

## Package leaflet: Information for the user

### Irbesartan Niche 150mg Film-Coated Tablets

### Irbesartan Niche 300mg Film-Coated Tablets

Irbesartan

**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.

The name of your medicine is Irbesartan Niche 150 mg or 300 mg Film-Coated Tablets. It will be called Irbesartan Niche for ease from here on.

#### What is in this leaflet:

1. What Irbesartan Niche is and what it is used for
2. What you need to know before you take Irbesartan Niche
3. How to take Irbesartan Niche
4. Possible side effects
5. How to store Irbesartan Niche
6. Contents of the pack and other information

#### 1. What Irbesartan Niche is and what it is used for

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

Irbesartan Niche is used in adult patients

- 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.

#### 2. What you need to know before you take Irbesartan Niche

##### Do not take Irbesartan Niche:

- if you are **allergic** to irbesartan or any of the other ingredients of this medicine (listed in section 6)
- if you are more than **3 months pregnant**. (It is also better to avoid Irbesartan Niche in early pregnancy – see pregnancy section)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

Irbesartan Niche should not be given to children and adolescents (under 18 years).

#### Warnings and precautions

**Talk to your doctor before taking Irbesartan Niche** and if any of the following apply to you:

- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**
- if you receive Irbesartan Niche 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**
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take Irbesartan Niche”

You must tell your doctor if you think you are (or might become) pregnant. Irbesartan Niche 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).

### **Children and adolescents**

This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

### **Other medicines and Irbesartan Niche**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Irbesartan Niche” and “Warnings and precautions”).

Irbesartan Niche does not usually interact with other medicines.

### **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.

### **Irbesartan Niche with food and drink**

Irbesartan Niche can be taken with or without food.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

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

Niche 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.

### **Breast-feeding**

Tell your doctor if you are breast-feeding or about to start breast-feeding. Irbesartan Niche 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 is newborn, or was born prematurely.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed. Irbesartan Niche 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.

## **3. How to take Irbesartan Niche**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Irbesartan Niche is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan Niche with or without food. Try to take your daily dose at about the same time each day. It is important that you continue to take Irbesartan Niche until your doctor tells you otherwise.

### **The recommended dose is:**

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

The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

### **Use in children and adolescents**

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

### **If you take more Irbesartan Niche than you should**

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

### **If you forget to take Irbesartan Niche**

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 medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of these effects may be serious and may require medical attention.

### **Serious allergic reactions**

As with similar medicines, rare cases of allergic skin reactions (rash, urticaria (hives)), as well as localised 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 Irbesartan Niche and contact your doctor immediately.**

### **Other side effects**

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

**Very common** (may affect more than 1 in 10 people):

- if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.

**Common** (may affect up to 1 in 10 people):

- dizziness
- feeling sick/vomiting
- fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatine kinase enzyme).

In patients with high blood pressure and type 2 diabetes with kidney disease the following side effects were also reported:

- 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
- decreased levels of a protein in the red blood cells (haemoglobin).

**Uncommon** (may affect up to 1 in 100 people):

- 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.

Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, reduced number of platelets, 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).

Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance,

Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Irbesartan Niche

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

This medicine does not require any special storage conditions.

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 Irbesartan Niche film-coated tablets contain:

- The **active substance** is Irbesartan. Irbesartan Niche film-coated tablets contain 150 milligrams (mg) or 300 mg of Irbesartan.
- The **other core ingredients** are mannitol (E421), croscarmellose sodium, colloidal anhydrous silica (E551), poloxamer 188, magnesium stearate (E572) and for the **film-coating** opadry white 03B28796 which contains hypromellose (E464), titanium dioxide (E171) and macrogol.

### What Irbesartan Niche film-coated tablets look like and contents of the pack

- The **150 mg tablets** are white to off-white coloured, oval shaped, biconvex, film-coated tablets with “U” debossed on one side and “I” debossed on the other side. The tablet is approximately 4.8 mm thick, 12.5 mm long and 6.5 mm wide.
- The **300 mg tablets** are white to off-white coloured, oval shaped, biconvex, film-coated tablets with “U” debossed on one side and plain on the other side. The tablet is approximately 5.6 mm thick, 15.7 mm long and 8.1 mm wide.

The 150 mg and 300 mg tablets are supplied in white opaque PVC/PVdC-Aluminium blister packs of 10, 14, 28, 30, 56, 84, 90 or 98.

Not all pack sizes will be marketed.

## Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Niche Generics Limited,  
1 The Cam Centre,  
Wilbury Way, Hitchin,  
Hertfordshire SG4 0TW,  
United Kingdom.

The Manufacturer is:

Niche Generics Limited,  
Unit 5, 151 Baldoyle Industrial Estate,  
Dublin 13,  
Ireland.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

United Kingdom and Ireland: Irbesartan Niche

**This leaflet was last revised in 10/2017.**