

Package leaflet: Information for the user
Doralese®
Tiltab® 20 mg film-coated 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.

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1. What Doralese is and what it is used for

Doralese Tiltab Tablets (called 'Doralese' in 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 Doralese is used for

- Doralese 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
- Doralese can be used for patients who do not need or want an operation and also for patients waiting for an operation.

How Doralese works

- Doralese 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 Doralese

Do not take Doralese

- if you are allergic to indoramin or any of the ingredients of Doralese (listed in section 6)
- if you have heart failure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Doralese:

- 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 apply to you, talk to your doctor or pharmacist before taking Doralese. You may need to be given another medicine or your dose may need to be lowered.

Other medicines and Doralese

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

Doralese with alcohol

Do not drink alcohol if Doralese makes you feel drowsy. Alcohol can increase the amount of Doralese 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 Doralese 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 for advice before taking this medicine.

Driving and using machines

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

Doralese 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 Doralese

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 Doralese than you should

- If you take more Doralese 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 Doralese

- 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 Doralese

- Do not stop taking Doralese 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 Doralese 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 (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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Doralese

- 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 Doralese 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 is made of Opadry OY- 3736 and purified water. The polish contains: carnauba wax.

What Doralese looks like and contents of the pack

- Doralese Tiltab 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 60 tablets.

Marketing Authorisation Holder

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Manufacturer

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