



## **Dibenol<sup>®</sup>**

Glibenclamide  
**Oral Antidiabetic**

### **COMPOSITION**

Dibenol<sup>®</sup> tablet : Each tablet contains Glibenclamide BP 5 mg.

### **PHARMACOLOGY**

Dibenol<sup>®</sup> is an orally effective hypoglycaemic agent that reduces blood sugar concentration. It stimulates the mobilization of endogenous insulin with a lower dosage and with few incidence of side effects that any available anti-diabetic.

Dibenol<sup>®</sup> is readily absorbed from the gastrointestinal tract. Maximum blood concentrations after a single dose are reached in 2-4 hours and the effect lasts at least 24 hours. It may be effective for patients whose blood sugar concentration can not be adequately controlled by tolbutamide.

### **INDICATION**

Dibenol<sup>®</sup> is used in the treatment of non insulin dependent diabetes melitus (NIDDM). It is ineffective in completely pancreatectomized patients and in juvenile-onset type of diabetes, in which the pancreas has lost all or nearly all of its capacity to secrete insulin. Such patients require insulin and attempts to control them with oral therapy are dangerous and doomed to failure.

### **DOSAGE AND ADMINISTRATION**

Initially stabilization dosage:

Dibenol<sup>®</sup> half tablet (2.5 mg) should be taken initially during or immediately after breakfast. 3-5 days after initiation of the drug, the blood sugar level and urine sugar level should be checked. Daily dose of 1/2 tablet may be continued as maintenance therapy if good control has been achieved. If the result is not good, increment of daily dose in steps of 1/2 tablet is necessary at intervals of 3-5 days up to a maximum of 3 tablets. Daily doses in excess of 10 mg may be taken in 2 divided doses.

Patients should be given 1/2 to 1 tablet of Dibenol<sup>®</sup> in changing over from other oral anti-diabetics with a similar action.

Change over from insulin to Dibenol<sup>®</sup> :

The mildly diabetic patient whose insulin requirement is fewer than 20 units daily, can be started on the initial dosage of Dibenol<sup>®</sup> with immediate discontinuation of insulin.

ORAL ANTIDIABETIC PREPARATIONS

## Dibenol®

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If the insulin requirement is moderate or high, the changeover should be made gradually by giving insulin and Dibenol® simultaneously and slowly cutting down the dose of insulin.

When insulin requirements are increased as in fever, surgical interventions or trauma, the Dibenol® alone is inadequate and the patient must be given insulin to carry him or her through such critical situation.

This changeover from insulin to Dibenol® is strictly for NIDDM of fairly recent onset which is being controlled on small doses of insulin. This should preferably be done in hospital or with daily medical supervision.

### **CONTRAINDICATION AND PRECAUTION**

Severe metabolic de-compensation with acidosis, pre-comatose states and diabetic coma, severe renal or hepatic dysfunction or serious impairment of typhoid or adrenal function; pregnancy, diabetes mellitus complicated by fever, trauma or gangrene.

Weight reduction is of the greatest importance in the treatment of diabetes. A vigorous effort must be made by the patient and the physician to reduce the patient's weight as an integral part of diabetic treatment, irrespective of the drug chosen.

### **SIDE EFFECT**

Dibenol® is well tolerated. Few side effects that may arise include nausea, vomiting, epigastric pain, dizziness, weakness, paraesthesia and headache. Allergic skin reactions and haemopoietic reactions (leukopenia, thrombocytopenia, etc.) are occasionally observed.

### **DRUG INTERACTION**

Alcohol, cyclophosphamide, dicoumarol, monoamino oxidase inhibitors, phenylbutazone, propranolol and other beta-adrenergic blocking agents and certain long-acting sulphonamides may enhance the hypoglycemic effect of Dibenol®.

### **USE IN PREGNANCY AND LACTATION**

There is no information on the use of glibenclamide in human pregnancy but it has been in wide, general use for many years without apparent ill consequence. Animal studies have shown no hazard.

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It has not yet been established whether glibenclamide is transferred to human milk. However, other sulphonylureas have been found in milk and there is no evidence to suggest that glibenclamide differs from the group in this respect.

### **STORAGE CONDITION**

Should be stored in a dry place below 30°C.

### **HOW SUPPLIED**

Dibenol® tablet: Box containing 20 x 10 tablets in blister pack.

