 health care provider for advice before taking this medicine.

METHYLPHENIDATE HCL-DOUGLAS 10 mg should not be used during pregnancy or lactation as safety has not been demonstrated.

No effects on fertility has been seen in animals

### **Driving and using machines**

METHYLPHENIDATE HCL-DOUGLAS 10 mg may make you feel dizzy, drowsy, blur your vision, cause hallucination or other central nervous system side-effects, which can affect your concentration.

If you experience such symptoms, do not drive or use machines, or do other activities that need quick reactions.

### **METHYLPHENIDATE HCL-DOUGLAS 10 mg contains lactose.**

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take METHYLPHENIDATE HCL-DOUGLAS 10 mg.

METHYLPHENIDATE HCL-DOUGLAS 10 mg may have an effect on the control of your blood sugar if you have diabetes mellitus.

### **3. How to take METHYLPHENIDATE HCL-DOUGLAS 10 mg**

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

Always use METHYLPHENIDATE HCL-DOUGLAS 10 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will usually start treatment with a low dose and increase it gradually as required.

The maximum daily dose is 60 mg.

Swallow the tablet with water.

#### **Children**

The doctor will tell you how many tablets of METHYLPHENIDATE HCL-DOUGLAS 10 mg to give your child.

The starting dose is usually 5 mg once or twice daily.

#### **Adults**

Your doctor will tell you how many tablets to take. The usual dose is 20 mg to 30 mg daily.

In order to reduce the risk of sleeplessness, the last dose should be taken not later than 6 pm.

#### **If you or your child do not feel better after one month of treatment**

If there is no improvement, tell your doctor. They may decide that a different treatment is needed.

Your doctor will tell you how long your treatment with METHYLPHENIDATE HCL-DOUGLAS 10 mg will last.

If you use METHYLPHENIDATE HCL-DOUGLAS 10 mg more often or use more of it and do not use it properly, may cause abnormal behaviour and you may become addicted to it.

The doctor may cease treatment with METHYLPHENIDATE HCL-DOUGLAS 10 mg periodically to check whether it is still needed. Treatment with METHYLPHENIDATE HCL-DOUGLAS 10 mg is not permanent and may be discontinued during or after puberty.

If you have the impression that the effect of METHYLPHENIDATE HCL-DOUGLAS 10 mg is too strong or too weak, tell your doctor or pharmacist.

### **Your doctor will do some tests**

- Before you start treatment with METHYLPHENIDATE HCL-DOUGLAS 10 mg to ensure that it will be safe to use
- During treatment with METHYLPHENIDATE HCL-DOUGLAS 10 mg at least every 6 months and when the dosage is changed.
- The tests include:
  - Checking your pulse and blood pressure
  - Measuring your height and weight and checking your appetite
  - Checking whether there are any problems or changes to your mood, state of mind or any other mental changes, or if any have worsened while taking METHYLPHENIDATE HCL-DOUGLAS 10 mg.

### **If you or your child take more METHYLPHENIDATE HCL-DOUGLAS 10 mg than you should**

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

The symptoms of overdose are agitation, changes in heartbeat (slow, fast, uneven), confusion, panicked state, dry nose and mouth, fever, headache, muscle spasms and uncontrolled

movements, dilated pupils, increased blood pressure, chest pain, breathing difficulties, increased sweating, flushing, seizures, fits, tremors, vomiting, red-brown urine which could be signs of abnormal muscle breakdown (rhabdomyolysis).

#### **If you or your child forget to take METHYLPHENIDATE HCL-DOUGLAS 10 mg**

Do not take a double dose to make up for forgotten individual doses. If a dose of METHYLPHENIDATE HCL-DOUGLAS 10 mg 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.

#### **If you stop taking METHYLPHENIDATE HCL-DOUGLAS 10 mg**

If you or your child suddenly stop taking METHYLPHENIDATE HCL-DOUGLAS 10 mg, the ADHD symptoms may return, or mental depression can occur. Your doctor may want to gradually reduce the amount of METHYLPHENIDATE HCL-DOUGLAS 10 mg taken daily before stopping treatment completely. Do not stop taking or giving METHYLPHENIDATE HCL-DOUGLAS 10 mg to your child without speaking to your doctor.

#### **4. Possible side effects**

METHYLPHENIDATE HCL-DOUGLAS 10 mg can have side effects.

Not all side effects reported for METHYLPHENIDATE HCL-DOUGLAS 10 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METHYLPHENIDATE HCL-DOUGLAS 10 mg, please consult your health care provider for advice.

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

- Swelling of face, throat, lips or tongue, or difficulty in swallowing or breathing (signs of a 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 the blood vessels in the brain)
- Fast heartbeat, chest pains, irregular heartbeats
- Bruising (sign of thrombocytopenia purpura)
- Muscle twitching or tics, uncontrollable twitching and jerking (sign of dyskinesia)
- A sore throat and fever or chills (signs of a low white blood cell count)
- Uncontrollable writhing movements of the face and/or trunk and limbs (choreo-athetoid movements)
- Fits (such as seizures, convulsions)
- Prolonged, painful erection (priapism)
- Blistering or itching of the skin (exfoliative dermatitis)
- Formation of red blotches on the skin (erythema multiforme)
- Seeing, feeling or hearing things that do not exist (hallucinations)

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:

- Sore throat with a runny nose
- Lack of appetite, decreased appetite, reduced height and weight gain
- Sleeplessness, nervousness, aggression, agitation, anxiety,

feeling depressed, irritability, abnormal behaviour, clenching of teeth

- Headache, dizziness, drowsiness, hyperactivity

Fast or irregular heartbeat

- High blood pressure
- Cough, sore throat
- Stomach pain and discomfort, runny stomach, nausea, vomiting, dry mouth
- Hair loss, itching, rash, hives
- Joint pain
- Fever, reduced growth in children during long term treatment
- Nosebleeds

Less frequent side effects:

- Low red blood cell count (anaemia), low white blood cell count (leucopenia)
- Anger, mood changes, mood swings, restlessness, thoughts of suicide as well as attempted suicide (including completed suicide), uncontrolled speech and body movements, sleep disorder, feeling unusually excited, over-active and uninhibited, feeling disoriented, changes in sex drive, abnormal thinking, having a lack of feeling or emotion, doing things over and over, obsessing over one thing.
- Tremors, loss of skin sensation or other body functions due to a temporary lack of blood supply to the brain, sedation.
- Double vision, blurred vision, trouble focusing, dilated pupils.
- Chest pain, heart attack and stopped heartbeat.
- Coldness in fingers and toes, tingling and changing colour when cold (from white to blue, then to red – Raynaud's phenomenon)

- Shortness of breath
- Constipation
- Increased liver enzymes, abnormal liver function
- Muscle pain, twitching and cramps
- Blood in the urine
- Breast enlargement in men
- Chest pain, exhaustion and sudden death
- Heart murmur

Frequency unknown:

- Levels of red blood cells, white blood cells and platelets that are too low (pancytopenia)
- Confusion, thought disturbances, addiction, repetitive and excessive speech
- Migraine, stuttering
- Inability to open the mouth or jaw (trismus)
- Loss of bladder control
- Erectile dysfunction
- Chest discomfort, excessive sweating

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

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of METHYLPHENIDATE HCL-DOUGLAS 10 mg.

## **5. How to store METHYLPHENIDATE HCL-DOUGLAS 10 mg**

Store all medicines out of reach of children.

- Store at or below 30 °C
- Keep the blister in the outer carton until required for use.
- Protect from light and moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the carton or blister.

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 HCL-DOUGLAS 10 mg contains**

- The active substance is methylphenidate hydrochloride 10 mg
- The other ingredients are Lactose, microcrystalline cellulose (Avicel PH102), pregelatinised maize starch and stearic acid.

### **What METHYLPHENIDATE HCL-DOUGLAS 10 mg looks like and contents of the pack**

White or off-white, circular, flat bevel-edged tablets, engraved “M” breakline “P” on one face and “10” on the other face.

PVC/PE/PVDC/Aluminium blister packs of 30 tablets, 10 tablets per blister, packed in an outer carton.

### **Holder of Certificate of Registration**

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