PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

FORMINAL 500 (tablet)

FORMINAL 850 (tablet)

Metformin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking FORMINAL

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

1. What FORMINAL is and what it is used for

FORMINAL is used to treat high blood sugar levels especially in those who are over-weight.

2. What you need to know before you take FORMINAL

Do not take FORMINAL if

- you are hypersensitive (allergic) to metformin or any of the other ingredients of FORMINAL (refer to the list of other ingredients listed in section 6).;
- you suffer from diabetic ketoacidosis, diabetic pre-coma, or have a history thereof;
- you have impaired renal function.
- you suffer from pancreatitis and chronic liver disease.
- you have a history of or states associated with lactic acidosis such as shock or pulmonary insufficiency.
- you have cardiac failure and had a recent myocardial infarction.
- you have conditions associated with hypoxia;
- you have hepatic insufficiency, acute alcohol intoxication, or an alcoholic;
- you are pregnant or breastfeeding since the safety and efficacy have not been established;
- you are a child under 12 years old, since the safety and efficacy have not been established;

Warnings and precautions

Tell your doctor

- if you suffer from lactic acidosis;
- if you have kidney problems;
- if you have liver problems,
- if you need to take iodinated contrast agents for a test that you take FORMINAL.
- if you need to go for surgery that you take FORMINAL.

  or
- if you take alcohol.

Other medicines and FORMINAL

If you are taking medicines on a regular basis, using FORMINAL at the same time with another medicine may cause undesirable interactions. (This includes all complementary and traditional medicines). Please consult your doctor, pharmacist or other health care professional for advice.

FORMINAL with alcohol

Avoid taking alcohol and alcohol-containing medications.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby while taking FORMINAL or you, 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.

Driving and using machines The ability to drive a motor vehicle or operate machinery may be impaired by FORMINAL when taken in combination with other antidiabetic medicine. This applies particularly in combination with alcohol.

It is not always possible to predict to what extent FORMINAL may interfere with the daily activities of a patient. Patients should ensure they do not engage in activities until they are aware of the measure to which FORMINAL affects them.

3. How to take FORMINAL

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

Always take FORMINAL 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 FORMINAL will last. Do not stop treatment early. If you have the impression that the effect of FORMINAL is too strong or too weak, tell your doctor or pharmacist.

Initially the dose may be 1 tablet 3 times daily; however, this can change depending on your blood sugar levels as determined by your doctor.

FORMINAL is not indicated for use in children under the age of 12 years.

If you take more FORMINAL than you should

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

If you forget to take FORMINAL

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

4. Possible side effects

FORMINAL can have side-effects. Not all side effects reported for FORMINAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FORMINAL, please consult your doctor, pharmacist, or other health care professional for advice.

The following side effects can occur with the use of FORMINAL

Common side effects

Haematological:

Vitamin B12 deficiency

Nervous system disorders:

Metallic taste

Gastro-intestinal effects:

Anorexia, nausea, vomiting, constipation, diarrhoea

Uncommon side effects

Other

Hypoglycaemia, hypersensitivity

Haematological:

- Megaloblastic anaemia

Genitourinary / Kidney:

▪ A build-up of ketones in the blood, making the blood acidic (ketoacidosis) and excretion of abnormally large amounts of ketone bodies in the urine (ketonuria)

Liver:

▪ Severe liver disease that causes inflammation of the liver and a problem with bile transport (cholestatic hepatitis)

Reporting of side effects

If you get side effects, talk to your doctor or 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 FORMINAL.

5. How to store FORMINAL

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep well closed. Do not remove tablets from unit carton until required for use.
- Keep all medicines in a safe place, out of reach of children.
- Return all unused or expired 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 FORMINAL contains

FORMINAL 500

- The active substance is metformin hydrochloride 500 mg.
- The other ingredients are:

Tablet core: Maize starch, Povidone K-30, Puri_ed water, Magnesium stearate

Film-coating: Flexicoat SCH White Protect consisting of magnesium silicate hydroxide, titanium dioxide, polyvinyl alcohol-polyethylene glycol graft copolymer and polyvinyl alcohol (PVA), polyvinyl alcohol, silicon dioxide. Puri_ed water.

FORMINAL 850

- The active substance is metformin hydrochloride 850 mg.
- The other ingredients are:

Tablet core: Maize starch, Povidone K-30, Puri_ed water, Magnesium stearate

Film-coating: Flexicoat SCH White Protect consisting of magnesium silicate hydroxide, titanium dioxide, polyvinyl alcohol-polyethylene glycol graft copolymer and polyvinyl alcohol (PVA), polyvinyl alcohol, silicon dioxide. Puri_ed water.

What FORMINAL looks like and contents of the pack

FORMINAL 500 is white to off white, round, biconvex film-coated tablets, embossed with ‘A’ on one side and ‘115’ on other side.

FORMINAL 500 is supplied in:

- White High Density Polyethylene (HDPE) bottles with an induction seal wad in the child resistant cap along with a silica gel desiccant in pack sizes of 60, 100 or 500 tablets.
- Clear, push-through PVC/Aluminium printed blister strips of 10 or 14 tablets each, packed into a unit-carton containing 56, 60, 84 or 100 tablets.
- Printed patient ready Low Density Polyethylene (LDPE) packs of 56 or 84 tablets.

FORMINAL 850 is white to off white, round, biconvex _lm-coated tablets, with “A” embossed on one side and “117” embossed in one bisect on the other side. The break line in FORMINAL 850 is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

FORMINAL 850 is supplied in:

- White High Density Polyethylene (HDPE) bottles with an induction seal wad in the child resistant cap along with a silica gel desiccant in pack sizes of 60, 100 or 300 tablets.
- Clear, push-through PVC/Aluminium printed blister strips of 10 or 14 tablets each, packed into a unit-carton containing 56, 60, 84 or 100 tablets.
- Printed patient ready Low Density Polyethylene (LDPE) packs of 56 or 84 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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