Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Indoramin 20 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film-coated tablet contains indoramin hydrochloride equivalent to 20 mg of indoramin base.

Excipient with known effect
Each film-coated tablet contains 152 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet (Tablet)

Pale yellow biconvex triangular film coated tablet, bearing a raised kite shape on each face.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of urinary outflow obstruction due to benign prostatic hyperplasia.

4.2 Posology and method of administration

Posology

Hyperplasia
Adults Males only:
20 mg twice daily. Dosage may be increased in 20 mg increments at two-weekly intervals up to maximum of 100 mg per day if required.

Elderly:
20 mg at night may be adequate.

Paediatric population:
Not recommended.

Method of administration
For oral administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
Use in patients with established cardiac failure
Use in patients currently receiving monoamine oxidase inhibitors

4.4 Special warnings and precautions for use

Indoramin should only be used with caution in patients with hepatic or renal insufficiency or in those with Parkinson's disease, epilepsy or a history of seizures, or those with a history of depression.

There is as yet no experience of use in patients with decreased renal function or in those undergoing regular dialysis.

Clearance of Indoramin may be affected in the elderly so that a reduced dose or reduced frequency of dose may be appropriate. The elderly are also sensitive to the hypotensive effect of the drug.

Incipient cardiac failure should be controlled before treatment with Indoramin.

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 cataract operations current or past use of alpha-1 blockers should be made known to the ophthalmic surgeon in advance of surgery.

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 interactions

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 may enhance their hypotensive action, particularly in the elderly. Titration of dosage of the latter may therefore be needed.

The serum levels of Indoramin and alcohol may be raised by concurrent use, causing more sedation than with either drug alone.

Indoramin has an extensive protein binding property. This should be borne in mind when other drugs with high protein affinity are to be used concurrently.

4.6 Fertility, pregnancy and lactation

Not applicable as Indoramin is not for use in women.

4.7 Effects on ability to drive and use machines

Indoramin has minor influence on the ability to drive and use machines. This product may cause drowsiness. Patients should not drive or operate machinery unless it has been shown not to affect physical or mental capacity. This is particularly seen in the initial stages of treatment.

4.8 Undesirable effects

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	Exacerbation of Parkinson's disease
	Unknown	Dizziness Headache Sedation Drowsiness

Vascular disorders	Unknown	Hypotension (including postural hypotension), with or without syncope may occur
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
Investigations	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
HPRA Pharmacovigilance
Website: www.hpra.ie

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 acts predominantly as an antagonist of post-synaptic alpha-1-adrenoceptors.

5.2 Pharmacokinetic properties

Absorption
After absorption Indoramin undergoes significant first pass metabolism in the gut or liver of active metabolites.

Elimination
Elimination is via bowel and kidney with T½ of up to 9 hours.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Amberlite IRP 88
Magnesium stearate

Film-coating:
Hypromellose
Iron Oxide Yellow (E172)
Iron Oxide Black (E172)
Titanium Dioxide (E171)
Macrogol 400
Carnauba wax
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/PVdC/Aluminium blister packs of 4, 8, 15, 30 or 60.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited Vision Exchange BuildingTriq it-Territorjals, Zone 1,Central Business District,Birkirkara, CBD 1070Malta

8 MARKETING AUTHORISATION NUMBER

PA22643/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 February 1989

Date of last renewal: 21 February 2009

10 DATE OF REVISION OF THE TEXT

October 2020