PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

Mefedinel™ 18 (prolonged release tablets)

Mefedinel™ 27 (prolonged release tablets)

Mefedinel™ 36 (prolonged release tablets)

Mefedinel™ 54 (prolonged release tablets)

Methylphenidate hydrochloride.

MEFEDINEL 18 contains sugar (6,31 mg lactose monohydrate per tablet).

MEFEDINEL 27 contains sugar (8,17 mg lactose monohydrate per tablet).

MEFEDINEL 36 contains sugar (8,43 mg lactose monohydrate per tablet).

MEFEDINEL 54 contains sugar (6,76 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking MEFEDINEL

- 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 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 is and what it is used for.

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

3. How to take MEFEDINEL.

4. Possible side effects.

5. How to store MEFEDINEL.

6. Contents of the pack and other information.

1. What MEFEDINEL is and what it is used for

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

- Attention-Deficit Hyperactivity Disorder (ADHD) in children and adolescents aged 6 to 17 and adults aged 18 to 65 who meet specific criteria for ADHD. ADHD is a medical condition where the child has difficulty concentrating, staying focused and sitting still.

How it works:

- MEFEDINEL 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

Do not take MEFEDINEL if:

- You are allergic to methylphenidate or any of the other ingredients of MEFEDINEL (listed in section 6).
- You have a thyroid problem.
- You have increased pressure in your eye (glaucoma).

- You have a tumour of your adrenal gland (pheochromocytoma).
- You have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs.
- You have ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or were born with a heart problem.
- You have had a problem with the blood vessels in your brain - such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis).
- You are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) (see 'Other medicines and MEFEDINEL').
- You suffer from anxiety, tension or agitation.
- You or a family member suffers from Tourette's syndrome (a condition characterised by uncontrolled speech and body movements).
- You are pregnant or breastfeeding.

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

Warnings and precautions

- MEFEDINEL 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 is not for use in children under 6 years of age and in elderly patients.
- MEFEDINEL does not have to be taken forever. Treatment will generally stop after puberty.

Talk to your doctor before taking MEFEDINEL if:

- You have thoughts about killing or trying to kill yourself.
- You have problems with your heart (including heart defects) or an increased heartbeat. MEFEDINEL can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- You have high blood pressure. MEFEDINEL can increase blood pressure.
- You have low blood pressure. MEFEDINEL can cause dizziness or fainting in people with low blood pressure.
- You have problems with sudden changes in your blood pressure or your heart rate.
- You have cardiovascular disease or past medical history of stroke.
- You have liver problems. You may need a lower dose.
- You have psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious.
- You have mania (feeling elated or over-excited, which causes unusual behaviour) and agitation.
- You have aggressive feelings.
- You have unfriendly and angry (hostility) feelings.
- You have a history of epilepsy or have had seizures for any other reason. MEFEDINEL might lead to an increase in seizure frequency.
- You have different moods than usual (mood swings) or feel very unhappy.
- You have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words.
- You have kidney problems.
- You have a problem with swallowing or swallowing whole tablets.
- You have a narrowing or blockage of your gut or food-pipe.

- You have had any abnormal brain scans (EEGs).
- You have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- You are a girl and have started your periods (see the pregnancy, breast-feeding and contraception section below).

Other mental health problems include:

- Feeling anxious or tense.
- Feeling depressed or guilty.

Tell your doctor or pharmacist if any of the above apply to you before starting treatment. This is because MEFEDINEL can make these problems worse. Your doctor will want to monitor how the medicine affects you.

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 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.

Other medicines and MEFEDINEL

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

Do not take MEFEDINEL with medicines called MAOIs (monoamine oxidase inhibitors) used for depression, or if you have taken an MAOI in the last 14 days. See section 2 “Do not take MEFEDINEL”.

Tell your doctor or pharmacist if you are taking any of the following medicines for depression or anxiety:

- Tricyclic antidepressant.
- Selective Serotonin Reuptake Inhibitor (SSRI).
- Serotonin and Norepinephrine Reuptake Inhibitor (SNRI).

Taking MEFEDINEL with these type of medicines could cause a life threatening increase of serotonin in the brain (serotonin syndrome), which may lead to feeling confused or restless, sweating, shivering muscle jerks or fast heartbeat. If you develop these side effects, see a doctor straight away.

If you are taking other medicines, methylphenidate 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:

- Medicines for severe mental health problems.
- Medicines for Parkinson’s disease (such as levodopa).
- Medicines for epilepsy.
- Medicines used to reduce or increase blood pressure.

- Some cough and cold remedies, which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products.
- Medicines that thin the blood to prevent blood clots.

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 MEFEDINEL.

Having an operation

Tell your doctor if you are going to have an operation. You should not take methylphenidate on the day of your surgery 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.

Drug testing

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

MEFEDINEL with alcohol

Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Important information about some of the ingredients of MEFEDINEL

MEFEDINEL 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.

MEFEDINEL with food and drink

MEFEDINEL can be taken with or without food.

Alcohol should be avoided while taking MEFEDINEL. 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 if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other health care provider for advice.

Driving and using machines

You may feel dizzy, 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

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

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

You should take MEFEDINEL once each day in the morning with a glass of water. The tablet should be swallowed whole and not chewed, broken, or crushed. The tablet may be taken with or without food.

Always take MEFEDINEL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

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

If you take more MEFEDINEL than you should

In the event of overdosage, 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, headache, high fever, changes in heartbeat (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

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

If you suddenly stop taking MEFEDINEL, the ADHD symptoms may come back or unwanted effects such as depression may appear. Talk to your doctor before stopping MEFEDINEL.

4. Possible side effects

MEFEDINEL can have side effects.

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

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

- 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. You may need urgent medical attention.

Some side effects could be serious. If you have any of the side effects below, see a doctor straight away:

Frequent:

- Uneven heartbeat (palpitations).
- Mood changes or mood swings or changes in personality.

Less frequent:

- Thinking about or feeling like hurting or killing yourself.
- Seeing, feeling or hearing things that are not real (these are signs of psychosis).
- Uncontrolled speech and body movements (Tourette's syndrome).
- Signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- Feeling unusually excited, overactive and uninhibited (mania).
- Heart attack.
- Sudden death.
- Suicidal attempt.
- Fits (seizures, convulsions epilepsy).
- Skin peeling or purplish red patches.
- Inflammation or blocked arteries in the brain.
- Temporary paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain).
- Muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system.
- Decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily.
- A sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other drugs that may be taken in combination with methylphenidate.

Frequency unknown:

- Unwanted thoughts that keep coming back.
- Unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems).
- Prolonged erections, sometimes painful or an increased number of erections.

If you have any of the side effects above, see a doctor straight away.

Other side effects include the following, if they get serious; please tell your doctor or pharmacist:

Frequent:

- Headache.
- Feeling nervous.
- Not being able to sleep.
- Joint pain.
- Blurred vision.
- Tension headache.
- Dry mouth, thirst.
- Trouble falling asleep.
- High temperature (fever).
- Problems with sex drive.
- Unusual hair loss or thinning.
- Muscle tightness, muscle cramps.
- Loss of appetite or decreased appetite.
- Inability to develop or maintain an erection.
- Itching, rash or raised red itchy rashes (hives).

- Feeling unusually sleepy or drowsy, feeling tired.
- Excessive teeth grinding (bruxism).
- Feeling of panic.
- Tingling feeling, prickling, or numbness of the skin.
- Increased alanine aminotransferase (liver enzyme) level in your blood.
- Cough, sore throat or nose and throat irritation, upper respiratory tract infection, sinus infection.
- High blood pressure, fast heartbeat (tachycardia).
- Dizziness (vertigo), feeling weak, movements which you cannot control, being unusually active.
- Feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour.
- Upset stomach or indigestion, stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick.

Less Frequent:

- Dry eyes.
- Constipation.
- Chest discomfort.
- Blood in the urine.
- Listlessness.
- Shaking or trembling.
- Increased need to pass urine.
- Muscle pain, muscle twitching.
- Shortness of breath or chest pain.

- Feeling hot.
- Increases in liver test results (seen in a blood test).
- Anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping.
- Feeling disorientated or confused.
- Trouble seeing or double vision.
- Swelling of the breasts in men.
- Excessive sweating, redness of the skin, red raised skin rash.
- Muscle cramps.
- Small red marks on the skin.
- Abnormal liver function including sudden liver failure and coma.
- Changes in test results – including liver and blood tests.
- Abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing.
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (‘Raynaud’s phenomenon’).

Unknown frequency:

- Migraine.
- Dilated pupils.
- Very high fever.
- Slow, fast or extra heart beats.
- A major fit (‘grand mal convulsions’).
- Believing things that are not true.
- Severe stomach pain, often with feeling and being sick.

- Inability to control the excretion of urine (incontinence).
- Spasm of the jaw muscles that makes it difficult to open the mouth (Trismus).
- Stuttering.

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 MEFEDINEL.
Suspected side effects can also be reported directly to the Holder of Certificate of Registration (HCR) via the link: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store MEFEDINEL

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C.
- Keep the container tightly closed.
- Do not use after the expiry date printed on the label/carton.
- 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 MEFEDINEL contains

Each MEFEDINEL 18 (prolonged release tablet) contains 18 mg methylphenidate hydrochloride.

Each MEFEDINEL 27 (prolonged release tablet) contains 27 mg methylphenidate hydrochloride.

Each MEFEDINEL 36 (prolonged release tablet) contains 36 mg methylphenidate hydrochloride.

Each MEFEDINEL 54 (prolonged release tablet) contains 54 mg methylphenidate hydrochloride.

Excipients:

Medicine layer:

Butylhydroxytoluene, polyethylene oxide, povidone (K 25), stearic acid and succinic acid.

Push layer:

Butylhydroxytoluene, iron oxide red (E 172), polyethylene oxide, povidone (K 25), sodium chloride and stearic acid.

Membrane layer:

Cellulose acetate and poloxamer 188.

Medicine coat:

Hypromellose and succinic acid.

Film coat:

Lactose monohydrate, hypromellose, macrogol 4000 and titanium dioxide (E171).

In addition:

MEFEDINEL 18, 54: Iron oxide yellow (E 172) and Iron oxide red (E 172).

MEFEDINEL 27: Iron oxide black (E 172).

What MEFEDINEL looks like and contents of the pack

Prolonged release tablet.

MEFEDINEL 18: Light yellow, round, film-coated tablet with a delivery orifice on one side.

MEFEDINEL 27: Light grey, round, film-coated tablet with a delivery orifice on one side.

MEFEDINEL 36: White, round, film-coated tablet with a delivery orifice on one side.

MEFEDINEL 54: Red, round, film-coated tablet with a delivery orifice on one side.

HDPE bottles closed with a child-resistant, tamper evident PP screw cap with drying plug.

Pack sizes of 28, 30, 50, 56, 60, 98, 100 or 120 prolonged-release tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

This leaflet was last revised in

19 October 2022

Registration numbers

MEFEDINEL 18: 48/1.2/0092

MEFEDINEL 27: 48/1.2/0093

MEFEDINEL 36: 48/1.2/0094

MEFEDINEL 54: 48/1.2/0095

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07