Tablets

Amarit

Glimepiride B.P.

ایمارِٹ گولیاں

گلائی پرائڈ بی۔پی۔

Composition:
Each tablet contains:Glimepiride B.P.....1mg/2mg/3mg/4mg
Reko's Specs.

Properties:
Glimepiride, the active ingredient of Amarit, is a blood-sugar-lowering agent belonging to the sulfonylurea group.

Indications:
Non-insulin-dependent (type II) diabetes, whenever blood sugar levels cannot be controlled adequately by diet, Physical exercise and weight reduction alone.

Dosage:
In principle, the dosage of Amarit is governed by the desired blood sugar level. The dosage of glimepiride must be the lowest which is sufficient to achieve the desired metabolic control.
Treatment with Amarit must be initiated and monitored by a physician. Amarit must be taken at the times and in the dose, must never be corrected by subsequently taking a larger dose. Measures for dealing with such mistakes (in particular situation where a dose cannot be taken at the prescribed time must be discussed and agreed between physician and patient beforehand. A physician must be notified immediately if the dose taken is too high, or an extra dose has been taken.
The initial and the maintenance doses are set based on the results of regular checks of glucose in blood urine. Monitoring of glucose levels in blood and urine also serves to detect either primary or secondary failure of therapy.
Initial dose and dose titration: The usual initial dose is 1mg Amarit once daily. If necessary, the daily dose can be increased.
Any increase should be based on regular blood sugar monitoring, and should be gradual i.e., at intervals of one to two weeks, and carried out **stepwise, as follows:**
1mg 2mg 3mg 4mg 6mg , and in exceptional cases- 8mg.
Dose range in patients with well controlled diabetes: The usual dose range in patients with well controlled diabetes is 1 to 4mg Amarit daily. Only some patients benefit from daily doses of more than 6mg.
Distribution of doses: Timing and distribution of doses are decided by the physician, in consideration of the patient's current life-style. Normally, a single daily dose of Amarit is sufficient. This should be taken immediately before a substantial breakfast or if none is taken immediately before the first main meal. It is very important not to skip meals after taking Amarit. Secondary dosage adjustment. As the control of diabetes improves, sensitivity to insulin increases; therefore, glimepiride requirements may fall as treatment proceeds. To avoid hypoglycemia, a timely dose reduction or cessation of Amarit therapy must be considered.
A dose adjustment must also be considered whenever the patient's weight or life-style changes or other factor arise which cause an increased susceptibility to hypo-or hyperglycemia (see under "Special warnings and precautions")
Duration of treatment: Treatment with Amarit is normally a long-term therapy.
Change over from other oral antidiabetics to Amarit: There is no exact dosage relationship between Amarit and other oral blood-sugar-lowering agent. When substituting amarit for other such agents, the initial daily dose is 1mg; this applies even in changeovers from the maximum dose of another oral blood-sugar-lowering agent. Any Amarit dose increase should be in accordance with guidelines given above in "Initial dose and dose titration"
Consideration must be given to the potency and duration of action for the previous blood sugar-lowering agent. It may be necessary to interrupt treatment to avoid additive effects which would increase the risk of hypoglycaemia.

Contraindications:
Amarit is not suitable for the treatment of insulin-dependent (type 1) diabetes mellitus (e.g. for the treatment of diabetics with a history of ketoacidosis) of diabetic ketoacidosis or of diabetic precoma or coma.
Amarit must not be used in patients hypersensitive to glimepiride, other sulfonylureas, other sulfonamides, or any of the excipients (risk of hypersensitivity reactions).
No experience has been gained concerning the use of Amarit in patients with severe impairment of liver functions and dialysis patients. In patients with severe impairment of renal or hepatic function, a changeover to insulin is indicated, not least to achieve optimal metabolic control.
Use in pregnancy and lactation: To avoid risk of harm to the child, Amarit must not be taken during pregnancy a changeover to insulin is necessary. Patients planning a pregnancy must inform their physician, and should change over to insulin.
Ingestion of glimepiride with the breast milk may harm the child. Therefore, Amarit must not be taken by breast-feeding women, either a changeover to insulin or a complete discontinuation of breast-feeding is necessary.
Special warnings and precautions:
To achieve optimal control of blood sugar, a correct diet, regular and sufficient physical exercise and, if necessary. Reduction of body weight are just as important as regular intake of Amarit. Clinical signs of insufficiently lowered blood sugar (hyperglycaemia) are, e.g., increased urinary frequency, intense thirst, dryness of the mouth, and dry skin
When starting treatment, the patient must be informed about the effects and risks of Amarit and about its role in conjunction with dietary measures and physical exercise; the importance of adequate cooperation must also be stressed.
In the initial weeks of treatment, the risk of hyperglycaemia may be increased and necessitates especially careful monitoring Factors favouring hypoglycaemia include:
Unwillingness or (more commonly in older patients) incapacity of the patient of cooperate, undernutrition. Irregular mealtimes, or skipped meals.
Imbalance between physical exertion and carbohydrate intake
Alterations of diet Consumption of alcohol, especially in combination with skipped meals, Severe impairment of liver function
Overdosage with Amarit Certain uncompensated disorders of the endocrine system affecting carbohydrate metabolism (as for example in certain disorders of thyroid function and in anterior pituitary or adrenocortical insufficiency), Concurrent administration of certain other medicines (see "Interactions") The physician must be informed about such factors and about hypoglycaemia episodes, since these require particularly careful monitoring.
If such risk factors for hypoglycaemia are present, it may be necessary to adjust the dosage of Amarit or the entire therapy. This also applies whenever illness occurs during therapy or the patient's life-style changes. Those symptoms of hypoglycaemia which reflect the body's adrenergic counter-regulation (see under " Adverse effects ") may be milder or absent in those situations where hypoglycaemia develops gradually, in the elderly, and in patients with autonomic neuropathy or those 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 of sugar-sweetened 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.
It is known from other sulfonylureas that despite initially successful countermeasures, hypoglycaemia my reoccur. Therefore continued close observation is necessary. Severe hypoglycaemia requires, in

addition. Immediate treatment and follow-up by a physician and, in some circumstances, hospitalization.
If treated by different physicians (e.g. trauma, surgery, infections with fever) blood sugar control may deteriorate, and a temporary change to insulin may be necessary.
During treatment with Amarit, glucose levels in blood and urine must be checked regularly, as should. Additionally, the proportion of glycated haemoglobin.

Alertness and reactions may be impaired due to hypoglycaemia, especially when beginning or after altering treatment, or when Amarit is not taken regularly. This may, for example affect the ability to operate a vehicle or machinery.

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

Based on experience with glimepiride and on what is known of other sulfonylureas, the following interactions must be considered:

Potentiation of the blood-sugar-loweing effect and, thus, in some instances hypoglycaemia may occur when one of the following medicines is taken, for example: insulin and other, oral antidiabetics, ACE inhibitors, allopurinol, anabolic steroids and male sex hormones; chloramphenicol, coumarin derivatives, cyclophosphamide, disopyramide, fenfluramine, fenyramidol, filbrates, fluoxetine, guanethidine, ifosfamide, MAO inhibitors, miconazole, para-aminosalicylic acid, pentoxifylline (high dose parentera), phenylbutazone azapropazone, oxyphenbutazone, probenecid, quinolones, salicylates, sulfinpyrazone, sulfonamides, tetracyclines, tritoqualine, trofosfamide,

Weakening of the blood-sugar-lowering effect and, raised blood sugar levels may occur when one of the following medicines is taken, for example: acetazolemide, barbiturates, corticosteroids, diazoxide, diuretics, epinephrine (adrenaline) and other sympathomimetic agents, glucagons, laxatives (after protracted use), nicotinic acid (in high doses), estrogens and progestogens, phenothiazines, phenytoin, rifampicin, thyroid hormones.

H2 receptor antagonists, clonidine and reserpine may lead to either potentiating, or weakening of the blood sugar-lowering effect.

Beta-blockers decrease glucose tolerance. In patients with diabetes mellitus, this may lead to deterioration of metabolic control. In addition, beta blockers may increase the tendency to hypoglycaemia (due to impaired counter-regulation).

Both acute and chronic alcohol intake may potentiate or weaken the blood-sugar-lowering action of Amarit unpredictably.

The effect of coumarin derivatives may be potentiated or weakened.
Adverse effects:
Based on experience with glimepiride and on what is known of other sulfonylures, the following adverse edffects must be considered.
Hypoglycemia: As a result of the blood-sugar-lowering action of Amarit hypoglycemia may occur, and may also be prolonged.

Possible symptoms of hypoglycemia include headache, hunger, nausea, vomiting, lassitude, disordered sleep, restlessness, aggressiveness, impaired concentration, confusion, speech disorders, apasia, visual disorders, tremor, pareses, sensory disturbances, dizziness, helplessness, loss of self control, cerebral convulsions, somnolence and loss of consciousness up to and including coma, shallow respiration and bradycardia, In addition, signs of adrenergic counter-regulation may be present such as sweating, clammy skin, anxiety, tachycardia hypertension, palpitations, angina pectoris, and cardiac arrhythmias. The clinical picture of a severe hypoglycemic attack may resemble that of a stroke. Once hypoglycemia has been corrected, all of the above-mentioned symptoms almost always subside.

Eyes: Especially at the start of treatment, temporary visual impairment may occur due to the change in blood sugar levels.

Digestive tract: Occasionally, gastrointestinal symptoms such as the following may occur: nausea, vomiting , sensations of pressure or fullness in the epigastrium, abdominal pain, and diarrhea.

In isolated cases, liver enzyme levels may increase, and impairment of liver function (e.g. with cholestasis and jaundice) and hepatitis may develop, possibly resulting in liver failure.
Blood: Severe changes in the blood picture may be occur rarely, thrombopenia and, in isolated cases leucopenia, haemolytic anemia or, e.g erythrocytopenia, granulocyto-penia, agranulocytosis, and pancytopenia (e.g due to myelosuppression) may develop.
Other adverse reactions: Occasionally, allergic or pseudoallergic reactions may occur,e.g in the form of itching, urticaria or rashes such reactions are mild but may become more serious and be accompanied by dyspnea and a fall in blood pressure, sometimes progressing to shock it, urticaria occurs, a physician must be notified immediately.
In isolated cases, the following may occur allergic vasculitis, hypersensitivity of the skin to light, and a decrease in serum sodium.
Please consult a physician if you notice any of the adverse effects listed in this package insert of any other undesired effects or unexpected changes.
Since some adverse effects, such as severe hypoglycemia, certain changes in blood picture, severe allergic or pseudoallergic reactions, or liver failure, may under certain circumstances become life-threatening, it is essential that, if sudden or severe reactions do occur, you inform a physician at once, and on no account continue taking the drug without a physician's express guidance.
Storage.
Store below 30°C
Protect from sunlight & moisture,
The expiration date refers to the product correctly stored at the required conditions.
Presentation

Amarit 1mg	Pack of 20 tablets
Amarit 2mg	Pack of 20 tablets
Amarit 3mg	Pack of 20 tablets
Amarit 4mg	Pack of 20 tablets

Keep out of reach of Children.

REKO
Manufactured by:
REKO PHARMACAL (Pvt.) LTD.
13-km, Multan Road, Lahore-Pakistan
www.rekopharmacal.com
ISO 9001-2008 Certified