

Package leaflet: Information for the user
Indoramin
20 mg Film-coated Tablets

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**
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1. What Indoramin is and what it is used for

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

What Indoramin is used for

- Indoramin is used to treat 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
- Indoramin can be used for 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 (listed in section 6)
- if you have heart failure
- if you are taking or have recently taken a medicine for depression called monoamine oxidase inhibitor (MAOI). Check with your doctor if you are unsure as to whether you have taken a MAOI (see section 2 - Taking other medicines).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Indoramin:

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

If you are not sure if any of the above applies 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Indoramin can affect the way some other medicines work. Also some other medicines can affect the way Indoramin works. Tell your doctor or pharmacist if you are taking:

- **Monoamine oxidase inhibitors, sometimes called 'MAOIs', used for depression. Do not take Indoramin if you are already taking a MAOI**
- medicines used to lower your blood pressure or medicines which have the potential to lower your blood pressure (e.g. water tablets). When these are taken in combination with indoramin, dramatic drop of the blood pressure may result, especially in the elderly. If the combination is necessary, your doctor will monitor you very carefully to ensure that the dose of your blood pressure lowering medicine is adjusted gradually and carefully
- medicines which bind with protein in the blood (check with your pharmacist).

If any of the above applies to you, speak to your doctor or pharmacist.

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

Indoramin is not recommended for use in women.

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 (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 medicine.

3. How to take Indoramin

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

How much to take

- The usual 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 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 a dose, take it as soon as you remember. However, if it is nearly time for the 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:

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

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

Not known: frequency cannot be estimated from the available data:

- 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.

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

HPRA Pharmacovigilance

Website: www.hpra.ie

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 after EXP. The expiry date refers to the last day of that month.
- Store below 25°C.
- 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 substance is indoramin (as indoramin hydrochloride).
- Each Film-coated tablet contains 20 mg of indoramin.

- The other ingredients are: lactose monohydrate, magnesium stearate, microcrystalline cellulose and Amberlite IRP 88.

The film-coating contains:

hypromellose, yellow iron oxide (E172), black iron oxide (E172), titanium dioxide (E171) and macrogol 400 and purified water.

The polish contains: carnauba wax

(See end of section 2 for further information on lactose).

What Indoramin tablets look like and contents of the pack

- Indoramin are pale yellow, triangular film-coated tablets bearing a raised kite shape on each face. The special 'Tiltab' design helps you to pick up your tablets more easily.
- They are available in blister packs of 4, 8, 15, 30 or 60 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd, trading as Essential Generics, Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara, CBD 1070, Malta

Manufacturer

Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, the Netherlands.

This leaflet was last revised in June 2020

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