Irbesartan/Hydrochlorothiazide 150 mg/12.5 mg Film-coated tablets

Package leaflet: Information for the user

Irbesartan/Hydrochlorothiazide is a medicine used to treat high blood pressure. It may also be used to treat certain heart conditions (e.g. heart failure). It is often used in combination with another medicine like a diuretic.

Irbesartan/Hydrochlorothiazide tablets contain two active substances: irbesartan (50 mg, 100 mg, or 150 mg) and hydrochlorothiazide (12.5 mg). These substances have different ways of working in your body to help control blood pressure. This leaflet gives you information about the irbesartan part of the medicine. For information about the hydrochlorothiazide part, see the leaflet "Irbesartan/Hydrochlorothiazide tablets" and "Warnings and precautions".

If you are pregnant or breast-feeding, think you may be pregnant, or planning to have a baby, talk to your doctor before taking this medicine.

Before taking this medicine, read the information on the safety of this medicine. If you have any questions, ask your doctor or pharmacist.

Irbesartan/Hydrochlorothiazide tablets may have an effect on other medicines you are taking. Before starting treatment with Irbesartan/Hydrochlorothiazide tablets, you should talk to your doctor about the medicines you are on, and discuss their possible effects on each other.

Irbesartan/Hydrochlorothiazide tablets contain one of the following excipients: mannitol, microcrystalline cellulose, hypromellose, polyethylene glycol, hydroxypropyl cellulose, talc, titanium dioxide, red iron oxide, yellow iron oxide, black iron oxide, magnesium stearate, povidone K30, colloidal silica, silica colloidal anhydrous, polyethylene glycol 3350 and polyethylene glycol 4000.

When you have this medicine, you may experience:

• Diuretic effects. You may notice:
  - Thirst
  - Feeling hungry
  - Feeling lightheaded
  - Feeling a need to urinate
  - Feeling dizzy
  - Feeling tired
  - Feeling weak
  - Feeling faint
  - Feeling weak
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  - Feeling weak
  - Feeling faint
  - Feeling weak
  - Feeling faint
  - Feeling weak
  - Feeling faint
  - Feeling weak
  - Feeling faint

• Hypertensive crisis. If you notice:
  - Severe headache
  - Severe nausea
  - Severe vomiting
  - Severe shortness of breath
  - Severe chest pain

• Renal failure. If you notice:
  - Loss of appetite
  - Stomach irritation
  - Stomach cramps

• Liver disorders. If you notice:
  - Yellowing of the skin and/or whites of the eyes

• Kidney disorders. If you notice:
  - Changes in blood urea nitrogen
  - Changes in creatinine

• Cardiovascular disorders. If you notice:
  - Angina
  - Arrhythmias
  - Changes in blood pressure
  - Changes in heart rhythm

• Central nervous system disorders. If you notice:
  - Headache
  - Dizziness
  - Numbness
  - Tingling

• Mental disorders. If you notice:
  - Depression
  - Hallucinations

• Gastrointestinal disorders. If you notice:
  - Nausea
  - Vomiting
  - Diarrhea

• Respiratory disorders. If you notice:
  - Cough
  - Shortness of breath
  - Wheezing

• Auditory disorders. If you notice:
  - Tinnitus

• Dermatological disorders. If you notice:
  - Itching
  - Swelling
  - Blistering

• Blood disorders. If you notice:
  - Anemia
  - Leukopenia
  - Thrombocytopenia

• Endocrine disorders. If you notice:
  - Changes in blood glucose

• Metabolic disorders. If you notice:
  - Changes in cholesterol

• Neurological disorders. If you notice:
  - Changes in reflexes

• Other disorders. If you notice:
  - Changes in weight

If you get any other side effects, talk to your doctor or pharmacist. You may need medical attention. It may be possible that some side effects are serious. Always take this medicine exactly as described in this leaflet or as directed by your doctor. If you think you are having side effects, talk to your doctor or pharmacist. Your doctor or pharmacist will be able to help you decide whether or not you need medical attention and whether or not you need to stop taking this medicine. They will likely do so by asking you questions about the side effect.

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