PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MENGEN 500 mg (Tablet)

MENGEN 850 mg (Tablet)

MENGEN 1000 mg (Tablet)

Metformin Hydrochloride.

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 MENGEN CONTAINS

The active substance is metformin hydrochloride.

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

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

MENGEN 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.

Sugar free.

WHAT MENGEN 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.

BEFORE YOU TAKE MENGEN

Do not take MENGEN:

if you are hypersensitive (allergic) to Metformin Hydrochloride or any of the other ingredients of **MENGEN**.

if you experience diabetic coma, ketoacidosis, impairment of kidney function, chronic liver disease, pancreatitis, cardiac failure and recent myocardial infarction. History of, or states associated with, lactic acidosis such as shock or pulmonary insufficiency, alcoholism (acute or chronic), and conditions associated with hypoxemia.

if you are pregnant or breastfeeding your baby.

Do not use in children as safety and efficacy have not been established.

Take special care with MENGEN:

Taking oral hypoglycaemics may be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet with insulin.

Lactic acidosis is a medical emergency which must be treated in hospital.

MENGEN is excreted by the kidney and regular monitoring of renal function is advised in all diabetics.

MENGEN therapy should be stopped 2-3 days before surgery and clinical investigations such as intravenous urography and intravenous angiography, and reinstated only after control of kidney function has been regained.

Do not take **MENGEN** if you are suffering from serious infections, trauma or on low calorie intake. Check your Vitamin B_{12} levels annually.

During concomitant therapy with a sulphonylurea, blood glucose should be monitored because combined therapy may cause hypoglycaemia.

Taking MENGEN with food and drink:

Take **MENGEN** tablets in dived doses with meals.

Pregnancy and Breastfeeding:

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **MENGEN**.

Taking other medicines with MENGEN:

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

(This includes complementary or traditional medicines.)

MENGEN interacts with cimetidine and anticoagulants. Adjust dosages of cimetidine and anticoagulants as advised by your doctor or pharmacist.

HOW TO TAKE MENGEN

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

Always take **MENGEN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **MENGEN** is too strong or too weak, talk to your doctor or pharmacist.

Adults:

Initially, one 1000 mg or 850 mg tablet twice a day or one 500 mg tablet three times a day, with or after food. Good diabetic control may be achieved within a few days, but it is not unusual for the full effect to be delayed for up to two weeks. If control is incomplete a cautious increase in dosage to a maximum of 3 g daily is justified. Once control has been obtained it may be possible to reduce the dosage of **MENGEN.**

Elderly:

MENGEN may be used in the elderly, but not when kidney function is impaired.

If you take more MENGEN than you should:

In excessive dosage, and particularly if there is a possibility of accumulation, lactic acidosis may develop. Intense symptomatic and supportive therapy is recommended which should be particularly directed at correcting fluid loss and metabolic disturbance.

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 MENGEN:

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

POSSIBLE SIDE EFFECTS

MENGEN can have side effects.

Metabolism and nutrition disorders:

Very rare: Decrease of vitamin B_{12} and folic acid absorption with decrease of serum levels during long-term use of metformin. This change is generally without clinical significance.

Very rare: Lactic acidosis.

Nervous system disorders:

Common: Metallic taste.

Gastrointestinal disorders:

Very common: Gastrointestinal disorders such as nausea & vomiting.

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 this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

STORING AND DISPOSING OF MENGEN:

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).

PRESENTATION OF MENGEN

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, 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.

IDENTIFICATION OF MENGEN:

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

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

MENGEN 1000 mg: White, biconvex, oval shaped film-coated tablets with a scoreline in between '6' and '2' on one side and 'A' debossed on the other side.

REGISTRATION NUMBER/REFERENCE NUMBER

MENGEN 500 mg: A40/21.2/0638

MENGEN 850 mg: A40/21.2/0639

MENGEN 1000 mg: A40/21.2/0640

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FOR NAMIBIA ONLY:

Schedule: NS2

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Mengen 500 mg: 14/21.2/0647

Mengen 850 mg: 14/21.2/0648

Mengen 1000 mg: 14/21.2/0649