

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others.
- It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse.
- This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

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

**1. WHAT AMARYL M IS AND WHAT IT IS USED FOR**  
**Pharmacotherapeutic group and therapeutic indications**

AMARYL M is a medicine taken by mouth to help lower blood sugar. AMARYL M is used, with diet and physical exercise, to treat a certain form of diabetes (type 2 diabetes mellitus):

- in case of the use of glimepiride or metformin alone does not control your blood glucose level,
- in place of taking the combination of glimepiride tablet with a metformin tablet.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMARYL M**  
**Contraindications**

**Do not take AMARYL M:**

- if you have insulin-dependent diabetes (type 1 diabetes mellitus),
- if you have diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, feeling sick (nausea), frequent urination and muscular stiffness),
- if you are in a diabetic pre-coma,
- if you are allergic (hypersensitive) to glimepiride or metformin hydrochloride, or any of the other ingredients of AMARYL M (listed in section 6 under "Contents of the pack and other information"), to sulphonamides (medicines for bacterial infections such as sulfamethoxazole), other sulfonyleureas (medicines used to lower your blood sugar such as glibenclamide),

- if you are pregnant, planning to get pregnant or are breast-feeding,
- if you have or have had lactic acidosis (an increase in the amount of lactic acid in the body),
- if you have a severe kidney disease or kidney disorder,
- if you have recently had a heart attack or are treated for heart failure, or have severe circulatory problems or difficulty in breathing,
- if you have a liver disorder,
- if you drink a lot of alcohol,
- if you have a severe infection or are dehydrated,
- if you are going to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream. You will need to stop taking AMARYL M at the time of and for a few days after the procedure.

**Warnings and precautions**

Please follow closely the instructions for dosage, monitoring (blood and/or urine tests), diet and physical activity (physical work and exercise) as discussed with your doctor.

**Talk to your doctor or pharmacist before taking your medicine if you are recovering from an injury, operation, infections with fever, or from other forms of stress, inform your doctor as temporary change of treatment may be necessary.**

**Important information about lactic acidosis:**

Lactic acidosis is an increase in the amount of lactic acid in the blood. It is a rare, but serious, side effect of metformin. It is a medical emergency and must be treated in a hospital. This most often affects people who have severe kidney disease. You should be cautious against excessive alcohol intake, either acute or chronic, when taking this drug, since alcohol potentiates the effects of metformin.

The symptoms of lactic acidosis include: rapid breathing, stomach pain, nausea, vomiting, and feeling cold.

**If you experience some of these symptoms, stop taking AMARYL M and contact your doctor immediately.**

**Important information about hypoglycaemia (low blood sugar):**

When you take AMARYL M, you may get hypoglycaemia (low blood sugar). Please see below for additional information about hypoglycaemia, its signs and treatment.

*The following factors could increase the risk of you getting hypoglycaemia:*

- Undernourishment, irregular meal time, or missed or delayed meal or period of fasting,
- If you increase your body exercise and you don't eat enough food or eat food containing less carbohydrate than normal,
- Changes to your diet,
- Drinking alcohol (especially when you skip a meal),
- Having decreased kidney function,
- Having severe liver disease,
- If you suffer from certain uncompensated hormone induced disorders: disorders of thyroid glands, of the pituitary gland or adrenal cortex,
- Taking certain other medicines (see Section 2 under "Other medicines and AMARYL M"),
- Taking more AMARYL M than needed.

If such risk factors for hypoglycaemia are present, it may be necessary to adjust the dosage of AMARYL M, talk with your doctor or pharmacist. This also applies whenever illness occurs during therapy or any life-style changes.

**Symptoms of hypoglycaemia:**

The symptoms of hypoglycaemia (see Section 4) may be milder or absent in those situations where hypoglycaemia develops

gradually, in the elderly, and in patients with a certain type of nervous disease (autonomic neuropathy) or those receiving treatment with other medications called beta blockers, clonidine, reserpine, guanethidine, or other sympathomimetics.

**Treating hypoglycaemia:**

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, or sweetened tea. You should therefore always take some form of sugar with you (e.g. sugar cubes). Remember that artificial sweeteners are not effective.

**Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.**

**Laboratory Tests**

The level of sugar in your blood or urine should be checked regularly. Your doctor may also take blood tests to monitor your blood cell levels and liver function.

Lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase.

**Kidney function:**

Your kidney function should be measured before starting the treatment and monitored regularly:

- at least once a year in patients with normal kidney function,
- at least two to four times a year in patients with kidney disease and in elderly subjects.

Pay special attention to situations where your kidney function may become impaired, such as when starting new medicine for: lowering blood pressure, water retention or treatment with a medicine used for pain and inflammation (known as a non-steroidal anti-inflammatory).

**Surgery or injection of contrast medicines that contain iodine for examinations**

If you need to have a surgery or if you need to have an injection of contrast medicines that contain iodine into your bloodstream, for example for examinations such as X-ray or scan, you should stop taking AMARYL M for a certain period of time before and after the examination or surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

**Children and adolescents**

AMARYL M has not been studied in children and adolescents who are under 18 years of age.

**Other medicines and AMARYL M**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to change your dose of AMARYL M if you are taking other medicines, which may weaken or strengthen the effect of AMARYL M on the level of sugar in your blood.

The following medicines can increase the blood sugar lowering effect of AMARYL M. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other medicinal products to treat diabetes mellitus (such as insulin or other antidiabetics),
- Medicinal products to treat pain and inflammation (phenylbutazone, azopropazone, oxyphenbutazone, aspirin-like medicines),
- Medicinal products to treat urinary infections (such as some long acting sulfonamides),
- Medicinal products to treat bacterial and fungal infections

(tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin),

- Medicinal products to inhibit blood clotting (coumarin derivatives such as warfarin),
- Medicinal products supporting muscle build up (anabolics),
- Medicinal products used for male sex hormone replacement therapy,
- Medicinal products to treat depression (fluoxetine, MAO-inhibitors),
- Medicinal products lowering high cholesterol level (fibrates),
- Medicinal products lowering high blood pressure (ACE inhibitors),
- Medicinal products called anti-arrhythmic agents used to control abnormal heart beat (disopyramide),
- Medicinal products to treat gout (allopurinol, probenecid, sulfinpyrazone),
- Medicinal products to treat cancer (cyclophosphamide, ifosfamide, tofosfamide),
- Medicinal products used to reduce weight (fenfluramine),
- Medicinal product to increase circulation when given in a high dose intravenous infusion (pentoxifylline),
- Medicinal products to treat nasal allergies such as hay fever (tritoqualine),
- Medicinal products called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms.

The following medicines may decrease the blood sugar lowering effect of AMARYL M. This can lead to a risk of hyperglycaemia (high blood sugar level):

- Medicinal products containing female sex hormones (oestrogens, progestogens),
  - Medicinal products supporting urine production (thiazide diuretics),
  - Medicinal products used to stimulate the thyroid gland (such as levothyroxine),
  - Medicinal products to treat allergies and inflammation (glucocorticoids),
  - Medicinal products to treat severe mental disorders (chlorpromazine and other phenothiazine derivatives),
  - Medicinal products used to raise heartbeat, to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in life-threatening emergencies (adrenaline and sympathomimetics),
  - Medicinal products to treat high cholesterol level (nicotinic acid),
  - Medicinal products to treat constipation when they are used long term (laxatives),
  - Medicinal products to treat seizures (phenytoin),
  - Medicinal products to treat nervousness and sleep problems (barbiturates),
  - Medicinal products to treat increased pressure in the eye (acetazolamide),
  - Medicinal products to treat high blood pressure or lowering blood sugar (diazoxide),
  - Medicinal products to treat infections, tuberculosis (rifampicine),
  - Medicinal products to treat severe low blood sugar levels (glucagon),
  - Medicinal products to treat asthma (beta-2 agonists such as salbutamol).
- The following medicinal products can increase or decrease the blood sugar lowering effect of AMARYL M:
- Medicinal products to treat stomach ulcers (called H2 antagonists),
  - Medicinal products to treat high blood pressure or heart failure

such as beta-blockers, clonidine, guanethidine and reserpine. These can also hide the signs of hypoglycaemia, so special care is needed when taking these medicines.

AMARYL M may either increase or weaken the effects of the following medicines:

- Medicinal products inhibiting blood clotting (coumarin derivatives such as warfarin).

- Colesevelan, a medicine used to reduce cholesterol, has an effect on the absorption of AMARYL M. To avoid this effect, you should be advised to take AMARYL M at least 4 hours before colesevelan.

#### Iodinated contrast agents:

A build-up of acid in your blood (known as lactic acidosis) may occur if you take iodinated contrast materials for a special examination such as X-ray or scan, you should stop taking AMARYL M for a certain period of time before and after the examination (see section 2 under "Warnings and precautions").

#### **AMARYL M with alcohol**

You should avoid drinking alcohol and using alcohol-containing medicines. Alcohol intake may increase or decrease the blood-sugar-lowering action of AMARYL M in an unpredictable way. Alcohol intake also increases the risk of lactic acidosis.

#### **Pregnancy and breast-feeding**

You should not use AMARYL M if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or your pharmacist for advice before taking this medicine.

#### **Driving and using machines**

Your ability to concentrate or react may be impaired if your blood sugar is lowered (hypoglycaemia) or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines). Ask your doctor whether you can drive a car if you:

- have frequent episodes of hypoglycaemia,
- have fewer or no warning signals of hypoglycaemia.

#### **AMARYL M contains lactose.**

If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicinal product.

### **3. HOW TO TAKE AMARYL M**

Always take AMARYL M exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The dose of AMARYL M depends on your needs, condition and results of blood and urine sugar tests and is determined by your doctor. Do not take more tablets than your doctor has prescribed.

#### **Recommended dose**

It is recommended to start the treatment with the lowest effective dose and your doctor might increase the dose depending on your blood glucose level.

When switching from combination therapy of glimepiride plus metformin as separate tablets, AMARYL M should be administered on the basis of the dosage currently being taken.

- If your weight changes or if you change your lifestyle, or you are in a stress situation this may require changed AMARYL M doses, therefore inform your doctor.

- If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.

#### **How to take this medicine**

AMARYL M should be taken by mouth immediately before or with the meals. Swallow the tablets whole with about half a glass of water.

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

Hypoglycaemia: If you happen to have taken too much AMARYL

M or an additional dose there is a danger of hypoglycaemia (for the signs of hypoglycaemia, see section 4) and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, sweetened tea) and inform a doctor immediately.

When treating hypoglycaemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hyperglycaemia.

Persons in a state of unconsciousness must not be given food or drink.

Since the state of hypoglycaemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission into a hospital may be necessary, also as a measure of precaution. Show the doctor the package or remaining tablets, so the doctor knows what has been taken.

Severe cases of hypoglycaemia accompanied by loss of consciousness and severe neurological failure are cases of medical emergency requiring immediate medical treatment and admission into hospital. It should be ensured that there is always a pre-informed person that can call a doctor immediately if this happens to you.

**Lactic acidosis:** Because this medicine contains metformin, this may lead also to lactic acidosis (see section 2 under "Warnings and precautions"). This is a medical emergency requiring treatment in hospital. Please consult your doctor or pharmacist immediately.

#### **If you forget to take AMARYL M:**

Take your tablets with your next meal.

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

#### **If you stop taking AMARYL M**

If you interrupt or stop the treatment you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will get worse again.

If you have any further questions on the use of this medicine ask your doctor or pharmacist or nurse.

### **4.POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor immediately if you experience any of the following symptoms:**

•**Hypoglycaemia** (see also section 2 under "Warnings and precautions"):

Due to the blood-sugar-lowering action of AMARYL M, hypoglycaemia may occur, and may last for some time.

*Signs of hypoglycaemia include:*

- Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, disordered sleep, restlessness, aggression, impaired concentration, reduced alertness and reaction time, depression, confusion, speech and visual disorders, slurred speech, shakiness, partial paralysis, sensory disturbances, dizziness, helplessness
- The following signs may also occur: sweating, clammy skin, anxiety, accelerated heart beat, high blood pressure, palpitations, sudden strong pain in the breast that may radiate into neighbouring areas (angina pectoris and cardiac arrhythmias).

- If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

*Treating hypoglycaemia:*

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea. **Contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.**

•**Lactic acidosis** (see also section 2 under "Warnings and precautions"):

Some patients have experienced a condition called lactic acidosis (excess of lactic acid in your blood), particularly those whose kidneys are not working properly. Symptoms include: feeling cold or uncomfortable, nausea or vomiting, abdominal pain, or rapid breathing. **If you experience some of these symptoms, stop taking AMARYL M and consult a doctor immediately.**

•**Allergic reactions** (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock. **If hives or rash occurs, a physician must be notified immediately.**

•**Allergy (hypersensitivity)** of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions

•**Abnormal liver function** including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), increased liver enzymes, inflammation of the liver (hepatitis) or liver failure.

•**Digestive disorders:** Feeling of being sick, diarrhoea, feeling full or bloated, abdominal pain and loss of appetite.

•**Taste disturbance:** Taste of metal in your mouth.

•**Blood disorders:** Decrease in the number of blood cells:

-Blood platelets (which increases risk of bleeding or bruising including severe unusual bleeding or bruising under the skin)

-White blood cells (which makes infections more likely)

-Red blood cells (which can make the skin pale and cause weakness or breathlessness).

These problems generally get better after you stop taking AMARYL M.

•**Decrease in the amount of sodium level in your blood** (shown by blood tests).

•**Decreased vitamin B12 levels:** Low levels of vitamin B12 may be seen. Therefore if needed, monitor serum B12 levels.

•**Eyes disorders:** Problems with your sight may occur when beginning treatment with AMARYL M. This is due to changes in blood sugar levels and should soon improve.

#### **Reporting of side effects**

**If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.**

### **5. HOW TO STORE AMARYL M**

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not store above 30°C.

Do not use after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

#### **What AMARYL M contains**

**AMARYL M 1 / 250 mg, film-coated tablets**

-The active substances are glimepiride and metformin hydrochloride.

One tablet contains 1 mg of glimepiride and 250 mg of metformin hydrochloride.

-Other ingredients are: lactose, sodium starch glycolate, povidone K30, microcrystalline cellulose, crospovidone, magnesium stearate, hydroxypropylmethylcellulose, polyethylene glycol 6000, titanium

dioxide, carnauba wax, purified water.

**AMARYL M 1 / 500 mg, film-coated tablets**

- The active substances are glimepiride and metformin hydrochloride.

One tablet contains 1 mg of glimepiride and 500 mg of metformin hydrochloride.

- Other ingredients are: lactose monohydrate, sodium starch glycolate, povidone K30, microcrystalline cellulose, crospovidone, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, ferric oxide red, carnauba wax, purified water.

**AMARYL M 2 / 500 mg, film-coated tablets**

-The active substances are glimepiride and metformin hydrochloride.

One tablet contains 2 mg of glimepiride and 500 mg of metformin hydrochloride.

-Other ingredients are: lactose, sodium starch glycolate, povidone K30, microcrystalline cellulose, crospovidone, magnesium stearate, hydroxypropylmethylcellulose, polyethylene glycol 6000, titanium dioxide, carnauba wax, purified water.

#### **What AMARYL M looks like and contents of the pack**

AMARYL M 1/250 and AMARYL M 2/500 are supplied as white, oval, film-coated tablets.

The tablets are provided in blister packs containing 30 film-coated tablets.

AMARYL M 1/500 mg is supplied as pale pink, oval, film-coated tablets.

The tablets are provided in blister packs containing 30 film-coated tablets.

Not all strengths may be marketed.

**This leaflet was last approved in May 2014**

**Packed by Benta S.A.L.**  
Dbayeh-Lebanon



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**Sanofi-Aventis**

**Deutschland GmbH, Germany.**

#### **This is a medicament**

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you

- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament

- The doctor and the pharmacist are experts in medicine, its benefits and risks

- Do not by yourself interrupt the period of treatment prescribed for you

- Do not repeat the same prescription without consulting your doctor

- Medicament: keep out of reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists

