

# IRSTRAN FILM COATED TABLET

Irbesartan (150 mg, 300 mg)

## What is in this leaflet

1. What IRSTRAN FILM COATED TABLET is used for
2. How IRSTRAN FILM COATED TABLET works
3. Before you use IRSTRAN FILM COATED TABLET
4. How to use IRSTRAN FILM COATED TABLET
5. While you are using IRSTRAN FILM COATED TABLET
6. Side effects
7. Storage and disposal of IRSTRAN FILM COATED TABLET
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What IRSTRAN FILM COATED TABLET is used for

IRSTRAN FILM COATED TABLET is used for:

- treatment of essential hypertension
- treatment of diabetic kidney disease with an elevated serum creatinine (which indicates deterioration of kidney function) and presence of excess proteins in the urine (more than 300 mg/day) in patients with type 2 diabetes and hypertension.

## How IRSTRAN FILM COATED TABLET works

IRSTRAN FILM COATED TABLET consists of Irbesartan, which belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten and hence results in an increase in blood pressure.

IRSTRAN FILM COATED TABLET prevents binding of angiotensin-II to these receptors, causing the blood vessels to relax thus lowers the blood pressure.

IRSTRAN FILM COATED TABLET also function in slowing the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

## Before you use IRSTRAN FILM COATED TABLET

- When you must not take it  
Do not take IRSTRAN FILM COATED TABLET if
  - you have known hypersensitivity (allergic) to Irbesartan or any other ingredients in this medicine
  - you are more than 3 months pregnant.

IRSTRAN FILM COATED TABLET is not recommended for mothers who are breast-feeding as well as children and adolescents (under 18 years).
- Before you start to take it  
Tell doctor or pharmacist if you are allergic to any medicines or if have any other medical conditions. Please inform doctor or pharmacist if you are pregnant or lactating.
- Taking other medicines  
Seek for your doctor advice if you intended to take IRSTRAN FILM COATED TABLET with other medications (e.g. diuretics, other anti-hypertensive agents, aliskiren-containing products and ACE-inhibitors, lithium, potassium-sparing diuretics, potassium supplements, non-steroidal anti-inflammatory drugs (NSAIDs), etc.).

## How to take IRSTRAN FILM COATED TABLET

Always take the tablet exactly as directed by doctor or pharmacist. Check with doctor or pharmacist if you are not sure.

- How much to take  
*Adult:* Initially 150 mg (1 tablet of 150 mg), up to 300 mg (2 tablet of 150 mg or 1 tablet of 300 mg) once daily.

*Elderly over the age of 75 years or patients on haemodialysis:* Doctor may advise a lower starting dose of 75 mg.

- When to take it  
IRSTRAN FILM COATED TABLET should be taken at the same time daily, with or without food. Swallow tablet with a glass of water.
- How long to take it  
IRSTRAN FILM COATED TABLET should be taken regularly and as long as your doctor advised.
- If you forgot to take it  
If you miss 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. Do not take two doses at once.
- If you take too much (overdose)  
Contact your doctor immediately. Taking too many tablets may cause low blood pressure, increased or decreased of heart rate.

## While you are using IRSTRAN FILM COATED TABLET

- Things you must do  
*Pregnancy*  
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking IRSTRAN FILM COATED TABLET before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead. IRSTRAN FILM COATED TABLET is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant.
- Breast-feeding / Lactation*  
Tell your doctor if you are breast-feeding or about to start breast-feeding. IRSTRAN FILM COATED TABLET is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby

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is newborn, or was born prematurely.

- **Things you must not do**  
Do not start taking this medicine or change the dosage without first checking with your doctor. Do not give this medicine to anyone else, even if their symptoms or conditions seem similar to yours.
- **Things to be careful of**  
**Driving and using machines**  
IRSTRAN FILM COATED TABLET is unlikely to affect ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

## Side effects

**Blood and lymphatic system disorders:**  
Low blood platelet count.

**Immune system disorders:**  
Hypersensitivity reactions such as swelling of skin, rash, urticaria.

**Metabolism and nutrition disorders:**  
High potassium level.

**Nervous system disorders:** dizziness, low blood pressure when standing up from sitting or lying down, headache, vertigo.

**Ear and labyrinth disorder:** tinnitus.

**Cardiac disorders:** Increased heart rate.

**Vascular disorders:** Flushing, dizzy or lightheaded when suddenly standing up from a lying or sitting position.

**Respiratory, thoracic and mediastinal disorders:** Cough.

**Gastrointestinal disorders:** Nausea, vomiting, diarrhoea, indigestion/heartburn, altered taste sensation.

**Hepatobiliary disorders:** Hepatitis, abnormal liver function, yellowing of the skin and the whites of the eyes.

**Skin and subcutaneous tissue disorders:** Inflammation of small blood vessels (leukocytoclastic vasculitis).

**Musculoskeletal and connective tissue disorders:** Joint pain, muscle pain, breakdown of damaged skeletal muscle tissue, muscle cramps.

**Renal and urinary disorders:** Impaired renal function including cases of renal failure in patients at risk.

**Reproductive system and breast disorders:** Sexual dysfunction

**General disorders and administration site conditions:** Fatigue, chest pain

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of IRSTRAN FILM COATED TABLET

- **Storage**  
Store at temperature below 30°C. Keep out of the reach and sight of children.  
Do not use IRSTRAN FILM COATED TABLET after the expiry (EXP) date which is stated on the carton and on the blister. The expiry date refers to the last day of that month.

- **Disposal**  
Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

## Product description

- **What it looks like**  
The IRSTRAN FILM COATED TABLET 150 mg is a white film coated elliptical tablet, one side impressed with '150'.



IRSTRAN FILM COATED TABLET 300 mg is a white film coated elliptical tablet, one side impressed with '300'.



## - Ingredients

- Active ingredient  
Irbesartan
- Inactive ingredients  
Silicon Dioxide  
Cellulose Sodium  
Lactose  
Hydroxypropyl Methylcellulose  
Microcrystalline Cellulose  
Magnesium Stearate  
Opadry White
- **MAL numbers**  
IRSTRAN FILM COATED TABLET 150 mg  
MAL18086163AZ  
  
IRSTRAN FILM COATED TABLET 300 mg  
MAL18086164AZ

## Manufacturer

Y.S.P. Industries (M) Sdn. Bhd.  
Lot 3, 5, 7 & 12, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

## Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.  
Lot 3, 5, 7 & 12, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

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