

PROPOSED CLEAN PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S3****MENGEN 500 mg**, film-coated tablet**MENGEN 850 mg**, film-coated tablet**MENGEN 1000 mg**, film-coated tablet

Metformin Hydrochloride.

Sugar free.

Read all of this leaflet carefully before you start taking MENGEN.

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

1. What MENGEN is and what it is used for:

MENGEN is an oral hypoglycaemic medicine used for Type 2 (non-insulin dependent) diabetes mellitus when diet has failed and especially if you are overweight. MENGEN can be taken alone as initial therapy, or can be taken in combination with a sulphonylurea. MENGEN can also be used in insulin-dependent diabetes, in combination with appropriate diet.

2. What you need to know before you take MENGEN

Do not take MENGEN:

- if you are hypersensitive (allergic) to metformin hydrochloride or any of the other ingredients of MENGEN (listed in section 6).
- if you suffer from any type of metabolic acidosis (too much acid is in your body) such as lactic acidosis ('see Warnings and Precautions') or diabetic ketoacidosis (a condition in which substances called 'ketone bodies' accumulate in the blood, and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness, or your breath developing an unusual fruity smell).
- if you suffer from diabetic pre-coma (dangerously high blood sugar or dangerously low blood sugar).
- if you have severely reduced kidney function
- if you suffer from sudden onset conditions that can cause kidney problems. Conditions such as:
 - dehydration: (if you lost too much water from your body, due to long-lasting or severe diarrhoea, or if you have vomited several times in a row.
 - severe infection
 - have severe problems with your blood circulation (such as shock)
 - if you need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream
- if you suffer from sudden onset or long-lasting conditions which may cause low blood oxygen (hypoxia). Conditions such as:
 - heart failure or if you recently had a heart attack
 - inflammation of the pancreas (pancreatitis)
 - difficulty in breathing – if your lungs cannot supply enough oxygen to your organs

- shock – severe problems with your blood circulation that causes reduced oxygen delivery or increased oxygen consumption.
- if you drink a lot of alcohol or if your liver is not functioning optimally
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with MENGAN:

Risk of Lactic acidosis:

MENGAN may cause a very rare, but very serious side effect called lactic acidosis. that most often occurs if your kidneys or blood circulation system are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, ketosis, prolonged fasting, excessive alcohol intake, liver problems or any medical conditions in which a part of the body has a reduced supply of oxygen (such as a sudden onset severe heart disease) as well as certain medication (see ‘Other medicines and MENGAN’).

In case of dehydration (if you lost too much water from your body, due to long-lasting or severe diarrhoea, or if you have vomited several times in a row or have insufficient fluid intake) MENGAN should be briefly stopped and you should contact your healthcare professional.

Medication such as certain blood pressure medicine, medicine that increases urine output (diuretics), and anti-inflammatory medicine can cause sudden kidney problems and should be used with caution. Inform your healthcare provider if you are taking any such medicine.

Lactic acidosis is a medical emergency which must be treated in hospital. Symptoms of lactic acidosis include:

- vomiting
- stomach-ache
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing

- reduces body temperature and heartbeat.

During treatment with MENGEN, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

If you suffer from kidney problems and are on MENGEN treatment, your doctor will monitor your kidney function on a regular basis.

Do not use MENGEN if you suffer from acute or unstable heart failure (see 'Do not take MENGEN:')

Taking medicine that contains iodine:

Stop taking MENGEN for a short period if you are going to receive medicine containing iodine used for x-ray-based imaging. Your doctor will decide when you must stop and when to restart your treatment with MENGEN.

Surgery:

If you need to have major surgery, you must stop taking MENGEN during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with MENGEN.

Other Precautions:

You should continue with a balanced diet which consists of regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.

The usual tests for diabetes monitoring should be performed regularly.

MENGEN on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take MENGEN together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia.

Do not take MENGAN if you are suffering from conditions which may cause dehydration, serious infections, trauma or on low calorie intake (see 'Do not take MENGAN').

If you are on long-term MENGAN treatment, your Vitamin B12 levels should be checked at least once a year since MENGAN may cause mal absorption of Vitamin B12, which may result in a disease called megaloblastic anaemia (lack of enough red blood cells to carry adequate oxygen to your body's tissue which can make you feel weak and tired) (See 'Possible side-effects').

Children and adolescents

MENGAN can be used in children from 12 years of age and adolescents. The diagnosis of type 2 diabetes mellitus must be confirmed before treatment with MENGAN is initiated.

Other medicines and MENGAN

Always tell your healthcare professional if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Concomitant use not recommended

Iodinated contrast medicine – the use of contrast medicine that contains iodine given to you if you are going for an x-rays may lead to renal failure and lactic acidosis.

Combinations requiring precaution for use

- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE-inhibitors and angiotensin II receptor antagonists).
- medicines which increase urine production (diuretics)

- glucocorticoids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- medicines that may change the amount of MENGAN in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)

MENGAN and alcohol

Avoid consumption of alcohol and alcohol-containing medicine since this may increase the risk of lactic acidosis (see Warnings and precautions).

Pregnancy, breastfeeding and fertility

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before taking MENGAN.

Driving and using machines

It is not always possible to predict to what extent MENGAN may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which MENGAN affects you.

MENGAN on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines. However, take special care if you take MENGAN together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

3. How to take MENGAN

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

Always take MENGAN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take MENGAN in divided doses with or after a meal. This will avoid you having side effects affecting your digestion.

The usual dose for adults is one MENGAN 500 mg tablet three times a day or one MENGAN 850 mg twice a day or one MENGAN 1 000 mg tablet twice a day.

If you are elderly, your doctor will adjust the dose based on your kidney function.

The usual dose for children from 12 years of age and adolescents is one MENGAN 500 mg tablet once a day or one MENGAN 850 mg tablet once a day.

Your doctor will tell you how long your treatment with MENGAN will last. Do not stop treatment early because you feel better. If you have the impression that the effect of MENGAN is too strong or too weak, tell your doctor or pharmacist.

If you take more MENGAN 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.

If you forget to take MENGAN

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

4. Possible side effects

MENGEN can have side effects.

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

If any of the following happens, stop taking MENGEN 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,

These are all very serious side effects. If you have them, you may have had a serious reaction to MENGEN. 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:

- Lactic acidosis. This is a less frequent but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see Warning and precautions)

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:

- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- abdominal pain (belly pain)
- loss of appetite

These side effects most often happen at the beginning of the treatment with MENGAN. It helps if you spread the doses over the day and if you take MENGAN with or straight after a meal.

- constipation
- taste disturbance such as metallic taste

Less frequent side effects:

- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- low Vitamin B12 levels and folic acid in the blood.
- lack of enough red blood cells to carry adequate oxygen to your body's tissue which can make you feel weak and tired (megaloblastic anaemia).
- low blood sugar (hypoglycaemia)

Frequency unknown

- abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes).
- body produces high levels of blood acids called ketone (ketoacidosis)
- high levels of ketones (which occur when cells are broken down for energy) are present in the urine. (ketonuria)

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

5. How to store MENGAN

Store at or below 25 °C. Protect from light and moisture.

Keep the blisters in the original carton until required for use.

Store all medicines out of reach of children.

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 MENGAN contains

MENGAN 500 mg: Each film-coated tablet contains 500 mg metformin hydrochloride equivalent to 390 mg metformin.

MENGAN 850 mg: Each film-coated tablet contains 850 mg metformin hydrochloride equivalent to 663 mg metformin.

MENGAN 1000 mg: Each film-coated tablet contains 1000 mg metformin hydrochloride equivalent to 780 mg metformin.

The other ingredients are magnesium stearate, Opadry YS-1R-7006 (hypromellose, macrogol 400, macrogol 6000) and povidone.

What MENGAN looks like and contents of the pack

MENGAN 500 mg: White, biconvex, circular shaped film-coated tablets with 'A' debossed on one side and '60' debossed on the other side.

MENGAN 850 mg: White, biconvex, circular shaped film-coated tablets with 'A' debossed on one side and '61' debossed on the other side.

MENGAN 1 000 mg: White, biconvex, capsule shaped film coated tablets with break line on one side and 'A' and '90' on other side separated by break line.

1. Blister Pack:

Tablets are packed in clear PVC (250 microns) coated with PVdC (60 gsm) as the forming material and aluminium foil (25 microns) as the lidding material OR clear PVC (250 microns) as the forming material and aluminium foil (25 microns) as the lidding material, in the following pack sizes:

MENGEN 500 mg: 500's (50 x 10's), **100's** (10 x 10's), **84's** (6 x 14's - *Patient ready Packs*), **56's** (4 x 14's - *Patient ready Packs*)

MENGEN 850 mg: 300's (30 x 10's), **60's** (6 x 10's), **30's** (3 x 10's), **56's** (4 x 14's – *Patient ready packs*)

MENGEN 1000 mg: 60's (6 x 10's)

2. HDPE Container:

Tablets are packed in a HDPE container with a stock ribbed closure and induction sealing wad, in the following pack sizes:

MENGEN 500 mg: 56's, 84's, 100's, 400's, 500's

MENGEN 850 mg: 56's, 84's, 100's, 300's, 400's, 500's.

Holder of Certificate of Registration

Novagen Pharma (Pty) Ltd.

Office 2, 100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene – Pretoria

South Africa

(t) +27 12 345 3175

This leaflet was revised in

04 July 2022

Registration numbers

MENGEN 500 mg: A40/21.2/0638

MENGEN 850 mg: A40/21.2/0639

MENGEN 1000 mg: A40/21.2/0640

FOR NAMIBIA ONLY:

Schedule: NS2

Registration Numbers:

Mengen 500 mg: 14/21.2/0647

Mengen 850 mg: 14/21.2/0648

Mengen 1000 mg: 14/21.2/0649