SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dibenyline 10mg Capsules.
Phenoxybenzamine 10mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 10 mg Phenoxybenzamine hydrochloride BP.

Excipient with known effect:

Each 10mg of Phenoxybenzamine contains 179.9 mg of Lactose (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules

Size no. three hard gelatin capsule with opaque body and a clear red cap, both printed with ‘P10’ in grey. The capsules are filled with a white powder**.**

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypertensive episodes associated with Phaeochromocytoma.

4.2 Posology and method of administration

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 arrythmias 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).

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

Method of Administration

Oral

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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.

Excipients

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

See under Special Precautions and Warnings.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breast-feeding

No data available

Fertility

No data available

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 the following adverse reactions:

Not known (cannot be estimated from the available data)

System organ class	**Frequency**	**Adverse reactions**
Nervous system disorders	Not known	dizziness
Eye disorders	Not known	miosis
Cardiac disorders	Not known	compensatory tachycardia
Vascular disorders	Not known	postural hypotension
Respiratory, thoracic and mediastinal disorders	Not known	nasal congestion
Gastrointestinal disorders	Not known	gastro-intestinal upset
Reproductive system and breast disorders	Not known	inhibition of ejaculation
General disorders and administration site conditions	Not known	lassitude

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Symptoms

The main effect of overdosage is profound hypotension, which may last several hours, tachycardia and collapse.

Management

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.

5.1 Pharmacodynamic properties

Phenoxybenzamine is a non-competitive long acting alpha-adrenergic receptor antagonist, ATC code: C04AX02

5.2 Pharmacokinetic properties

Absorption

Phenoxybenzamine is incompletely absorbed from the gastrointestinal tract.

Distribution

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.

Biotransformation

Phenoxybenzamine is metabolized in the liver.

Elimination

It is 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

Talc

Hard Gelatin Capsules:

Titanium Dioxide E171

Indigotin E132

Erythrosine E127

Edible grey ink.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

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.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Ltd,

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8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0224

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10 DATE OF REVISION OF THE TEXT

25/06/2021