This package insert is continually updated:
please read carefully before using a new pack!

Daonil®

Active ingredient: Glibenclamide

Composition
Each tablet contains, as active ingredient, 5 mg glibenclamide.
Excipients: Lactose, maize starch, talc, colloidal anhydrous silica, magnesium stearate.

Indication
Non-insulin-dependent (type II) diabetes mellitus, whenever blood sugar levels cannot be controlled adequately by diet, physical exercise, or weight reduction alone.

Contraindications
Daonil must not be used for
– patients with insulin-dependent (type I) diabetes mellitus,
– treatment of diabetic ketoacidosis,
– treatment of diabetic precoma or coma,
– patients with serious renal dysfunction,
– patients with serious hepatic dysfunction,
– patients hypersensitive to glibenclamide or to any of the excipients (see under "Composition"),
– pregnant women,
– breast-feeding women.

Precautions
To achieve the goal of treatment with Daonil – optimal control of blood sugar –, adherence to correct diet, regular and sufficient physical exercise and, if necessary, reduction of body weight are just as necessary as regular intake of Daonil.
Clinical signs of hyperglycaemia are: increased urinary frequency, intense thirst, dryness of the mouth, and dry skin.
During treatment with Daonil, glucose levels in blood and urine must be measured regularly. In addition, it is recommended that regular determinations of the proportion of glycated haemoglobin be carried out.
When starting treatment, the patient must be informed about the effects and risks of Daonil and about its interaction with dietary measures and physical exercise; the importance of adequate cooperation must also be stressed.
As is necessary during treatment with any blood-sugar-lowering drug, the patient and the doctor must be aware of the risk of hypoglycaemia (excessive reduction in blood sugar).
Factors favouring hypoglycaemia include:
– unwillingness or (more commonly in older patients) incapacity of the patient to cooperate,
– undernutrition, irregular mealtimes, or skipped meals,
– alterations of diet or unaccustomed physical exertion,
– consumption of alcohol, especially in combination with skipped meals,
– impaired renal function,
– serious liver dysfunction,
– overdosage with Daonil,
– uncompensated disorders of the endocrine system affecting carbohydrate metabolism or counter-regulation of hypoglycaemia (as for example in certain disorders of thyroid function and in anterior pituitary or adrenocortical insufficiency),
– concurrent administration of certain other medicines (see under "Interactions").
The patient must inform the doctor about such factors and about hypoglycaemic episodes, since they may indicate the need for particularly careful monitoring.
If necessary, the dosage of Daonil or the entire therapy must be modified. This also applies whenever illness occurs during therapy or the patient's life-style changes.
Those symptoms of hypoglycaemia (excessive reduction in blood sugar) which reflect the body's adrenergic counter-regulation (see under "Adverse Reactions") may be milder or absent where hypoglycaemia develops gradually, where there is autonomic neuropathy (disorder of part of the nervous system) or where the patient is receiving concurrent treatment with beta-blockers, clonidine, reserpine, guanethidine, or other sympatholytic drugs.
Hypoglycaemia can, almost always, be promptly controlled by immediate intake of carbohydrates (glucose or sugar, e.g., in the form of sugar lumps, sugar-sweetened fruit juice or tea). For this purpose, patients must carry a minimum of 20 grams of glucose with them at all times. They may require the assistance of other persons to avoid complications. Artificial sweeteners are ineffective in controlling hypoglycaemia.
Despite initially successful countermeasures, hypoglycaemia (excessive reduction in blood sugar) may recur. Patients must, therefore, remain under close observation. Severe hypoglycaemia, or a protracted episode, which can only be temporarily controlled by usual amounts of sugar, further requires immediate treatment and follow-up by a doctor and, in some circumstances, in-patient hospital care.
If treated by different doctors (e.g. hospital stay, after an accident, illness while on holiday), the patients must inform them of their diabetic condition and previous treatment.
In exceptional stress situations (e.g. trauma, surgery, febrile infections), blood glucose regulation may deteriorate, and a temporary change to insulin may be necessary to maintain good metabolic control.
Persons allergic to other sulfonamide derivatives may develop an allergic reaction to glibenclamide as well.

Pregnancy and lactation
Daonil must not be taken during pregnancy. The patient must change over to insulin during pregnancy. Patients planning a pregnancy must inform their doctor. Such patients should change over to insulin.
To prevent possible ingestion with the breast milk, Daonil must not be taken by breast-feeding women. If necessary, the patient must change over to insulin, or must stop breast-feeding.

Adverse reactions
Hypoglycaemia: Hypoglycaemia (excessive reduction in blood sugar), sometimes prolonged and even life-threatening, may occur as a result of the blood-sugar-lowering action of Daonil.
Possible symptoms of hypoglycaemia include headache, ravenous hunger, nausea, vomiting, lassitude, sleepiness, disordered sleep, restlessness, aggressiveness, impaired concentration, alertness and reactions, depression, confusion, difficulty in speaking and even speech loss, visual disorders, tremor, pareses, sensory disturbances, dizziness, helplessness, loss of self-control, delirium, cerebral convulsions, somnolence and loss of consciousness up to and including coma, shallow respiration and slow heart rate (bradycardia).
In addition, signs of adrenergic counter-regulation may be present such as sweating, clammy skin, anxiety, rapid heart rate (tachycardia), hypertension, palpitations, angina pectoris, and cardiac arrhythmias.
The clinical picture of a severe hypoglycaemic attack may resemble that of a stroke.
The symptoms nearly always subside when hypoglycaemia is corrected.
Eyes: Especially at the start of treatment, there may be temporary visual impairment due to the change in blood sugar levels.
Digestive tract: Occasionally, gastrointestinal symptoms such as nausea, vomiting, sensations of pressure or fullness in the epigastrium, abdominal pain and diarrhoea may occur. However, despite continued treatment, these often subside and usually do not necessitate discontinuing Daonil.
In isolated cases, there may be elevation of liver enzyme levels and even impairment of liver function – e.g. with impaired excretion of bile pigment (cholestasis) and jaundice – and hepatitis which can regress after withdrawal of Daonil, although they may lead to life-threatening liver failure.
Blood: Potentially life-threatening changes in the blood picture may occur. They may include – rarely – mild to severe thrombopenia (e.g. presenting as purpura) and – in isolated cases – haemolytic anaemia, erythrocytopenia, leucopenia, granulocytopenia, agranulocytosis, and (e.g. due to myelosuppression) pancytopenia. In principle, these reactions are reversible once Daonil has been withdrawn.
Other adverse reactions: Occasionally, allergic or pseudoallergic reactions may occur, e.g. in the form of itching or rashes. In isolated cases, mild reactions in the form of urticaria may develop into serious and even life-threatening reactions with dyspnoea and fall in blood pressure, sometimes progressing to shock. In the event of urticaria, a doctor must therefore be notified immediately.
A hypersensitivity reaction may be directed against glibenclamide itself, but may alternatively be triggered by any of the excipients. Allergy to sulphonamide derivatives may also be responsible for an allergic reaction to glibenclamide.

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In isolated cases, allergic vasculitis (inflammation of blood vessels) may arise and, in some circumstances, may be life-threatening. In isolated cases, hypersensitivity of the skin to light may occur, and sodium concentration in the serum may decrease.

If you notice any adverse reactions, please consult a doctor.

Alertness and reactions may be impaired by hypoglycaemic or hyperglycaemic episodes, especially when beginning or after altering treatment, or when Daonil is not taken regularly. This may, for example, affect the ability to drive or operate machinery.

Interactions

Patients who take or discontinue taking certain other medicines while undergoing treatment with Daonil may experience changes in blood sugar control.

Potentiation of the blood-sugar-lowering effect and, thus, in some instances hypoglycaemia (excessive reduction in blood sugar) may occur when taking other drugs, including: insulin and other (oral) antidiabetics, ACE inhibitors, anabolic steroids and male sex hormones, azapropazone, chloramphenicol, coumarin derivatives, cyclophosphamide, disopyramide, fenfluramine, fenyramidol, fibrates, fluoxetine, ifosfamide, MAO inhibitors, miconazole, oxyphenbutazone, para-aminosalicylic acid, pentoxifylline (high dose parenteral), phenylbutazone, probenecid, quinolones, salicylates, sulfinpyrazone, sulfonamides, sympatholytic agents (such as beta-blockers and guanethidine), tetracyclines, tritoqualine, trofosfamide.

Weakening of the blood-sugar-lowering effect and, thus, raised blood sugar levels may occur when taking other drugs, including: acetazolamide, barbiturates, corticosteroids, diazoxide, diuretics, epinephrine (adrenaline) and other sympathomimetic agents, glucagon, laxatives (after protracted use), nicotinic acid (in high doses), oestrogens and progestogens, phenothiazines, phenytoin, rifampicin, thyroid hormones.

H_2-receptor antagonists, clonidine, and reserpine may lead to either potentiation or weakening of the blood-sugar-lowering effect.

Under the influence of sympatholytic drugs such as beta-blockers, clonidine, guanethidine, and reserpine, the signs of adrenergic counter-regulation to hypoglycaemia may be reduced or absent.

Both acute and chronic alcohol intake may potentiate or weaken the blood-sugar-lowering action of glibenclamide in an unpredictable fashion.

Glibenclamide may either potentiate or weaken the effect of coumarin derivatives.

Dosage

In principle, the dosage of Daonil is governed by the desired blood sugar level. The dosage of Daonil must be the lowest possible dose which is effective.

Treatment with Daonil must be initiated and monitored by a doctor. The patient must take Daonil at the times and in the doses prescribed by the doctor. Mistakes, e.g., forgetting to take a dose, must never be corrected by subsequently taking a larger dose. Measures for dealing with such mistakes (in particular forgetting a dose or skipping a meal) or in the event a dose cannot be taken at the prescribed time must be discussed and agreed between doctor and patient beforehand.

If it is discovered that too high a dose or an extra dose of Daonil has been taken, a doctor must be notified immediately.

Initial dose and dose titration: The usual initial dosage is ½ to 1 tablet Daonil once daily. It is recommended that treatment be started with the smallest possible dose. This applies in particular to patients who are prone to hypoglycaemia (excessive reduction in blood sugar) or who weigh less than 50 kg. If necessary, the daily dose can be raised. It is recommended that the dose be increased gradually, i.e. in increments of no more than ½ tablet and at intervals of one to two weeks, and that the increase be guided by regular blood sugar monitoring.

Dose range in patients with well-controlled diabetes; maximum doses: The usual single dose is ½ to 2 tablets Daonil. A single dose of 2 tablets must not be exceeded. Larger daily doses must be divided into at least two separate single doses.

The usual daily dose is 1 to 2 tablets Daonil. Exceeding a total daily dose of 3 tablets is not recommended, because higher daily doses of up to 4 tablets are more effective only in exceptional cases.

Distribution of doses: Timing and distribution of doses are to be decided by the doctor, taking into consideration the patient's current life-style. Normally a single daily dose of Daonil is sufficient.

It is recommended that daily doses of up to 2 tablets be taken before a substantial breakfast or before the first main meal, and any remaining portions of the total daily dose before the evening meal. It is very important not to skip meals after the tablets have been taken.

Secondary dosage adjustment: Glibenclamide requirements may fall as treatment proceeds. To avoid hypoglycaemia, timely dose reduction or cessation of Daonil therapy must therefore be considered.

Correction of dosage must also be considered, whenever
– the patient's weight changes, or
– the patient's life-style changes, or
– other factors arise, which cause an increased susceptibility to hypoglycaemia or hyperglycaemia (see under "Precautions").

Duration of treatment: Treatment with Daonil is normally a long-term therapy.

Changeover from other oral antidiabetics to Daonil: There is no exact dosage relationship between Daonil and other oral antidiabetics. When substituting Daonil for other oral antidiabetics (drugs to lower blood sugar), it is recommended that the procedure be the same as for initial dosage, starting with daily doses of ½ to 1 tablet Daonil. This applies even in cases where the patient is being switched from the maximum dose of another oral antidiabetic. Consideration must be given to the potency and duration of action of the previous antidiabetic agent. A break from medication may be required to avoid any summation of effects entailing a risk of hypoglycaemia.

Note: Glibenclamide is supplied by Hoechst in different pharmaceutical formulations in other countries. The patient is asked to consult a doctor before changing over to any other formulation.

Administration

Daonil tablets must be swallowed whole with sufficient amounts of liquid, e.g. with roughly half to one glass of water.

Expiry date

Do not use later than the date of expiry.

Presentation

30 and 100 tablets of 5 mg

Hoechst AG
D-65926 Frankfurt am Main
Germany

Hoechst

This is a medicament

– 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.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

إن هذا دواء

- الدواء مستحضر يؤثر على صحتك واستهلاكه خلافا للتعليمات يعرضك للخطر
- إتبع بدقة وصفة الطبيب وطريقة الإستعمال المنصوص عليها وتعليمات الصيدلاني الذي صرفها لك
- فالطبيب والصيدلاني هما الخبيران بالدواء وبنفعه وضرره
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك
- لا تكرر صرف الدواء بدون وصفة طبية

لا تترك الأدوية في متناول أيدي الأطفال

مجلس وزراء الصحة العرب
وإتحاد الصيادلة العرب