PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

IRBEWIN 75 mg (Tablets)

IRBEWIN 150 mg (Tablets)

IRBEWIN 300 mg (Tablets)

The active ingredient is irbesartan.

Read all of this leaflet carefully before you start taking IRBEWIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- IRBEWIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IRBEWIN CONTAINS:

The active substance in IRBEWIN tablets is irbesartan. Each tablet contains 75 mg, 150 mg or 300 mg irbesartan.

The other inactive ingredients are: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide and a film-coating.

WHAT IRBEWIN IS USED FOR:

IRBEWIN belongs to a group of medicines known as angiotensin II receptor blockers (ARB's). IRBEWIN is used in the treatment of high blood pressure (hypertension) and for the protection of the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired renal function.

BEFORE YOU TAKE IRBEWIN:

Do not take IRBEWIN:

- if you are hypersensitive (allergic) to irbesartan or any of the other ingredients of IRBEWIN (see “WHAT IRBEWIN CONTAINS”)
- if you have a history of angioedema (swelling around your face, throat or tongue) related to previous therapy with ARBs or to angiotensin converting enzyme inhibitors (ACEIs): You must never again be given these medicines
- if you have hereditary angioedema (swelling around your face, throat or tongue)

- if you have heart disease characterised by obstruction of blood flow and thickening of heart tissue (hypertrophic obstructive cardiomyopathy)
- if you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis) or a transplanted kidney
- If you have kidney problems and are taking fluoroquinolones (used to treat bacterial infections) at the same time (see “Taking other medicines with IRBEWIN”).
- if you have a decrease in blood supply flow through the aortic artery (aortic stenosis)
- if you have porphyria
- if you do not urinate or you have severe kidney problems
- if you are taking potassium-sparing diuretics (such as spironolactone, triamterene, amiloride)
- if you are taking a medicine containing lithium
- if you are pregnant or breastfeeding

If you are pregnant or breastfeeding your baby while taking IRBEWIN, please consult your doctor, pharmacist or other healthcare professional for advice.

You should not breastfeed your baby if you are taking IRBEWIN.

You must tell your doctor if you think you are (or might become) pregnant. IRBEWIN should not be used during pregnancy as it may cause serious harm to your baby.

IRBEWIN should not be given to children.

If any of the above apply to you, inform your doctor or pharmacist first and ask for their advice.

Take special care with IRBEWIN:

Tell your doctor if any of the following apply to you:

- if you get excessive vomiting or diarrhoea (sodium/volume-depleted patients)
- if you suffer from kidney problems
- if you are an elderly patient
- if you suffer from heart problems
- if you take IRBEWIN for diabetic kidney disease. In this case your doctor should perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function
- if you are taking a medicine containing lithium.

Taking IRBEWIN with food and drink:

You can take IRBEWIN with or without food.

Take the tablet with a sufficient quantity of liquid (e.g. one glass of water).

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

You must tell your doctor if you think you are (or might become) pregnant. Your doctor should immediately stop your treatment and switch you over to a different class of medicine. IRBEWIN should not be used in pregnancy as it may cause serious harm to your baby (see BEFORE TAKING IRBEWIN.

You should ensure adequate contraception while taking IRBEWIN if you are of childbearing age.

Driving and using machinery:

IRBEWIN is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. Do not drive or operate machinery until you are sure how IRBEWIN affects you. If you experience these symptoms, you should consult your doctor before attempting such activities.

Important information about some of the ingredients of IRBEWIN:

IRBEWIN contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking IRBEWIN.

Taking other medicines with IRBEWIN:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

It is also important to tell your doctor if you are taking other medicines to reduce your blood pressure; non-steroidal anti-inflammatory medicines (NSAIDs); or COX-2 inhibitors (medicines that reduce pain and inflammation).

Do not take IRBEWIN with fluoroquinolones (used to treat bacterial infections), such as levofloxacin, ciprofloxacin or moxifloxacin (see “DO NOT TAKE IRBEWIN”).

You may need to have your blood checked regularly if you take:

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as diuretics)
- medicines containing lithium Refer to “Do not take IRBEWIN”.

HOW TO TAKE IRBEWIN:

Do not share the IRBEWIN prescribed for you with others.

Always take IRBEWIN exactly as your doctor has instructed you. You should check with your

doctor or pharmacist if you are not sure.

The usual dose of IRBEWIN is 150 mg once a day. The dose may later be increased to 300 mg once daily, depending on your blood pressure response.
If you have high blood pressure and type 2 diabetes with kidney disease your doctor will take this into account.

If you have the impression that the effect of IRBEWIN is too strong or too weak, tell your doctor or pharmacist.

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

If you take more IRBEWIN than you should:
In the event of overdosage, consult your doctor or pharmacist.
If neither is available, contact the nearest hospital or poison control centre.

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

POSSIBLE SIDE EFFECTS:
IRBEWIN can have side effects.
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 IRBEWIN. If you think you are developing such a reaction or get short of breath, **stop taking IRBEWIN and seek immediate medical attention.**

Do not take another dose of IRBEWIN to see if the same reaction will happen again. If you have high blood pressure, you may experience the following side effects:

Frequent:

Dizziness, feeling sick/vomiting and fatigue, headache

Less frequent:

Fast heartbeat, cough, diarrhoea, indigestion, problems with sexual performance and chest pain

Frequency not specified:

Oedema

If you have high blood pressure and type 2 diabetes with renal problems, you may also experience the following side effects:

Frequent:

Increased blood potassium levels.

Low blood pressure and dizziness (especially when getting up from a lying or sitting position)

Some undesirable effects reported since marketing of IRBEWIN are:

Headache, liver function disorders, increased blood potassium levels, vertigo (lightheadedness) or a feeling you are about to fall, pain in joints and muscles, impaired kidney function, hypersensitive reactions (allergic)

Not all side effects reported for IRBEWIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IRBEWIN, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF IRBEWIN:

Store all medicines out of the reach of children.

IRBEWIN tablets should be stored in a dry place, at or below 25 °C. Store in the original package.

Do not use after the expiry date stated on the carton and on the blister.

Do not remove the tablets from the blister pack until you are ready to take the medicine. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF IRBEWIN:

IRBEWIN tablets are supplied in blister packs of 28 or 30.

IDENTIFICATION OF IRBEWIN:

IRBEWIN 75 mg tablets are white to off-white, biconvex, oval, film-coated tablets, engraved with a heart on one side and the number “2871” on the other side.

IRBEWIN 150 mg tablets are white to off-white, biconvex, oval, film-coated tablets, engraved with a heart on one side and the number “2872” on the other side.

IRBEWIN 300 mg tablets are white to off-white, biconvex, oval, film-coated tablets, engraved with a heart on one side and the number “2873” on the other side.

REGISTRATION NUMBER/REFERENCE NUMBER:

IRBEWIN 75 mg tablets: A40/7.1.3/0291

IRBEWIN 150 mg tablets: A40/7.1.3/0288

IRBEWIN 300 mg tablets: A40/7.1.3/0289

NAME AND ADDRESS OF REGISTRATION HOLDER:

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