

BESARTIN FILM COATED TABLETS

Irbesartan (150mg, 300mg)

What is in this leaflet

1. What Besartin are used for
2. How Besartin works
3. Before you use Besartin
4. How to use Besartin
5. While you are using Besartin
6. Side effects
7. Storage & disposal of Besartin
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Besartin are used for

Besartin contain a medicine called irbesartan. Irbesartan belongs to a group of medicines known as angiotensin-II receptor blocker. Besartin helps to keep your blood pressure under control.

Besartin tablets are used in adult patients to:

- Treat high blood pressure
- Protect the kidney in patients with high blood pressure and type 2 diabetes with evidence of impaired kidney function (nephropathy in type 2 diabetic patients).

How Besartin works

Besartin prevent the binding of angiotensin-II to angiotensin-II receptors, causing the blood vessels to relax and the blood pressure to lower.

Besartin slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Before you use Besartin

When you must not take it

Do not take Besartin tablets if you:

- allergic (hypersensitive) to irbesartan or any of the

other ingredients of Besartin tablets (*see ingredient list*)

- pregnant or planning to be pregnant
- breast feeding

If you have one of these conditions, do not take this medicine and inform your doctor.

Before you start to take it

If you have the following:

- liver disease
- kidney disease
- diabetes
- any other diseases

....If you have one of these conditions, **inform your doctor**. Your doctor will take it into account during your treatment with Besartin tablets.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to use Besartin

How much to use

Take Besartin exactly as directed by your doctor. Do not take more or take less than instructed by your doctor.

Follow your doctor's instructions carefully. Do not stop this medicine unless your doctor has advised you to do so.

When to use it

You may take Besartin with or without food. Try to take it at the same time each day. This

will help you remember when to take your medicine.

Besartin must be taken regularly for it to be effective. Continue taking Besartin even if there are signs of improvement. Do not stop taking Besartin unless instructed by your doctor.

How long to use it

You should continue to take Besartin tablets each day as long as prescribed by your doctor. If you have questions on the duration of your treatment, ask your doctor.

If you forget to use it

Take the missed dose as soon as you remember and then take the next tablet at the usual time.

However, if it is nearly time for the next dose, skip the missed dose. Take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose. Besartin must be taken exactly as directed for it to be effective. If you often forget to take your medicine, let your doctor and pharmacist know.

If you use too much (overdose)

If you have taken too much of Besartin tablets by accident, contact your doctor or hospital immediately for advice. Show them the pack of tablets. A medical treatment may be necessary.

The most likely symptoms of overdose are low blood pressure and increase rate of heart beat. Decrease in heart rate may also occur.

While you are using Besartin**Things you must do**

You may feel dizzy when getting up from a sitting or lying down position, especially if you are taking Besartin for the first time. This is common and should improve gradually as you get used to the medicine. It will help if you get up slowly from a sitting or lying down position. If you are taking Besartin for the very first time, you may take the first dose at bedtime to reduce dizziness. Thereafter, continue to take it as instructed by your doctor.

For as long as you are taking Besartin, you will need to have regular appointments with your doctor to monitor your blood pressure and check your response to the medication regularly. He may also need to do routine blood tests while you are being treated with Besartin.

Things you must not do

Do not stop the treatment without consulting your doctor.

Do not use Besartin tablets to treat any other conditions unless your doctor tells you to.

Do not give or recommend Besartin tablets to anyone else, even if they have the same condition as you.

Things to be careful of

Taking other medicines:
Inform your doctor if you are taking any of these medicines:

- Digoxin
- Any other blood pressure lowering medicines and diuretics
- Potassium supplements and potassium-sparing diuretics: use at the same time may increase blood potassium levels.

- Lithium: increase in blood lithium levels and toxicity may occur if lithium is administered at the same time as irbesartan.
- Non steroidal anti-inflammatory drugs (medicines used to treat pain and fever): decrease in blood pressure lowering effect may occur; may lead to an increased risk of worsening of kidney function, including possible kidney failure, and an increase in blood potassium. Caution should be exercised if you are elderly.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without a prescription.

Side effects

Like all medicines, Besartin tablets can cause side effects, although not everybody gets them.

Dizziness, headache, back pain and stomach upset are common side effects with irbesartan.

These are usually mild. Inform your doctor if these side effects are severe or does not go away. If you feel dizzy, do not drive or take part in any activity in which you need to be alert. Alert your doctor quickly if you experience:

- yellowing of skin and whites of eyes with decreased appetite, abdominal pain
- Feeling sick (nausea), diarrhoea, muscle weakness and change in heart rhythm
- chest pain which may spread to the neck and shoulders (heart attack), chest pain (angina)
- abnormal heart rhythm, shortness of breath, swelling of the feet or legs due to fluid build-up (heart failure), severe increase in blood pressure that can lead to a stroke

- kidney problems, symptoms include passing little or no urine, drowsiness, nausea, vomiting, breathlessness
- numbness or weakness, especially on one side of the body, confusion or trouble speaking or understanding speech, trouble seeing
- inflammation of small blood vessels mainly affecting the skin (leukocytoclastic vasculitis)

If any of the side effects gets serious, please tell your doctor.

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

Storage and Disposal of Besartin**Storage**

Store below 30°C, away from direct sunlight in a cool and dry place. Keep out of the reach of children.

Disposal

Do not use Besartin tablets after the expiry date which is stated on the label and carton.

If your doctor tells you to stop taking Besartin tablets or your tablets have passed their expiry date, ask your pharmacist or doctor what to do with any that are left over.

Do not simply throw the left over or expired products into the dustbin.

Product Description

What it looks like

Besartin 150 mg : White to off-white, oblong, biconvex, film-coated tablets with score line and 'G' embossed on one side and plain on the other side.

Besartin 300mg: White to off-white, oblong, biconvex, film-coated tablets with score line.

Ingredients

The active substance is irbesartan.

Inactive ingredients

Microcrystalline cellulose, starch pregelatinized, lactose monohydrate, poloxamer 188, croscarmellose sodium, magnesium stearate, Opadry White 20A28735.

MAL Number:

MAL17085052ACZ (150 mg)

MAL17085053ACZ (300 mg)

Manufacturer

Genepharma S.A.,
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Product Registration Holder

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