1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

MENOGRAINE 25 µg tablet

Clonidine

Contains sugar: Lactose monohydrate 30,118 mg, Sucrose 36,501 mg

Read all of this leaflet carefully because it contains important information for you

MENOGRAINE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use MENOGRAINE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MENOGRAINE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 28 days.

What is in this leaflet

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

1. What MENOGRAINE is and what it is used for

MENOGRAINE belongs to a group of medicines called anti-migraine preparations, used for the prevention of migraine.

2. What you need to know before you take MENOGRAINE

Do not take MENOGRAINE:

- If you are hypersensitive (allergic) to clonidine or any of the other ingredients of MENOGRAINE (listed in section 6).
- If you have porphyria (a group of disorders that can cause nerve or skin problems).
- If you suffer from a slower-than-expected heart rate, generally beating fewer than 60 beats per minute (bradydysrhythmia) which has been caused by conditions such as sick-sinus syndrome or AV block of 2nd or 3rd degree.

Warnings and precautions

Take special care with MENOGRAINE:

- If you are using methylphenidate, a medication to treat attention deficit hyperactivity disorder (ADHD).
- If you have a previous history of depression.
- If you have cerebrovascular disease (a condition that affects blood supply to the brain).
- If you have problems with your heart or previously had a heart attack.
- If you have problems with your kidneys.
- If you have Raynaud's syndrome (a condition in which some areas of the body e.g. fingers and toes feel numb and cold in response to cold temperatures or stress).
- If you have damage to your nerves that relay information between your brain and the rest of your body (peripheral nerves).
- If you have difficulty passing stools (constipation).

- Do not stop taking MENOGRAINE suddenly as it may cause rebound hypertension (high blood pressure), irritability, restlessness, sweating, increased heart rate, headache and nausea, discontinuation should be done over a period of 2 to 4 days.
- If MENOGRAINE is given concurrently with a beta blocking medicine (medicines used to lower blood pressure), MENOGRAINE should not be discontinued until several days after stopping the beta-blocker.
- If you are going to have anaesthesia, MENOGRAINE should not be stopped, but should be given intravenously during the operation to avoid the risk of rebound hypertension (high blood pressure).
- Intravenous injection of clonidine as contained in MENOGRAINE should be given slowly to avoid a possible increase in your blood pressure especially in patients already receiving other antihypertensive medicines (medicines used to lower your blood pressure) such as guanethidine or reserpine.
- If you wear contact lenses.

Children and adolescent

There is no experience with MENOGRAINE in children younger than 18 years.

Other medicines and MENOGRAINE

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

Tell your doctor if you are taking any of the following:

- If you take medicines used to treat depression (such as tricyclic antidepressants).
- If you take water tablets (diuretics).
- If you take medicines used to lower blood pressure (antihypertensives, such as guanethidine or reserpine).

- If you take medicines which are often used to slow the heart rate or lower the blood pressure (beta-blockers).
- If you are taking medicines for heart conditions (cardiac glycosides).
- If you take alcohol or other medicines that slow down the functioning of the brain.

MENOGRAINE with food and alcohol

Do not take MENOGRAINE with alcohol as it may aggravate the possible side effect of drowsiness and impaired concentration.

Pregnancy, breastfeeding and fertility

You should not take MENOGRAINE if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking MENOGRAINE.

Driving and using machines

Since adverse reactions such as drowsiness and impaired concentration have been reported in patients receiving MENOGRAINE, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that MENOGRAINE does not adversely affect your ability to do so (Read information about this in the section Possible side effects).

It is not always possible to predict to what extent MENOGRAINE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MENOGRAINE affects you (Read information about this in the section Possible side effects).

MENOGRAINE contains lactose and sucrose

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

3. How to take MENOGRAINE

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

Always take MENOGRAINE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of MENOGRAINE is one tablet morning and night, increasing to three tablets twice daily if necessary.

If you take more MENOGRAINE 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 and symptoms of overdosage are narrowing of your pupil, sleepiness including coma, high blood pressure, slower than usual heart rate, severe drop in body temperature, difficulty breathing including stopping to breathe while sleeping, seizures, occasionally vomiting and dryness of the mouth.

If you forget to take MENOGRAINE

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of MENOGRAINE, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking MENOGRAINE

Do not stop taking MENOGRAINE suddenly as it may cause rebound hypertension (high blood pressure), irritability, sweating, increased heart rate, headache and nausea. (Read information about this in the section Take special care with MENOGRAINE).

4. Possible side effects

MENOGRAINE can have side effects.

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

If any of the following happens, stop taking MENOGRAINE 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,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MENOGRAINE. You may need urgent medical attention or hospitalisation.

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

- Chest pain;
- changes in the way your heart beats, for example, if you notice it beating faster or if it skips a beat;

- shortness of breath, fatigue, swollen legs and rapid heartbeat as these are symptoms of heart failure;
- nausea, vomiting, abdominal pain, abdominal swelling (distention) and constipation as these may be symptoms of colonic pseudo-obstruction.

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:

- Feeling abnormally sad or down;
- disturbances in your sleep;
- drowsiness, dizziness, headache;
- feeling sleepy and having trouble focusing and staying awake;
- slight orthostatic hypotension (a form of low blood pressure that happens when you stand up from sitting or lying down);
- dry mouth;
- constipation;
- feeling sick, queasiness, feeling that one is about to vomit;
- vomiting;
- a sore or painful lump under the tongue, pain or swelling below the jaw or ears;
- tiredness.

Less frequent side effects:

- Gynaecomastia (enlargement of a man's breasts);
- numbness, tingling, pins and needles, cold, warmth, tingling pressure of the skin;
- seeing or hearing things that are not really there (hallucinations);
- cramps;

- Raynaud's syndrome (a condition in which some areas of the body e.g. fingers and toes feel numb and cold in response to cold temperatures or stress);
- abnormalities in liver function tests for a short period of time;
- large doses have been associated with initial increases in blood pressure and high blood sugar levels that may be experienced only for a short time.

Side effects with an unknown frequency:

- Anxiety;
- anorexia (loss of appetite);
- parotid pain (swelling happens in parotid glands on both sides of the face, giving the appearance of "chipmunk cheeks");
- vivid dreams;
- loss of male sexual ability (impotence) and loss of sex drive (libido), difficulty in achieving and maintaining erection in males;
- confusional state, being unable to tell what is real and what is not;
- urinary retention (the inability to empty the bladder completely) or incontinence (lack of voluntary control over urination);
- dry, itching, or burning sensations in the eye, difficulty focusing especially near, decrease in production of tears;
- nasal dryness;
- fluid retention usually for a short time;
- vague feeling of bodily discomfort; a general feeling of being unwell.

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, pharmacist or nurse. 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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of MENOGRAINE.

5. How to store MENOGRAINE

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep container tightly closed.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

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

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 MENOGRAINE contains

The active substance is 25 µg of clonidine hydrochloride.

The other ingredients are acacia powder, calcium carbonate, cetyl palmitate, indigo carmine aluminium lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose,

sodium starch glycollate, starch maize, sucrose, talc, titanium dioxide (CI 77891).

Contains sugar: Lactose monohydrate 30,118 mg, Sucrose 36,501 mg

What MENOGRAINE looks like and contents of the pack

MENOGRAINE is a blue, sugar-coated, biconvex tablet. Packs of 30 and 100 tablets in white polypropylene securitainers sealed together with a package insert, foam insert or rayon, using a round white, flat-topped low-density polyethylene (LDPE) closure.

Packs of 30 and 100 tablets in white, opaque, round high-density polyethylene (HDPE) containers, sealed together with white absorbent cotton using a white, opaque polypropylene fine-ribbed screw cap.

Packs of 20 tablets in polyvinyl chloride (PVC) blister strips sealed using aluminium foil. The blister strips are packed together with a package insert, into pre-printed cardboard unit cartons.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS1 90/7.3/001042

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