

Package leaflet: Information for the patient

Licolin 75 mg tablets

Licolin 150 mg tablets

Licolin 300 mg 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. 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

What is in this leaflet:

1. What Licolin 75 mg/150 mg/300 mg tablets is and what it is used for
2. What you need to know before you take Licolin 75 mg/150 mg/300 mg tablets
3. How to take Licolin 75 mg/150 mg/300 mg tablets
4. Possible side effects
5. How to store Licolin 75 mg/150 mg/300 mg tablets
6. Content of the pack and other information

1. What Licolin 75 mg/150 mg/300 mg tablets is and what is used for

Licolin 75 mg/150 mg/300 mg tablets 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. Licolin 75 mg/150 mg/300 mg tablets prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Licolin 75 mg/150 mg/300 mg tablets slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Licolin 75 mg/150 mg/300 mg tablets is used in the treatment of high blood pressure (hypertension essential) and for the protection of the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function.

2. What you need to know before you take Licolin 75 mg/150 mg/300 mg tablets

Do not take Licolin 75 mg/150 mg/300 mg tablets

- if you are allergic (hypersensitive) to irbesartan or any other ingredients of Licolin 75 mg/150 mg/300 mg tablets
- if you are more than 3 months pregnant. (It is also better to avoid Licolin 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Licolin 75 mg/150 mg/300 mg tablets

- if you suffer from excessive vomiting or diarrhoea

- if you suffer from kidney problems
- if you suffer from heart problems
- if you are to undergo any surgery or receive anaesthetics, you should also tell your doctor about it
- You must tell your doctor if you think you are (or might become) pregnant. Licolin 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).
- 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 Licolin”

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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 Licolin 75 mg/150 mg/300 mg tablets

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

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 Licolin” and “Warnings and precautions”).

Licolin 75 mg/150 mg/300 mg tablets does not usually interact with other medicines. Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines (such as certain diuretics) or lithium-containing medicines.

As with other blood pressure lowering drugs, the effect of irbesartan may be reduced when you take non-steroidal anti-inflammatory drugs.

Licolin 75 mg/150 mg/300 mg tablets with food and drink

Licolin 75 mg/150 mg/300 mg tablets can be taken before, during or after meals. The tablets should be swallowed with a drink of water.

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 Licolin before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Licolin. Licolin 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. Licolin 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. Licolin 75 mg/150 mg/300 mg tablets 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, you should consult your doctor before attempting such activities.

Important information about some of the ingredients of Licolin 75 mg/150 mg/300 mg tablets

Licolin 75 mg/150 mg/300 mg tablets contains lactose monohydrate (see "Further information"). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take LICOLIN 75 MG/150 MG/300 MG TABLETS

Always take Licolin 75 mg/150 mg/300 mg tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

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.

Licolin 75 mg/150 mg/300 mg tablets is for oral use and is taken before, during or after meals. The tablets should be swallowed with a drink of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Licolin 75 mg/150 mg/300 mg tablets until your doctor tells you otherwise.

Licolin 75 mg/150 mg/300 mg tablets should not be given to children (under 18 years).

If you take more Licolin 75 mg/150 mg/300 mg tablets than you should

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately.

Too high a dose could cause dizziness, fainting, rapid or pounding heartbeat.

If you forget to take Licolin 75 mg/150 mg/300 mg tablets

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, irbesartan can cause side effects, although not everybody gets them. Some effects may be serious and may require medical attention.

As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), 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 this medicine 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 this irbesartan were:

- Very common (at least 1 in 10 patients or more): if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.
- Common (at least 1 in 100 and less than 1 in 10 patients)
dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measure the muscle and heart function (creatinine kinase enzyme).
In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.
- Uncommon (at least 1 in 1000 and less than 1 in 100 patients): heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with the 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 (condition known as leukocytoclastic vasculitis). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Licolin 75 mg/150 mg/300 mg tablets

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

Do not use Licolin 75 mg/150 mg/300 mg tablets 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.

Store in the original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Licolin 75 mg/150 mg/300 mg tablets contains

- The active substance is irbesartan. Each tablet contains 75/150/300 mg of irbesartan.
- The other ingredients are cellulose microcrystalline (E460), croscarmellose sodium (E468), lactose monohydrate, magnesium stearate (E572), silica colloidal anhydrous (E551), maize starch, povidone K29/32 (E-1201) and hydrogenated castor oil.

What Licolin 75 mg/150 mg/300 mg tablets looks like and contents of the pack

Licolin 75 mg/ tablets are white, cylindrical, biconvex tablets.

Licolin 150 mg/ tablets are white, cylindrical, biconvex, scored on one side tablets.

Licolin 300 mg/ tablets are white, oblong, biconvex, scored on one side tablets.

Licolin 75 mg/150 mg/300 mg tablets are supplied in blisters of pack sizes of 14, 28, 56 or 98.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Laboratorios LICONSA ,S.A
Gran Vía Carlos III, 98 7th floor
08028 Barcelona
Spain

Manufacturer:

Laboratorios LICONSA, S.A.
Avda. Miralcampo, N° 7,
Polígono Industrial Miralcampo
19200 Azuqueca de Henares (Guadalajara),
Spain

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

75 mg:

Ireland:	Licolin 75 mg tablets
Netherlands:	Licolin 75 mg Tablet
Austria:	Licolin 75 mg Tablette
United Kingdom:	Irbesartan 75 mg tablets

150 mg:

Ireland:	Licolin 150 mg tablets
Netherlands:	Licolin 150 mg Tablet
Austria:	Licolin 150 mg Tablette
United Kingdom:	Irbesartan 150 mg tablets

300 mg:

Ireland:	Licolin 300 mg tablets
Netherlands:	Licolin 300 mg Tablet
Austria:	Licolin 300 mg Tablette
United Kingdom:	Irbesartan 300 mg tablets

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