

## 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 20 mg indoramin (as hydrochloride).

Excipient of known effect: Each film-coated tablet contains 186.53 mg lactose monohydrate

For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Film-coated tablet.

9mm x 9mm shield shaped, normal convex, white film coated tablet debossed 'G' on one side and 'IR' on the other.

### 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

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 special precautions for use**

Incipient cardiac failure should be controlled before treatment with Indoramin 20 mg tablets.

Caution should be observed in prescribing Indoramin 20 mg tablets for patients with hepatic or renal insufficiency.

A few cases of extrapyramidal disorders have been reported in patients treated with Indoramin 20 mg tablets. Caution should be observed in prescribing Indoramin 20 mg tablets 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 20 mg tablets 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 past use of alpha-1 blockers should be made known to the ophthalmic surgeon in advance of surgery.

Caution should be observed in prescribing Indoramin 20 mg tablets for patients with a history of depression.

Clearance of Indoramin 20 mg tablets may be affected in 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 20 mg tablets in patients being treated with a monoamine oxidase (MAO) inhibitor.

Concomitant use of Indoramin 20 mg tablets with antihypertensive drugs or drugs with hypotensive properties e.g. antidepressants, anxiolytics, hypnotics and moxislyte 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 20 mg tablets, 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 20 mg 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 20 mg tablets 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 20 mg tablets 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 20 mg tablets, 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 pruritis 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google Play or Apple App Store.

## 4.9 Overdose

Information available at present of the effects of acute overdosage in human beings with Indoramin 20 mg tablets is limited. Effects seen have included deep sedation leading to coma, hypotension and fits.

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 medicine still in the stomach of the conscious patient.
2. Ventilation should be monitored and assisted if necessary.
3. Circulation support and control of hypotension should be maintained.
4. 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.

## 5.1 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 20 mg 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 older people. 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  
Polacrillin potassium (Amberlite IRP88)  
Magnesium stearate

Film-coating:

Opadry OY-LS-28908 (Titanium dioxide, lactose monohydrate, macrogol 4000 and hypromellose)  
Purified water

### **6.2 *Incompatibilities***

Not applicable.

### **6.3 Shelf life**

Two years.

### **6.4 Special precautions for storage**

Do not store above 25°C. Store in original package. (Blisters).

Do not store above 25°C. Keep the container tightly closed. (Plastic bottles).

### **6.5 Nature and contents of container**

PVC/PVDC / Aluminium foil blisters.  
Polyethylene tablet containers with polypropylene caps.

Polypropylene tablet containers with tamper evident polyethylene caps.

Pack sizes: 60.

**6.6 Instructions for disposal**

Not applicable.

**7 MARKETING AUTHORISATION HOLDER**

Generics (U.K.) Limited T/A Viatris,  
Station Close,  
Potters Bar,  
EN6 1TL,  
United Kingdom.

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 04569/0473

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
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25/02/2009

**10 DATE OF REVISION OF THE TEXT**

13/04/2026