

## **PATIENT INFORMATION LEAFLET**

Read all of this leaflet carefully before you start taking AMARYL tablets.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- AMARYL 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.

**SCHEDULING STATUS:** S3

### **PROPRIETARY NAME AND DOSAGE FORM:**

**AMARYL 1** (tablets)

**AMARYL 2** (tablets)

**AMARYL 3** (tablets)

**AMARYL 4** (tablets)

### **WHAT AMARYL CONTAINS:**

The active ingredient in your AMARYL tablets is glimepiride.

Each tablet also contains lactose, magnesium stearate, microcrystalline cellulose, polyvidone 25 000 and sodium starch glycolate. In addition the tablets contain colouring agents. The 1 mg tablets contain red ferric oxide; the 2 mg and 3 mg tablets contain yellow ferric oxide; and the 2 mg and 4 mg contain indigo carmine aluminium lake.

**WHAT AMARYL IS USED FOR:**

Amaryl is one of a group of medicines called oral hypoglycaemics, which are used for the treatment of diabetes in patients whose blood sugar levels are not adequately controlled by diet and exercise alone. Diabetes is a disease where the body does not produce enough insulin to control the level of blood sugar. Oral hypoglycaemics help control blood sugar levels.

**BEFORE TAKING AMARYL:****Do not take Amaryl if:**

- you are allergic to glimepiride, other medicines used to treat high blood sugar levels or any of the ingredients listed above.
- you are pregnant or breastfeeding.
- you have liver problems.
- you have Type 1 insulin-dependant diabetes mellitus.

**Take special care with Amaryl:**

- Stressful situations (e.g. trauma, surgery and febrile infections) may affect blood sugar levels and your medication may need to be adjusted.
- Amaryl must be used with caution in patients with kidney problems and G6PD-deficiency.
- If your blood sugar level is not lowered (hyperglycaemia) sufficiently with Amaryl, you may experience increased urinary frequency, intense thirst, and dryness of the mouth.
- If your blood sugar level is too low (hypoglycaemia), you may experience the following: tiredness, headache, rapid heartbeat, cold sweat, nervousness or shakiness, nausea and hunger pangs. Low blood sugar (hypoglycaemia) may occur if you miss or delay meals, take more Amaryl than is needed, have severe kidney or liver disease, change the type and intensity of physical activity or are recovering from an injury,

operation, fever or other illnesses.

**Pregnancy and breastfeeding:**

**If you are pregnant or breastfeeding your baby while using Amaryl please consult your doctor, pharmacist or other healthcare professional for advice.**

You should not use AMARYL if you are pregnant or breastfeeding your baby.

**Driving and using machinery:**

You may feel sleepy or have blurred vision when beginning or altering treatment with Amaryl; this may also happen if you forget to take your Amaryl. If this happens do not drive or operate machinery.

**Important information about some of the ingredients of AMARYL:**

AMARYL contains lactose monohydrate, a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking AMARYL.

**Taking other medicines with Amaryl**

**If you are taking other medicines on a regular basis including complementary and traditional medicines, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.**

Certain other medicines, even those bought without a prescription can affect the action of Amaryl, especially: antibacterials/antifungals (medicines to treat bacterial and fungal infections),

oral contraceptives (the pill), medicines for the heart or blood pressure, analgesics (pain killers), diuretics (water tablets), medicines to treat depression, gout, ulcers or epilepsy, or medicines to stop blood clotting.

#### **HOW TO TAKE AMARYL:**

**Do not share AMARYL prescribed for you with others.**

Your doctor will tell you when and how to take your medicine. The usual starting dose is 1 mg glimepiride (AMARYL 1) each day but this may be increased by your doctor after each 1-2 weeks of treatment. Amaryl should usually be taken before or with the first meal of the day, and should be swallowed whole with some liquid.

#### **If you forget to take or missed a dose of AMARYL:**

If you miss a dose, never double up on the next dose to make up for the one missed.

#### **If you take more AMARYL than you should:**

**In the event of overdose, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.**

#### **SIDE EFFECTS:**

**Not all side effects reported for Amaryl are included in this leaflet. Should your general health worsen while taking Amaryl, please consult your doctor, pharmacist or other healthcare professional for advice.**

Side effects to Amaryl may include an upset stomach (e.g. nausea, vomiting, diarrhoea), rash or itching skin. Your sight may be affected, but this should soon improve. Rarely, an elevation of

the liver enzymes or an impairment of liver functions may occur. Tell your doctor if you notice anything unusual or unexpected, or if these symptoms are bad or they last a long time.

It is important to know what symptoms to expect when hypoglycaemia (low blood sugar) occurs.

Ask your doctor or pharmacist for more information if you are not sure how to recognize this.

The symptoms may include a cold sweat, tiredness, headache, rapid heartbeat, hunger pangs, irritability, nervousness or nausea. Tell your doctor if you notice any such symptoms.

Tell your doctor if you get a lot of infections with sore throats or mouth ulcers, if you bruise more easily while you are taking AMARYL, or if you look pale.

#### **STORAGE AND DISPOSAL OF AMARYL:**

##### **KEEP OUT OF SIGHT AND REACH OF CHILDREN.**

Store below 25 °C. Keep your tablets in the blister strips in which they are packed.

Do not use the tablets after the expiry date shown on the carton or blister strip. If your tablets expire, take them to your pharmacist so that he or she can get rid of them safely.

#### **PRESENTATION OF AMARYL:**

Amaryl is presented in a blister pack of 15 and 30 tablets and comes in 4 strengths.

#### **IDENTIFICATION OF AMARYL:**

1 mg: Pink oblong tablets, biplanar with score-line on both sides

2 mg: Green oblong tablets, biplanar with score-line on both sides

3 mg: Pale yellow oblong tablets, biplanar with score-line on both sides

4 mg: Light blue oblong tablets, biplanar with score-line on both sides

#### **REGISTRATION NUMBER:**

1 mg: 30/21.2/0060

2 mg: 30/21.2/0061

3 mg: 30/21.2/0062

4 mg: 30/21.2/0063

**NAME AND THE BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF  
REGISTRATION:**

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