

if the above applies to you, do not take this medicine and consult your doctor or pharmacist.

## Patient Information Leaflet

## Diameril

### 1 mg, 2 mg, 3 mg, 4 mg, 6 mg tablets

### Glimepiride

**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, consult your doctor or pharmacist.
- 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, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet**

- What Diameril is and what it is used for
- What you need to know before you take Diameril
- How to take Diameril
- Possible side effects
- How to store Diameril
- Contents of the pack and other information

#### 1.What Diameril is and what it is used for

Diameril contains glimepiride which is an orally active blood sugar lowering drug. This drug belongs to a blood sugar lowering group of medicines called sulfonylurea. Diameril works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

Diameril is used to treat a certain form of diabetes (type 2 diabetes mellitus) when diet, physical exercise and weight reduction alone have not been able to control your blood sugar levels.

#### 2.What you need to know before you take Diameril Do not take Diameril:

- if you are allergic (hypersensitive) to: glimepiride or other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of this medicine (listed in Section 6)
- 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 coma
- if you have severe kidney disease
- if you have a severe liver disease.

if the above applies to you, do not take this medicine and consult your doctor or pharmacist.

#### Warnings and precautions

Consult to your doctor or pharmacist before taking Diameril.

Take special care with Diameril:

- 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
- if you have a severe liver or kidney disorder
- lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anemia) can occur in patients missing the enzyme glucose-6-phosphate dehydrogenase.

If any of these apply to you, consult your doctor or pharmacist.

#### Children and adolescents

The information available on the use of Diameril in people under 18 years of age is limited. Therefore, its use in these patients is not recommended.

**Important information about hypoglycemia (low blood sugar)**
When you take Diameril, you may get hypoglycemia (low blood sugar). Please see below for additional information about hypoglycemia, its signs and treatment.

#### • Factors that could increase the risk of you getting hypoglycemia:

- Undernourishment, irregular meal time, missed or delayed meal or period of fasting
- Changes to your diet
- Taking more Diameril than needed
- Having decreased kidney function
- Having severe liver disease
- if you suffer from particular hormone-induced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex)
- Drinking alcohol (especially when you skip a meal)
- Taking certain other medicines (See Taking other medicines below)
- if you increase your body exercise and you do not eat enough or eat food containing less carbohydrate than normal

#### • Signs of hypoglycemia 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 for hypoglycemia:

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.

- 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.

#### Other medicines and Diameril

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 Diameril if you are taking other medicines, which may weaken or strengthen the effect of this medicine on the level of sugar in your blood.

The following medicines can increase the blood sugar lowering effect of Diameril. This can lead to a risk of hypoglycemia (ow blood sugar):

- Other medicinal products to treat diabetes mellitus (such as insulin or mefformin)
- Medicinal products to treat pain and inflammation (azopropazone, oxyphenbutazone, Acetylsalicylic acid -i 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, sulfipyrazone)
- Medicinal products to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)
- Medicinal products used to reduce weight (fenfluramine)
- Medicinal products 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 Diameril. This can lead to a risk of hyperglycemia (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 heart beat, 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 (axatives)
- Medicinal products to treat seizures (phenytoin)
- Medicinal products to treat nervousness and sleep problems (barbiturates)
- Medicinal products to treat increased pressure in the eye (azetazolamide)
- 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)

The following medicinal products can increase or decrease the blood sugar lowering effect of Diameril:

- 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 hypoglycemia, so special care is needed when taking these medicines

Diameril may either increase or weaken the effects of the following medicines:

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

#### Diameril with food, drink and alcohol

Alcohol intake may increase or decrease the blood sugar lowering action of Diameril in an unpredictable way.

#### Pregnancy and breast-feeding

Pregnancy

Diameril should not be taken during pregnancy.

#### Breast feeding

Diameril may pass into breast milk therefore it should not be taken during breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor or 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 (hypoglycemia), or raised (hyperglycemia) 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). Please consult your doctor whether you can drive a car if you:

- have frequent episodes of hypoglycemia,
- have fewer or no warning signals of hypoglycemia

**Important information about some of the ingredients of Diameril**
Diameril contains lactose. If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicine.

#### 3.How to take Diameril

Always take this medicine exactly as your doctor has told you. Consult your doctor if you are not sure.

#### Taking this medicine

- Take this medicine by mouth, just before or with the first main meal of the day (usually breakfast). If you do not have breakfast you should take the product on schedule as prescribed by your doctor. It is important not to leave out any meal when you are on Diameril.

- Swallow the tablets whole with at least half glass of water. Do not crush or chew the tablets

The dose of Diameril 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.

- The usual starting dose is one Diameril 1 mg tablet once a day - if necessary, your doctor may increase the dose after each 1 - 2 weeks of treatment
- The maximum recommended dose is 6 mg Diameril per day
- A combination therapy of glimepiride plus mefformin or of glimepiride plus insulin may be initiated. In such a case your doctor will determine the proper doses of glimepiride, mefformin or insulin individually for you
- If your weight changes or if you change your lifestyle, or you are in a stress situation this may require changed Diameril 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 consult your doctor

#### If you take more Diameril than you should

If you happen to have taken too much Diameril or an additional dose there is a danger of hypoglycemia (signs of hypoglycemia see Section 2 - Take special care with Diameril) and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, sweetened tea) and consult your doctor immediately. When treating hypoglycemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hyperglycemia. Persons in a state of unconsciousness must not be given food or drink

Since the state of hypoglycemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission into 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 hypoglycemia 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 preinformed person that can consult your doctor in case of emergency.

#### If you forget to take Diameril

Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

##### If you stop taking Diameril

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 deteriorate again. Keep taking Diameril until your doctor tells you to stop.

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

#### 4. Possible side effects

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

#### Consult your doctor immediately if you experience any of the following symptoms:

- 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.
- Allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into seious reactions
- Abnormal liver function including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure.
- Severe hypoglycemia including loss of consciousness, seizures or coma (See Section 2).

#### Other side effects of Diameril include:

Rare

- Decrease in the number of blood cells: Blood platelets (which increases risk of bleeding or bruising). 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 Diameril

#### Very rare

- Feeling or being sick, diarrhoea, feeling full or bloated, and abdominal pain
- Decrease in the amount of sodium level in your blood (shown by blood tests)

#### Unknown

Problems with your sight may occur when beginning treatment with Diameril. This is due to changes in blood sugar levels and should soon improve. Increased liver enzymes

If you get any side effects, consult to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### 5. How to store Diameril

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Store below 30°C.
- Store in the original package in order to protect from moisture.
- Do not use any Diameril pack that is damaged
- Do not throw away any medicines via wastewater . Consult 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 Diameril contains**

The active substance in Diameril is glimepiride

- Diameril 1 mg: Each tablet contains 1 mg glimepiride
- Diameril 2 mg: Each tablet contains 2 mg glimepiride
- Diameril 3 mg: Each tablet contains 3 mg glimepiride
- Diameril 4 mg: Each tablet contains 4 mg glimepiride
- Diameril 6 mg: Each tablet contains 6 mg glimepiride

The other ingredients are: microcrystalline cellulose, lactose monohydrate, magnesium stearate, sodium starch glycolate and povidone.

#### What Diameril looks like and contents of the pack

Diameril 2, 3, 4 and 6 mg tablets are white round tablets scored into two on one side.

Diameril 1 mg tablets are white round tablets.

- Diameril 1 mg: Box of 30 tablets.
- Diameril 2 mg: Box of 30 tablets.
- Diameril 3 mg: Box of 30 tablets.
- Diameril 4 mg: Box of 30 tablets.
- Diameril 6 mg: Box of 30 tablets.

#### Marketing Authorisation Holder and Manufacturer

Pharmaline, srl - Lebanon.

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Registration N° Lebanon for Diameril 1 mg 148220/03

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Registration N° Lebanon for Diameril 4 mg 148223/03

Registration N° Lebanon for Diameril 6 mg 168119/10

These problems generally get better after you stop taking Diameril

#### Very rare

- Feeling or being sick, diarrhoea, feeling full or bloated, and abdominal pain
- Decrease in the amount of sodium level in your blood (shown by blood tests)

##### 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.

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