

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dibenyline Capsules 10mg
Phenoxybenzamine 10mg Capsules

2. Qualitative and Quantitative Composition

Each capsule contains 10 mg Phenoxybenzamine hydrochloride BP.

3. Pharmaceutical Form

Capsules

4.1. Therapeutic Indications

Hypertensive episodes associated with Pheochromocytoma.

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 daily in two doses. Concomitant beta-adrenergic blockade may be necessary to control tachycardia and arrhythmias notably when tumours are secreting an appreciable amount of adrenaline as well as noradrenaline.

Elderly: Use with caution: 10mg 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. Contra-indications

Do not use 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

Use 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 which 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 Dibenylamine in pregnancy and it should not be used in pregnancy unless essential.

4.7. Effects on Ability to Drive and Use Machines

None known.

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. Gastro-intestinal 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.

Treat hypotension with plasma expanders and 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.

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.

6.1. List of Excipients

Lactose

Talc

Hard Gelatin Capsules:

Titanium Dioxide E171

Indigotin E132

Erythrosine E127

Edible grey ink.

6.2. Incompatibilities

None known.

6.3. Shelf Life

60 months.

6.4. Special Precautions for Storage

Store in a dry place and protect from light.

6.5. Nature and Contents of Container

Polypropylene securitainers, amber glass bottles, polythene containers and blisters. (PVC/PVDC/Aluminium foil). In packs of 30 and 100.

6.6. Instruction for Use/Handling

No special instructions.

7. Marketing Authorisation Holder

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8. Marketing Authorisation Number

PL 12762/0224

9. Date of First Authorisation/Renewal of the Authorisation

28/02/1994

10 DATE OF REVISION OF THE TEXT

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