Amaryl® Abbreviated Prescribing Information

1. NAME AND PRESENTATION: Amaryl 1mg tablet, Amaryl 2 mg tablet, Amaryl 3 mg tablet, Amaryl 4 mg tablet. Each tablet contains 1 mg, 2mg, 3 mg & 4 mg glimepiride. **2. THERAPEUTIC INDICATIONS:** Amaryl is indicated for the treatment of type 2 diabetes mellitus when diet, physical exercise, and weight reduction alone are not adequate. **3. POSOLOGY AND METHOD OF ADMINISTRATION:** Dose is determined by the results of blood and urinary glucose determinations. The starting dose is 1 mg glimepiride per day. If good control is achieved, this dose should be used for maintenance therapy. If control is unsatisfactory, the dose should be increased, based on the glycaemic control, in a stepwise manner with an interval of about 1 to 2 weeks between each step, to 2, 3, or 4 mg glimepiride per day. The maximum recommended dose is 6 mg glimepiride per day. In patients not adequately controlled with the maximum daily dose of metformin, concomitant glimepiride therapy can be initiated. Normally, a single daily dose of glimepiride is sufficient. It is recommended that this dose be taken shortly before or during a substantial breakfast or if none is taken shortly before or during the first main meal. *Switch over from other oral hypoglycaemic agents to Amaryl:* A switch over from other oral hypoglycaemic agents to Amaryl can generally be done. The recommended starting dose is 1 mg glimepiride per day. **4. CONTRA-INDICATIONS:** Glimepiride is contraindicated in patients with the following conditions: • Hypersensitivity to glimepiride, other sulfonylureas, or sulfonamides or to any of its excipients. • Insulin dependent diabetes, • Diabetic coma • Ketoacidosis • Severe renal or hepatic function disorders. In case of severe renal or hepatic function disorders, a changeover to insulin is required. **5. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Amaryl must be taken shortly before or during a meal. When meals are taken at irregular hours or skipped altogether, treatment with Amaryl may lead to hypoglycaemia. Hypoglycaemic Symptoms can almost always be promptly controlled by immediate intake of carbohydrates (sugar). In patients with severe impairment of renal or liver function, change over to insulin is indicated. **6. PREGNANCY:** There are no adequate data from the use of glimepiride in pregnant women. Glimepiride should not be used during the whole pregnancy. In case of treatment by glimepiride, if the patient plans to become pregnant or if a pregnancy is discovered, the treatment should be switched as soon as possible to insulin therapy. **7. Lactation** The excretion in human milk is unknown. Glimepiride is excreted in rat milk. As other sulfonylureas are excreted in human milk and because there is a risk of hypoglycemia in nursing infants, breast feeding is advised against during treatment with glimepiride **8. DRUG INTERACTIONS:** Glimepiride is metabolized by cytochrome P450 2C9 (CYP2C9). Its metabolism is known to be influenced by concomitant administration of CYP2C9 inducers (e.g. rifampicin) or inhibitors (e.g. fluconazole). (Please see full SmPc). **9. EFFECTS ON ABILITY TO DRIVE:** No studies on the effects on the ability to drive and use machines have been performed. The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia or hyperglycaemia or, for example, as a result of visual impairment. **10. UNDESIRABLE EFFECTS:** Rare: hypoglycemia, these hypoglycemic reactions mostly occur immediately, may be severe and are not always easy to correct. Thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, erythropenia, haemolytic anaemia and pancytopenia. Very rare: nausea, vomiting, diarrhoea, abdominal distension, abdominal discomfort and abdominal pain, which seldom lead to discontinuation of therapy. leukocytoclastic vasculitis, mild hypersensitivity reactions that may develop into serious reactions with dyspnoea, fall in blood pressure and sometimes shock. **11. SHELF LIFE:** [Amaryl 1 mg, 2 mg, 3 mg, 4 mg]: 3 years **12**. **SPECIAL PRECAUTIONS FOR STORAGE:** [Amaryl 1 mg, 2 mg, 3 mg]: Do not store above 30°C. Store in the original package in order to protect from moisture **13. MARKETING AUTHORISATION HOLDER:** Sanofi-Aventis Deutschland GmbH 6592 Frankfurt am Nain Germany **14. DATE OF REVISION OF THE TEXT:** October 2022

More detailed information available upon request from: Sanofi Winthrop Industrie, Mecca Street, Al Hijaz Towers for Investment, 8th Floor; PO BOX 922464, Amman 11192 – Jordan Tel: (962) 6 55 63 6 60.

To report an adverse event or if you have any medical enquiry, email us at:

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