

CONVERIUM

Irbesartan (150mg, 300mg)

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What CONVERIUM is used for

CONVERIUM is used

- To treat high blood pressure (*essential hypertension*)
- To protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function

How CONVERIUM works

CONVERIUM 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. This results in an increase in blood pressure. Irbesartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Irbesartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Before you use CONVERIUM

When you must not use it

Do not take CONVERIUM:

- If you are allergic (hypersensitive) to irbesartan or any other ingredients of CONVERIUM
- If you are more than 3 months pregnant (it is also better to avoid CONVERIUM in early pregnancy – see pregnancy section)

Converium should not be given to children and adolescents (under 18 years)

Pregnancy and Lactation

You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Converium before you become pregnant or as soon as you know you are pregnant and will advise you to take another

medicine instead of CONVERIUM. CONVERIUM is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Tell your doctor if you are breast-feeding or about to start breast-feeding. CONVERIUM is not recommended for mother who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Before you start to use it

Tell your doctor or pharmacist if you:

- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**
- if you receive CONVERIUM for **diabetic kidney disease**. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function
- if you are **going to have an operation** (surgery) or **be given anaesthetics**

You must tell your doctor if you think that you are (or might become) pregnant. CONVERIUM is not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

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.

You may need to have blood checks if you take:

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as certain diuretics)
- medicines containing lithium

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.

How to use CONVERIUM

How much to use

- **Patients with high blood pressure**
The usual dose is 150mg once a day. The dose may later be increased to 300mg once daily depending on blood pressure response.

- **Patients with high blood pressure and type 2 diabetes with kidney disease**

In patients with high blood pressure and type 2 diabetes, with kidney disease, therapy should be initiated at 150mg irbesartan once daily and titrated up to 300 mg once daily as the preferred maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on **haemodialysis**, or those **over the age of 75 years**.

When to use it

Always take CONVERIUM exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How long to use it

Try to take your daily dose at about the same time each day. It is important that you continue to take CONVERIUM until your doctor tells you otherwise.

If you forget to use it

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you use too much (overdose)

If you accidentally take too many tablets, contact your doctor immediately.

While you are using it

Things you must do

CONVERIUM

Irbesartan (150mg, 300mg)

Take your medicine exactly as your doctor has advised you.

Tell the doctor, pharmacist or dentist treating you that you are taking CONVERIUM.

Tell your doctor immediately if you become pregnant while taking this medication

Things you must not do

CONVERIUM should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

Things to be careful of Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. CONVERIUM is unlikely to affect your 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

Like all medicines, CONVERIUM can cause side effects, although not everybody gets them. Some of these effects may be serious and may require medical attention.

As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), as well as localized swelling of the face, lips and/or tongue have been reported in patients taking irbesartan. If you get any of these symptoms or get short of breath, **stop taking CONVERIUM and contact your doctor immediately.**

The frequency of the side effects listed below is defined using the following convention:

Very common: at least 1 in 10 patients or more

Common: at least 1 in 100 and less than 1 in 10 patients

Uncommon: at least 1 in 1000 and less than 1 in 100 patients

Side effects reported in clinical studies for patients treated with irbesartan were:

- Very common: blood tests may show an increased level of potassium.

- Common: dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatinase kinase enzyme). Dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles.

- Uncommon: heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain.

Some undesirable effects have been reported since marketing of irbesartan but the frequency for them to occur is not known. These undesirable effects are: headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) of Vaccines (AEFI)].

Storage and disposal of CONVERIUM

Storage

Keep out of the reach and sight of children.

Store below 30°C.

Disposal

Do not use CONVERIUM after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

CONVERIUM tablets 150mg: White, round flat, scored tablets having a diameter of 10.5mm. The tablet can be divided into equal halves.

CONVERIUM tablets 300mg: White, round flat, scored tablets having a diameter of 12.7mm. The tablet can be divided into equal halves.

The tablets are folded into PVC/PVDC/aluminium foil blisters. Each blister contains 7 or 10 tablets. Available pack sizes are: 14 tablets; 28 tablets; 30 tablets; 60 tablets and 100 tablets

Ingredients

Active ingredients

The active substance is irbesartan. Each tablet of CONVERIUM 150mg contains 150mg irbesartan. Each tablet of CONVERIUM 300 mg contains 300mg irbesartan.

Inactive ingredients

Lactose monohydrate, Pregelatinized Starch, Croscarmellose Sodium, Colloidal Anhydrous Silica, Poloxamer 188, Microcrystalline Cellulose, Magnesium Stearate.

MAL No.

CONVERIUM Tablet 150mg
CONVERIUM Tablet 300mg

Manufacturer

Medochemie (Far East) Ltd. (Oral Facility)
No. 40 Street 6 Vietnam Singapore Industrial Park II, Binh Duong Industry Service Urban Complex, Hoa Phu ward, Thu Dau Mot city, Vietnam

Product Registration Holder

Komedic Sdn Bhd
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