SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Indoramin 20 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ’22 mg’ of Indoramin hydrochloride equivalent to 20mg of Indoramin.

Excipient(s) with known effect:

Each film-coated tablet contains ‘172.2mg’ of lactose (as lactose monohydrate). For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Pale yellow, triangular, biconvex, film coated tablets embossed with a key on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Indoramin is indicated in adults for conditions in which alpha blockade is indicated and the management of urinary outflow obstruction due to benign prostatic hyperplasia.

4.2 Posology and method of administration

Posology

Hyperplasia
Adults:

20 mg twice daily

Dosage may be increased in 20 mg increments at two-weekly intervals up to max. 100 mg per day if required.

Elderly:
20 mg at night may be adequate.

Paediatric population
Not recommended. There is no relevant use of indoramin in the paediatric population

Route of administration

Oral

4.3 Contraindications

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

Patients with established heart failure.
Patients already under treatment with a monoamine oxidase inhibitor.

4.4 Special warnings and precautions for use

Special warnings

Incipient cardiac failure should be controlled before treatment with indoramin.

Caution should be observed in prescribing indoramin for patients with hepatic or renal insufficiency.

A few cases of extrapyramidal disorders have been reported in patients treated with indoramin. Caution should be observed in prescribing indoramin in patients with Parkinson's disease.

In animals and in the one reported case of overdose in humans, convulsions have occurred. Due consideration should be given and great caution exercised in the use of indoramin in patients with epilepsy.

The 'Intraoperative Floppy Iris Syndrome' (IFIS, a variant of small pupil syndrome) has been observed during cataract surgery in some patients on or previously treated with tamsulosin. Isolated reports have also been received with other alpha-1 blockers and the possibility of a class effect cannot be excluded. As IFIS may lead to increased procedural complications during the cataract operation current or part use of alpha-1 blockers should be made known to the ophthalmic surgeon in advance of surgery.

Caution should be observed in prescribing indoramin for patients with a history of depression.

Clearance of indoramin may be affected in the elderly. A reduced dose, and/or reduced frequency of dosing may be sufficient in some elderly patients.

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

Do not use indoramin in patients being treated with a monoamine oxidase (MAO) inhibitor.

Concomitant use of indoramin with antihypertensive drugs or drugs with hypotensive properties e.g. antidepressants, anxiolytics, hypnotics and moxisylyte, may enhance their hypotensive action. Titration of dosage of the latter may therefore be needed.

Alcohol can increase both the rate and extent of absorption of indoramin, but no untoward effects have been reported at recommended doses.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Animal experiments indicate no teratogenic effects but indoramin tablets should not be prescribed for pregnant women unless considered essential by the physician.

Breast-feeding

There are no data available on the excretion of indoramin in human milk, but the drug should not be administered during lactation unless in the judgement of the physician such administration is clinically justifiable.

4.7 Effects on ability to drive and use machines

Drowsiness is sometimes seen in the initial stages of treatment with indoramin or when dosage is increased too rapidly. If drowsiness occurs, patients should be warned not to drive or operate machinery and to avoid CNS depressants including alcohol.

4.8 Undesirable effects

In general, indoramin is well tolerated.

The following undesirable effects have been observed and reported during treatment with indoramin with the following frequencies: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

MedDRA System Organ Class	Frequency	Undesirable effects
Immune system disorders	Rare	Hypersensitivity
Psychiatric disorders	Unknown	Depression

Nervous system disorders	Rare Unknown	Parkinson's disease Dizziness Headache Sedation or Drowsiness Somnolence
Vascular disorders	Unknown	Hypotension, with or without syncope Orthostatic hypotension (postural hypotension)
Respiratory, thoracic and mediastinal disorders	Unknown	Nasal congestion
Gastrointestinal disorders	Unknown	Dry mouth
Skin and subcutaneous tissue disorders	Rare	Rash Pruritus
Reproductive system and breast disorders	Unknown	Ejaculation failure
General disorders and administration site conditions	Unknown	Fatigue
Investigation	Unknown	Weight increased

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Information available at present of the effects of acute overdosage in human beings with indoramin is limited. Effects seen have included deep sedation leading to coma, hypotension and fits.

In cases of overdose QTc prolongation can occur, sometimes complicated by severe arrhythmias, such as Torsades de Pointes.

Results of animal work suggest that hypothermia may also occur.
Suggested therapy is along the following lines:

1. Recent ingestion of large numbers of tablets would require gastric lavage or a dose of ipecacuanha to remove any of the product still in the stomach of the conscious patient.
2. Cardiac monitoring should be initiated immediately and continued for at least 24 hours.
3. Ventilation should be monitored and assisted if necessary.

4. Circulation support and control of hypotension should be maintained.
5. If convulsions occur diazepam may be tried.

Temperature should be closely monitored. If hypothermia occurs, rewarming should be carried out very slowly to avoid possible convulsions.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alpha-adrenoreceptor antagonists, ATC code: C02CA02.

Mechanism of action

Indoramin is an alpha adrenoceptor blocking agent. It acts selectively and competitively on post-synaptic alpha-1 receptors, causing a decrease in peripheral resistance. It also produces relaxation of hyperplastic muscle in the prostate.

5.2 Pharmacokinetic properties

Absorption

Indoramin is rapidly absorbed from Indoramin tablets and has a half-life of about five hours.

Distribution
There is little accumulation during long-term treatment.

Biotransformation
When three volunteers and four hypertensive patients were treated with radiolabelled indoramin at doses of 40-60 mg daily for up to three days, plasma concentrations reached a peak one to two hours after administration of single doses. Over 90% of plasma indoramin was protein bound.

Elimination
After two or three days 35% of the radioactivity was excreted in the urine and 46% in the faeces. Extensive first pass metabolism was suggested.

Elderly
Clearance of indoramin may be affected in the elderly. A reduced dose or reduced frequency of dosing may be sufficient in some elderly patients.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Lactose Monohydrate

Microcrystalline Cellulose

Magnesium Stearate

Polacrillin potassium

Tablet film coat

Opadry yellow 02B520014 which consists of

Hypromellose

Titanium dioxide (E 171)

Polyethylene glycol

Yellow iron oxide (E172)

Black iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Tablets are packed in PVC/PVDC – Alu blisters containing 28, 30, 56, 60 & 84 tablets.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Brown & Burk UK Ltd

5 Marryat Close

Hounslow West

Middlesex

TW4 5DQ

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 25298/0156

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/01/2020

10 DATE OF REVISION OF THE TEXT

03/11/2025