Product Information

Dibenyline Capsules

1. NAME OF THE MEDICINAL PRODUCT

Dibenyline Capsules 10mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 10 mg Phenoxybenzamine hydrochloride.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Treatment of hypertensive episodes associated with phaeochromocytoma and treatment of benign prostatic hypertrophy.

4.2. Posology and Method of Administration

Method of Administration: Oral

Posology

Adults: The usual starting dose is 10 mg daily. This may be increased by 10 mg daily until control of hypertensive episodes is achieved, or postural hypotension occurs.
Usually the dosage required is 1-2 mg/kg body weight split into 2 doses. Concomitant beta-adrenergic blockade may be necessary to control tachycardia and arrythmias notably when tumours are secreting an appreciable amount of adrenaline as well as noradrenaline.

Elderly: Use with caution, 10 mg daily dose should be sufficient (see Contra-Indications and Cautions below).

Children: There is little experience in children but, doses of 1 to 2 mg/kg daily have been used successfully.

4.3. Contraindications

Phenoxybenzamine should not be used in patients who have had a cerebrovascular accident; or in the recovery period (usually 3-4 weeks) after acute myocardial infarction.

4.4. Special Warnings and Precautions for Use

Phenoxybenzamine should be used with great caution in patients in whom a fall in blood pressure and/or tachycardia may be undesirable, such as the elderly or those with severe heart disease, congestive heart failure, cerebrovascular disease or renal damage. The mode of action should be borne in mind, if used concurrently with α-sympatho-mimetics or myocardial depressants.

Phenoxybenzamine is carcinogenic in the rat and has shown mutagenic activity in the bacterial Ames test and mouse lymphoma assay. It should only be used after very careful consideration of the risks, in patients in whom alternative treatment is inappropriate.

4.5. Interactions with other Medicaments and other forms of Interaction

See under Special Precautions and Warnings.

4.6. Pregnancy and Lactation

There is little evidence of safety of Dibenyline in pregnancy and it should not be used in pregnancy or during breastfeeding unless essential.

4.7. Effects on Ability to Drive and Use Machines

Dibenyline may occasionally cause a drop in blood pressure on standing up. This may result in temporary dizziness and sometimes fainting.

4.8. Undesirable Effects

Side effects are generally mild and transient, but may include postural hypotension with dizziness and compensatory tachycardia, nasal congestion, inhibition of ejaculation, miosis and lassitude. Gastrointestinal upset has also been reported.

4.9. Overdose

The main effect of overdosage is profound hypotension, which may last several hours, tachycardia and collapse. Treatment consists of the induction of vomiting and/or gastric lavage together with appropriate symptomatic and supportive measures.

Hypotension should be treated with plasma expanders and placing the patient in the "head down" position.

Noradrenaline is of little value when α-adrenergic receptors are blocked. Adrenaline should not be used since stimulation of β-adrenergic receptors will further increase blood pressure.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties
Phenoxybenzamine is a non competitive long acting α-adrenergic receptor antagonist.

5.2. Pharmacokinetic Properties
Phenoxybenzamine is incompletely absorbed from the gastrointestinal tract. The maximum effect is attained in about 1 hour after an intravenous dose. Following oral administration the onset of action is gradual over several hours and persists for 3-4 days following a single dose. The plasma half-life is about 24 hours. Phenoxybenzamine is metabolised in the liver and excreted in the urine and bile but small amounts remain in the body for several days. It has prolonged action probably owing to stable covalent bonding.

5.3. Preclinical Safety Data
No further information of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients
Lactose (179.9mg)
Talc
Hard Gelatin Capsules:
Titanium Dioxide E171
Indigotin E132
Erythrosine E127
Edible grey ink.

6.2. Incompatibilities
None known.

6.3. Special Precautions for Storage
Store in a dry place and protect from light.

6.4. Nature and Contents of Container
Polypropylene securitainers, amber glass bottles, polythene containers and blisters.
(PVC/PVDC/Aluminium foil).
In packs of 30 capsules.

6.5. Instruction for Use/Handling
No special instructions.

7. **Manufacturer:** Goldshield Pharmaceuticals Limited, UK

8. **Registration Owner:** Rafa Laboratories LTD., P.O. Box 405, Jerusalem
   Registration Number: 312721094

The format and content of this document have been approved by the Ministry of Health in February 2012.