

Package Leaflet: Information for the user
Indoramin 20mg Tablets
(indoramin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Indoramin is and what it is used for
2. What you need to know before you take Indoramin
3. How to take Indoramin
4. Possible side effects
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1. What Indoramin is and what it is used for

Indoramin 20mg Tablets (called 'Indoramin' throughout this leaflet) contain a medicine called indoramin (as indoramin hydrochloride). This belongs to a group of medicines called 'alpha-blockers' (also called alpha adrenoceptor antagonists).

What Indoramin is used for

- A condition where your prostate becomes bigger, called 'benign prostatic hyperplasia' or BPH. The prostate is a gland found underneath the bladder in men. It surrounds the tube (called the urethra) which carries urine from the bladder to the outside of the body.

If the prostate gland becomes bigger, it may squeeze on the urethra and make it hard for you to pass urine. When your prostate grows:

- the flow of your urine may be weaker or you may have to pass urine more often than before
- this can happen during the day or you can find you have to get up more often during the night
- you may have to wait for the flow of your urine to start
- you may find it difficult to stop the flow of your urine completely

As men get older their prostate grows in size and some men will suffer these symptoms.

- Patients who do not need or want an operation and also for patients waiting for an operation.

How Indoramin works

- Indoramin relaxes muscles in your bladder, prostate gland and the tube that carries urine from the bladder to the outside of the body
- this will help your urine flow better.

2. What you need to know before you take Indoramin

Do not take Indoramin if you:

- are allergic to Indoramin or any of the ingredients of this medicine (listed in Section 6)
- have heart failure

- are taking monoamine oxidase inhibitors, sometimes called 'MAOIs', used for depression (see **Other medicines and Indoramin**).

Warnings and precautions

Talk to your doctor or pharmacist before taking Indoramin if you have:

- liver or kidney problems
- Parkinson's disease
- epilepsy
- ever had depression.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Indoramin. You may need to be given another medicine or your dose may need to be lowered.

Other medicines and Indoramin

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal preparations. This is because Indoramin can affect the way some other medicines work. Also some other medicines can affect the way Indoramin works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- monoamine oxidase inhibitors, sometimes called 'MAOIs', used for depression. Do NOT take Indoramin if you are already taking a MAOI
- medicines used for high blood pressure such as water tablets (diuretics) or beta-blockers
- medicines that can lower blood pressure such as water tablets (diuretics), moxisylytes (medicines used for circulation problems) and medicines used for depression, anxiety or to help you sleep
- medicines that may make you sleepy such as pain killers, antidepressants, tablets for your nerves and antihistamines.

Cataract eye surgery patients

If you are due to have eye surgery because of a cataract (cloudiness of the lens):

- Tell your eye specialist before the operation that you are using or have previously used Indoramin
- Indoramin and other medicines of the same type (alpha-blockers) may cause problems during the surgery which can be managed if your specialist is told before your operation.

Indoramin with alcohol

Do NOT drink alcohol if Indoramin makes you feel drowsy. Alcohol can increase the amount of Indoramin that gets from your stomach into your blood stream. This could make you feel more drowsy.

Pregnancy and breast-feeding

Occasionally a doctor may prescribe Indoramin for a woman. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel sleepy while taking Indoramin. If this happens, do NOT drive or use any tools or machines. If you feel very sleepy, tell your doctor.

Indoramin contains lactose

Indoramin contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Indoramin

Always take Indoramin exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

- The recommended dose is one tablet (20 mg) twice a day.
- The tablet should be swallowed with water.
- Some elderly patients may need just one tablet at night.
- Your doctor may increase your dose to a maximum total daily dose of 100 mg.
- Do NOT take more than your doctor has recommended.

If you take more Indoramin than you should

If you take more Indoramin than you should, contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. Symptoms of overdose have included deep sedation leading to coma, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), abnormally low blood pressure and fits.

If you forget to take Indoramin

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

Do NOT take a double dose to make up for a forgotten dose.

If you stop taking Indoramin

Do not stop taking Indoramin without talking to your doctor. If you stop taking your tablets, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

- when you start taking Indoramin you may feel sleepy. This will usually go after a few days.

Other less common side effects include dry mouth, stuffy nose, weight gain, dizziness, failure to ejaculate, depression, headache and dizziness caused by low blood pressure, which can occur on standing. The dizziness may or may not be accompanied by fainting.

Rare side effects (affects less than 1 in 1,000 people)

- allergic (hypersensitivity) reactions, such as a rash and itching
- Parkinson's disease may get worse.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Indoramin

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information

What Indoramin contains

- The active ingredient is indoramin (as indoramin hydrochloride). Each film-coated tablet contains indoramin hydrochloride equivalent to 20 mg of indoramin base.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, polacrillin potassium and opadry yellow 02B520014 which consists of hypromellose, titanium dioxide (E171), polyethylene glycol, yellow iron oxide (E172) and black iron oxide (E172).

What Indoramin looks like and contents of the pack

Indoramin 20mg Tablets are pale yellow, triangular, biconvex film coated tablets which are embossed with key on both sides.

This medicine comes in blister packs of 28, 30, 56, 60 & 84 tablets.

Marketing Authorisation Holder & Manufacturer

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