

**Please read this leaflet carefully in full before taking this medicinal product.**

It contains important information on your treatment.

If you have further questions, ask your doctor or pharmacist.

This medicinal product has been prescribed for you personally. Do not give it to anyone else, as you may cause this person harm, even if he/she has the same symptoms as you.

Keep this leaflet, you may need to refer to it again.

**GLUCOVANCE 500 mg/5 mg, film-coated tablet.**

Metformin .....	390 mg
in the form of metformin hydrochloride.....	500 mg
Glibenclamide .....	5 mg

For one film-coated tablet

The other components are: Microcrystalline cellulose, Croscarmellose sodium, Povidone K30, Magnesium stearate,

Film-coating: Opadry 31-F-22700 (yellow) (lactose monohydrate, hypromellose, titanium dioxide, macrogol, yellow iron oxide, red iron oxide, Quinoline Yellow Lake).

**1. WHAT IS GLUCOVANCE 500 mg/5 mg, film-coated tablet AND WHEN SHOULD IT BE USED?**

This medicinal product is available as a film-coated tablet packed in box of 30 tablets.

This medicinal product is a fixed combination of two oral antidiabetics from different pharmacological classes: metformin (biguanides) and glibenclamide (hypoglycaemic sulfonylureas)

Combined with a proper diet, this medicinal product is indicated for the treatment of adult-onset diabetes (type 2 diabetes mellitus).

**2. INFORMATION NECESSARY BEFORE TAKING GLUCOVANCE 500 mg/5 mg, film-coated tablet**

**Do not use GLUCOVANCE 500 mg/5 mg, film-coated tablet in the following cases:**

- Allergy to metformin hydrochloride, to glibenclamide, to other sulfonylureas or to any of the ingredients of the medicinal product,
- Insulin-dependent diabetes (type 1), loss of diabetes control with ketoacidosis
- Renal insufficiency, even moderate (kidney failure with elevation of creatinine levels in the blood),
- Severe infection (respiratory tract infection, urinary tract infection),
- For a 2-day period after a radiological examen involving the use of iodinated contrast materials
- Heart failure, respiratory insufficiency, recent myocardial infarction
- Hepatic insufficiency (liver failure),
- Persistent diarrhoea, repeated vomiting,
- In association with a medicinal product containing miconazole,
- In case of high consumption of alcoholic beverages,
- During breast-feeding,
- Porphyrin accumulation of pigments (porphyrin) in the body,

**Special precautions to be observed with GLUCOVANCE 500 mg/5 mg, film-coated tablet:**

**Special warnings:**

**Lactic acidosis**

During treatment, the onset of vomiting and abdominal pain accompanied by muscle cramps or general malaise with intense fatigue may be a sign of severe loss of diabetes control.

Notify your doctor promptly and do not take your medication before your doctor's visit.

**Hypoglycaemia (decrease of blood glucose levels):**

During treatment, you may experience hypoglycaemia. The warning signs of hypoglycaemia are mainly tremor, blurred vision, sweating, palpitations. Carbohydrate (sugar) intake generally allows to counter hypoglycaemia.

However, in some cases, you may need to be hospitalised to bring your blood glucose back under control.

The following information is necessary to avoid episodes of hypoglycaemia:

- It is important to adhere to a consistent meal schedule, including breakfast, since the risk of hypoglycaemia is increased if you skip a meal, do not eat enough or eat foods with an imbalanced carbohydrate content;
- Age, renal insufficiency, hepatic insufficiency and certain adrenal or pituitary disorders can make you more susceptible to hypoglycaemia;
- The risk of hypoglycaemia is increased by a diet that is too strict or poorly balanced, by strenuous or prolonged exercise, by alcohol intake or by concomitant use of other hypoglycaemic drugs (cf. Taking other medicinal products).

**Precautions for use:**

- During treatment, you should respect diet with regular carbohydrate (sugar) intakes during the day. If you are overweight, you should also respect energy-restricted diet.
- Your doctor will periodically order laboratory tests to determine creatinine levels in your blood to check your renal function. Renal function must be adequate because this medicinal product is eliminated primarily by the kidneys.
- You should inform your doctor if you are taking any other medicinal products or if you have an infectious disease such as flu, respiratory tract infection or urinary tract infection.
- Certain diseases as well as some medications (e.g. corticoids, certain diuretics, ritodrine, salbutamol and terbutaline, ACE inhibitors) may cause a more or less severe loss of blood glucose control.
- If you are hospitalised for tests, a surgical procedure or for any other reason (trauma, ...), tell the doctor you are taking this medicinal product.
- For some radiological examen involving the use of iodinated contrast agents, your doctor will instruct you to temporarily stop taking this medicinal product prior to, or at the time of the test and not take it again until 48 hours afterwards, and only after renal function has been re-evaluated and found to be normal.
- Blood and urine sugar level should regularly be checked.
- As this medicinal product contains lactose, it should not be used in patients with galactosemia, glucose and galactose malabsorption syndrome or in case of lactase deficiency (rare metabolic diseases).

**IN CASE OF DOUBT DO NOT HESITATE TO REQUEST THE OPINION OF YOUR DOCTOR OR PHARMACIST.**

**Taking GLUCOVANCE 500 mg/5 mg, film coated tablet with food or drink**

Avoid any consumption of alcoholic beverages.

#### **Pregnancy**

The use of this medicinal product during pregnancy is inadvisable.

In case of pregnancy, the treatment of diabetes necessarily requires the use of insulin.

If you learn you are pregnant while taking this medicinal product, you will have to switch to insulin.

Inform your doctor who will modify your treatment.

Inform your doctor if you are planning to become pregnant.

#### **Breast-feeding**

This medicinal product is contra-indicated during breast-feeding.

Ask your doctor or pharmacist before taking any medicinal product.

#### **Ability to drive and use machines**

Due to the potential risk of hypoglycaemia associated with the treatment, caution is advised if you drive. This is of importance if usual symptoms are decreased or do not occur or if you experience frequent hypoglycaemia.

Your ability to drive should be re-evaluated in such circumstances.

#### **List of excipients with a potential effect**

Lactose

#### **Taking other medicinal products:**

Please inform your doctor or pharmacist if you are taking or recently took other medicinal products such as corticoids, ACE inhibitors (angiotensin converting enzyme inhibitors), diuretics, ritodrine, salbutamol, terbutaline, iodinated contrast agents, beta-blockers, fluconazole, miconazole, phenylbutazone, desmopresin, danazol or alcohol containing medicinal products even in the case of a drug obtained without prescription.

#### **3. HOW SHOULD GLUCOVANCE 500 mg/5 mg, film coated tablet BE TAKEN?**

This medicinal product is to be used in adults only.

The dosage of this medicinal product is determined individually by your doctor according to laboratory test results (glycaemia). The mean usual dosage is from 1 to 4 tablets daily (taken at the beginning of meal).

#### **Oral route**

The tablets should be swallowed whole without chewing at the beginning of meals, as following:

- 1 intake per day, at breakfast if the dosage is 1 tablet daily;
- 2 intakes per day, at breakfast and at dinner if the dosage is 2 or 4 tablets daily;
- 3 intakes per day, at breakfast, at noon and at dinner if the dosage is 3 tablets daily.

It is important to adhere to a consistent meal schedule, including breakfast, since the risk of hypoglycaemia is increased if you skip a meal, do not eat enough or eat foods with an imbalanced carbohydrate content.

This medicinal product must be taken every day without interruption, unless otherwise directed by your doctor.

**IN ALL CASES YOU SHOULD STRICTLY CONFORM TO YOUR DOCTOR'S PRESCRIPTION.**

#### **Instructions if you have taken more GLUCOVANCE 500 mg/5 mg, film coated tablet then you should**

Immediately inform your doctor or pharmacist

#### **Instructions if you forgot to take GLUCOVANCE 500 mg/5 mg, film coated tablet**

Take the next dose at the usual time; do not double the dose.

#### **Risk of withdrawal syndrome**

Not applicable

#### **4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS OF GLUCOVANCE 500 mg/5 mg, film coated tablet?**

As all medicinal products, Glucovance 500 mg/5 mg may cause undesirable effects:

- Gastrointestinal disturbances such as nausea, vomiting, diarrhoea or abdominal pain may occur at the beginning of treatment. These effects are usually transitory (lasting about 10 days). If symptoms persist, stop taking this medicinal product and consult your doctor.
- Hypoglycaemia (low blood glucose levels) (cf. special precautions). During treatment, the signs of hypoglycaemia may occur such as tremor, blurred vision, sweating, palpitations. Take immediately some sugar and follow your doctor's recommendations.
- During treatment, the onset of vomiting and abdominal pain accompanied by muscle cramps or general malaise with intense fatigue may be a sign of severe loss of diabetes control. This may be due to lactic acidosis. Stop taking this medicinal product right away and consult your doctor immediately.
- Other undesirable effects:
  - Skin reactions: urticaria, itching, skin eruptions.
  - Jaundice, hepatitis.
  - Porphyrinuria: accumulation of pigments (porphyrin) in the body.
  - Laboratory abnormalities of the liver, kidneys or blood.

**INFORM YOUR DOCTOR OR PHARMACIST IF YOU EXPERIENCE ANY UNDESIRABLE EFFECT NOT APPEARING IN THIS LEAFLET.**

#### **5. STORAGE OF GLUCOVANCE 500 mg/5 mg, film coated tablet**

Store at a temperature that does not exceed 30°C.

Store in the original primary packaging.

Keep out of the reach and sight of children.

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

This leaflet was last approved on 18 October 2001.

Packed by **Pharmaline - Lebanon**

Licensed by **Merck Santé s.a.s. - France**