

Applicant : Sandoz SA (Pty) Ltd
Proprietary name : MEFEDINEL 10
Dosage form and strength : Tablet. Each tablet contains 10 mg methylphenidate hydrochloride.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

MEFEDINEL 10 (tablet)

Active ingredient: Methylphenidate hydrochloride 10 mg.

MEFEDINEL 10 contains sugar (42,99 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking MEFEDINEL 10

- 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.
- MEFEDINEL 10 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 MEFEDINEL 10 is and what it is used for.
2. What you need to know before you take MEFEDINEL 10.
3. How to take MEFEDINEL 10.
4. Possible side effects.
5. How to store MEFEDINEL 10.
6. Contents of the pack and other information.

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1. What MEFEDINEL 10 is and what it is used for

MEFEDINEL 10 contains the active substance methylphenidate and is used to treat:

- Attention-deficit and hyperactivity disorder (ADHD) in children aged six years and older.
ADHD is a medical condition where the child has difficulty concentrating, staying focused and sitting still.
- 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.
- MEFEDINEL 10 is not for use as a treatment for ADHD in children under 6 years of age or in adults. It is not known if it is safe or of benefit in these people.

How it works:

MEFEDINEL 10 improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour.

2. What you need to know before you take MEFEDINEL 10

Do not take MEFEDINEL 10

- If you are hypersensitive (allergic) to methylphenidate or any of the other ingredients of MEFEDINEL 10 (listed in section 6).
- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression or have taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may

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cause a sudden increase in your blood pressure (see 'Other medicines and MEFEDINEL 10').

- have a thyroid problem.
- have been diagnosed with or have a history of depression.
- have been diagnosed with or have a history of an eating disorder called anorexia.
- have or have had a history of suicidal tendencies.
- Have been diagnosed with or have a history of psychotic symptoms, a severe mood disorder, mania, schizophrenia or psychopathic/borderline personality disorder.
- have increased pressure in your eye (glaucoma).
- have a tumour of your adrenal gland (phaeochromocytoma).
- have a very high blood pressure or narrowing of the vessels, possibly resulting in pain in the arms and legs.
- ever had heart problems such as a history of a heart attack, irregular heartbeat, pain and discomfort in the chest, heart failure, heart disease or significant problems with the structure or function of the heart that were present at birth.
- If you suffer from anxiety, tension or agitation
- If you or a family member suffers from Tourette's syndrome (a condition characterised by uncontrolled speech and body movements)
- If you are pregnant or breastfeeding.

Do not take MEFEDINEL 10 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take MEFEDINEL 10. This is because MEFEDINEL 10 can make these problems worse.

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Warnings and precautions

- MEFEDINEL 10 treatment is not indicated in all children with ADHD. Your doctor will decide if your child should use this medicine, based on a very thorough assessment of the severity and how long your child's symptoms are in relation to their age.
- MEFEDINEL 10 is not for use in children under 6 years of age and in elderly patients.
- MEFEDINEL 10 does not have to be taken forever. Treatment will generally stop after puberty.

Talk to your doctor or pharmacist before taking MEFEDINEL 10 if you have:

- thoughts about killing yourself or trying to kill yourself.
- problems with your heart (including heart defects) or an increased heartbeat.
MEFEDINEL 10 can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- high blood pressure. MEFEDINEL 10 can increase blood pressure.
- low blood pressure. MEFEDINEL 10 can cause dizziness or fainting in people with low blood pressure.
- problems with sudden changes in your blood pressure or your heart rate.
- heart or blood vessels disease or past medical history of stroke.
- 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).
- Kidney or liver problems. You may need a lower dose.

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- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious.
- mania (feeling elated or over-excited, which causes unusual behaviour) and agitation.
- aggressive feelings.
- unfriendly and angry (hostility) feelings.
- a history of epilepsy or have had seizures for any other reason. MEFEDINEL 10 might lead to an increase in seizure frequency.
- different moods than usual (mood swings) or feel very unhappy.
- hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words.

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.

Children and adolescents:

- If your child is not growing or gaining height or weight as expected as MEFEDINEL 10 treatment may need to be interrupted
- If your child is on long-term treatment (longer than 12 months) your doctor will monitor their weight and height.

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Other medicines and MEFEDINEL 10

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

Do not take MEFEDINEL 10 if you are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or if you have taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may cause a sudden increase in your blood pressure. (see 'Do not take MEFEDINEL 10').

If you are taking other medicines, MEFEDINEL 10 may affect how well they work or may cause side effects.

If you are taking any of the following medicines, check with your doctor or pharmacist before taking MEFEDINEL 10:

- other medicines for depression (e.g. Amitriptyline & fluoxetine).
- medicines for severe mental health problems (e.g. amphetamine).
- medicines for epilepsy (e.g. Phenytoin, phenobarbitone).
- medicines used to reduce or increase blood pressure (e.g. clonidine or phentermine)
- some cough and cold remedies which contain ingredients that can affect blood pressure

It is important to check with your pharmacist when you buy any of these products (e.g. Phenylephrine, pseudoephedrine).

- medicines that to prevent blood clots (e.g. Warfarin).

If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

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Important information about some of the ingredients of MEFEDINEL 10:

MEFEDINEL 10 contains sugar (lactose monohydrate).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MEFEDINEL 10.

MEFEDINEL 10 with food and drink

MEFEDINEL 10 can be taken with or without food.

Alcohol should be avoided while taking MEFEDINEL 10. Alcohol may make the side effects of this medicine worse.

Pregnancy and breastfeeding

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.

Do not take MEFEDINEL 10 if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other health care provider for advice.

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Driving and using machines

You may feel dizzy, drowsy, have problems focusing or have blurred vision when taking methylphenidate. If these happen, it may be dangerous to do things such as drive or use machines.

This medicine can affect your ability to drive. Do not drive or use machines whilst taking this medicine until you know how this medicine affects you.

3. How to take MEFEDINEL 10

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

Always take MEFEDINEL 10 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.

Your doctor will tell you how long your treatment with MEFEDINEL 10 will last.

If you have the impression that the effect of MEFEDINEL 10 is too strong or too weak, tell your doctor or pharmacist.

If you take more MEFEDINEL 10 than you should

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

Signs of overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing,

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headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth, muscle spasms, fever, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you forget to take MEFEDINEL 10

Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

If you stop taking MEFEDINEL 10

If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping MEFEDINEL 10.

4. Possible side effects

MEFEDINEL 10 can have side effects.

Not all side effects reported for MEFEDINEL 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MEFEDINEL 10, please consult your healthcare provider for advice.

If any of the following happens, stop taking MEFEDINEL 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:

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- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MEFEDINEL 10. You may need urgent medical attention.

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

- Suicidal tendencies.
- Chest pain,
- Changes in the way your heart beats, for example, if you notice it beating faster or slower.
- Changes in heart rate.
- Heart attack.
- Changes in blood pressure.
- Difficulty breathing.
- Heart murmur.
- Irregular growth in children.
- Development of addiction/dependence to MEFEDINEL 10.
- Red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea.

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Tell your doctor if you notice any of the following:

Frequent side effects:

- Frequent infections such as fever, severe chills, sore throat or mouth ulcers, tiredness, headaches.
- Loss of appetite.
- Eating disorder
- Nervousness, difficulty sleeping, over activity, feelings of deep sadness and unworthiness.
- Anxiety, irritability, aggression, mood swings, agitation, abnormal behaviour or thinking, anger.
- Fear, disorientation, sexual urge disorder, lack of interest, repetitive behaviours, over-focussing, confusional state.
- Drowsiness, dizziness, uncontrollable twitching, jerking or writhing movements, repeatedly blink your eyes, shrugging of the shoulders or blurting out unusual sounds or offensive words that can't be easily controlled .
- Stomach pain, nausea, vomiting, dry mouth, diarrhoea, toothache.
- Swollen joint pain.
- Fatigue.
- Runny or stuffy nose, sneezing, coughing.

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- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold (Raynaud's phenomenon).
- Tremor (shaking or trembling movements in one or more parts of the body).
- Excessive sweating (hyperhidrosis)
- Hair loss

Less frequent side effects:

- An inflammation of the stomach lining (Gastroenteritis)
- Being short of breath when exercising, dizziness and looking pale which may be an indication of low blood cells.
- Visual problems such as blurred vision, double vision or dilated pupils
- Psychosis (losing some contact with reality. Can involve seeing or hearing things that people cannot see or hear-hallucination, and believing things that are not there-delusions)
- Constipation.
- Liver problems.
- Rash, itching, hives, fever, hair loss, unusual bleeding or bruising under the skin, flaking or peeling of the skin, swelling.
- Blood in the urine.
- Breast enlargement in men.
- Muscle pain, aching muscles, muscle tenderness or weakness, not caused by exercise, muscle twitching.
- Reduced weight and height gain in children.

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- Disorder of the blood vessels in the brain e.g. weakening of blood aneurysm, stroke, inflammation of blood vessels (Cerebrovascular disorders).
- Tics (fast, repetitive muscle movements that result in sudden and difficult to control body jolts or sounds).

Side effects for which the frequency is not known:

- Levels of red blood cells, white blood cells and platelets that are too low (pancytopenia)
- Dilated pupils (mydriasis)
- Nosebleeds

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MEFEDINEL 10.

Suspected adverse reactions can also be reported directly to the HCR via the website:

<https://pvi1j.solutions.iqvia.com> or the e-mail address, adverse.event.sac@sandoz.com

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5. How to store MEFEDINEL 10

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C.
- Keep blisters in the outer carton until required for use.
- Do not use after the expiry date stated on the label / carton.
- Return all unused medicines 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 MEFEDINEL 10 contains

Each MEFEDINEL 10 10 (tablet) contains 10 mg methylphenidate hydrochloride.

MEFEDINEL 10 contains sugar (42,99 mg lactose monohydrate per tablet)

Excipients: Calcium hydrogen phosphate dihydrate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch.

What MEFEDINEL 10 looks like and contents of the pack

Tablet.

White, round, bevelled flat tablet, scored on both sides and radially.

The tablet can be divided into equal doses.

Round, white HDPE bottle, white polypropylene cap with permaseal liner, or

White opaque PVC film sealed with aluminium push through foil, or

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White opaque PVC/PE/PVdC film sealed with aluminium push through foil. The blister strips are packed in an outer cardboard carton.

Pack size of 30 tablets

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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58/1.2/0111

Access to the corresponding Professional Information

TBA

¹Company Reg. No.: 1990/001979/07