SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Doralese Tiltab Tablets 20 mg

Indoramin 20 mg 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 tablets (tablets)

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Conditions for which alpha blockade is indicated.

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.

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

Patients with established heart failure.

Patients already under treatment with a monoamine oxidase inhibitor.

4.4 Special warnings and precautions for use

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

Drowsiness or sedation can occur on starting treatment with indoramin, and also if dosage is increased too rapidly. Less commonly, dry mouth, nasal congestion, weight gain, dizziness, failure of ejaculation, depression, fatigue, headache and hypotension (including postural hypotension) with or without syncope may occur.
Rarely, Parkinson's disease could be exacerbated.
Rarely, hypersensitivity reactions including rash and pruritus may occur.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Lactose monohydrate
Microcrystalline cellulose
Amberlite IRP-88
Magnesium Stearate

Film-coating:
Opadry OY-3736
Purified Water
Carnauba wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Blister packs - packs of 60 tablets.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited
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Surrey TW20 8RN
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8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0089

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25th February 1998

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15/02/2025