

FRONT

Pharmacode

For the use of a Registered Medical Practitioner in a Hospital or a Laboratory only.

DYNACARD-150/300

(Irbesartan Tablets 150/300 mg)

Prescribing Information

Product Description

Dynacard 150 - White to off white, biconvex, oval shaped, film coated tablets with 'U22' engraved on one side and plain on the other side.
Dynacard 30 - White to off white, biconvex, oval shaped, film coated tablets with 'U23' engraved on one side and plain on the other side.

PHARMACOLOGY

Mechanism of Action

Irbesartan is a potent, orally active, selective angiotensin-II receptor (type AT1) antagonist. It blocks all actions of angiotensin-II mediated by the AT1 receptor. This selective antagonism results in an increase in plasma-renin levels and angiotensin II levels, and a decrease in plasma aldosterone concentration.

Irbesartan does not inhibit angiotensin-converting enzyme (ACE) (kininase II) which is an enzyme that produces angiotensin II and also metabolizes bradykinin into inactive metabolites. The effect of Irbesartan can be seen within 1-2 weeks after the start of therapy. When taken long-term, the antihypertensive effects are maintained. Blood pressure will gradually return toward baseline upon withdrawal of therapy. The addition of thiazide-type diuretics has been shown to have an additive effect. The efficacy of Irbesartan is not influenced by age or gender.

Pharmacokinetics: After oral administration, Irbesartan is well absorbed. The bioavailability of Irbesartan is not influenced by concomitant food intake. Irbesartan is metabolized via glucuronide conjugation and oxidation by the liver. The major circulating metabolite is Irbesartan glucuronide.

Irbesartan is mainly oxidized by the cytochrome P450 enzyme CYP2C9. Irbesartan and its metabolites are eliminated by both biliary and renal pathways.

Renal Impairment: In patients with renal impairment or those undergoing haemodialysis, the pharmacokinetic parameters of Irbesartan are not significantly altered. Haemodialysis does not remove Irbesartan.

Hepatic Impairment: The pharmacokinetic parameters of Irbesartan are not significantly altered in patients with mild to moderate cirrhosis. Studies have not been performed in patients with severe hepatic impairment.

INDICATIONS AND USAGE

- Irbesartan is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.
- Irbesartan is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300 mg/day) in patients with type 2 diabetes and hypertension.

DOSAGE AND ADMINISTRATION

The usual recommended initial and maintenance dose is 150 mg once daily, with or without food.

Irbesartan at a dose of 150 mg once daily generally provides a better 24 hour blood pressure control than 75 mg. However, initiation of therapy with 75 mg could be considered, particularly in haemodialysed patients and in the elderly over 75 years.

In patients insufficiently controlled with 150 mg once daily, the dose of Irbesartan can be increased to 300 mg, or other antihypertensive agents can be added. In particular, the addition of a diuretic such as hydrochlorothiazide has been shown to have an additive effect with Irbesartan.

In hypertensive type 2 diabetic patients, therapy should be initiated at 150 mg irbesartan once daily and titrated up to 300 mg once daily as the preferred maintenance dose for treatment of renal disease.

Renal impairment: no dosage adjustment is necessary in patients with impaired renal function. A lower starting dose (75 mg) should be considered for patients undergoing haemodialysis

Hepatic impairment: no dosage adjustment is necessary in patients with mild to moderate hepatic impairment. There is no clinical experience in patients with severe hepatic impairment.

Elderly patients: although consideration should be given to initiating therapy with 75 mg in patients over 75 years of age, dosage adjustment is not usually necessary for the elderly.

Paediatric patients: irbesartan is not recommended for use in children and adolescents due to insufficient data on safety and efficacy.

CONTRAINDICATIONS

Irbesartan is contraindicated in patients who are hypersensitive to any component of this product.

WARNING AND PRECAUTIONS

Intravascular Volume Depletion : Volume-and/or sodium-depleted conditions should be corrected before the administration of Irbesartan as symptomatic hypotension may occur especially after the 1st dose.

Renal Impairment : The monitoring of potassium and serum creatinine levels are recommended when Irbesartan is used in patients with renal impairment.


Lithium : It is not recommended to add lithium while on Irbesartan therapy (see Interactions).

Aortic and Mitral Valve Stenosis, Obstructive Hypertrophic Cardiomyopathy : As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.

Primary Aldosteronism : Patients with primary aldosteronism generally will not respond to antihypertensive drugs which act by inhibiting the renin angiotensin system. Thus, the use of Irbesartan is not recommended.

General : In patients whose vascular tone and renal function depend mainly on the activity of the reninangiotensin-aldosterone system (eg, patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with angiotensin converting enzyme inhibitors or angiotensin-II receptor antagonists that acts on this system has been associated with acute hypotension, azotaemia, oliguria or rarely, acute renal failure. Caution has to be taken with patients who have ischemic cardiopathy or ischemic cardiovascular disease as excessive blood pressure decrease could result in a myocardial infarction or stroke.

Use in children : There is no sufficient data to support the use of Irbesartan in children.

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
Market/Country : Export Co-ordinator Name : Sachin Software : Corel Draw

SAP Code : 3015XXX Item type : Carton Date: 12/12/2018 Version : X6

Product Name : Dynacard Artist Name : Ajay

Actual Size : 140 mm x 210 mm (L x H) (Front & Back) Reference SAP Code : 3010099

Print Repeat : ----- Layout No. -----

CMYK/Pantone :  Black

Reason : New Development

Path : Z:\art-work-documents\Venaa - Final Artworks in CDR\Current 08.2010\Formulation\Export\Malaysia

NOTE TO THE PRINTER:

Processor / Printer shall not make any correction / changes / deviation in the approved artwork.

If any discrepancy observed in the artwork, Printer / Processor shall return the artwork to USV.

Prepared by RA	Checked by RA	Checked by CQA	Checked by Legal	Approved by RA

BACK

DRUG INTERACTIONS

No significant drug-drug pharmacokinetic interactions have been found with digoxin and warfarin.

Diuretics and Other Antihypertensive Agents: Irbesartan has been safely administered with other antihypertensive agents eg, β -blockers, long-acting calcium-channel blockers and thiazide diuretics. However, they may increase the hypotensive effects of Irbesartan. **Potassium Supplements and Potassium-Sparing Diuretics:** Concomitant administration of drugs that may increase serum potassium levels (eg, heparin, potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium) is not recommended as it may lead to an increase in serum potassium.

Lithium: Concomitant use of lithium with angiotensin-converting enzyme inhibitors has been reported to have toxicity and a reversible increase in serum lithium concentrations. Similar effects have been very rarely reported with Irbesartan. Therefore, this combination is not recommended. **Nonsteroidal Anti-Inflammatory Drugs (NSAIDs):** NSAIDs may decrease the antihypertensive effect when administered with angiotensin II antagonists. As with ACE inhibitors, concomitant use of angiotensin II antagonists and NSAIDs may lead to an increased risk of worsening of renal function, including possible acute renal failure, and an increase in serum potassium, especially in patients with poor preexisting renal function. The combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and periodical monitoring of renal function after initiation of concomitant therapy is recommended.

PREGNANCY AND LACTATION

Use in pregnancy: The use of angiotensin-II receptor antagonists is not recommended during the 1st trimester of pregnancy. Irbesartan is contraindicated during the 2nd and 3rd trimesters of pregnancy as it is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). If exposure does occur from the 2nd trimester of pregnancy, ultrasound check of renal function and skull is recommended while infants whose mothers have taken angiotensin-II receptor antagonists should be closely observed for hypotension. Alternative antihypertensive treatments which have an established safety profile for use in pregnancy is recommended for patients planning pregnancy. When pregnancy is diagnosed, treatment with angiotensin-II receptor antagonists should be stopped immediately.

Use in lactation: There is no information available to support the use of Irbesartan during breastfeeding.

Therefore, it is not recommended and alternative treatments with better established safety profiles are preferable.

Adverse Effects / Undesirable Effects

Investigations: hyperkalaemia, increases in plasma creatine kinase

Cardiac disorders: tachycardia

Vascular disorders: orthostatic hypotension, flushing

Nervous system disorders: headache, dizziness

Respiratory, thoracic and mediastinal disorders: cough, upper respiratory infection

Gastrointestinal disorders: nausea, vomiting, diarrhoea, dyspepsia/heartburn, dysgeusia

General disorders and administration site conditions: fatigue

Renal and urinary disorders: impaired renal function including cases of renal failure in patients at risk

Skin and subcutaneous tissue disorders: urticaria, leukocytoclastic vasculitis

Musculoskeletal and connective tissue disorders: arthralgia, myalgia (in some cases associated with increased plasma creatine kinase levels), rhabdomyolysis, muscle cramps

Immune system disorders: hypersensitivity reactions such as angioedema, rash, urticaria

Hepato-biliary disorders: hepatitis, abnormal liver function, cholestasis, jaundice

Hematologic disorders: thrombocytopenia

Reproductive system and breast disorders: sexual dysfunction

Ear and labyrinth disorders: tinnitus

SYMPTOMS AND TREATMENT OF OVERDOSE

No data are available in regard to overdosage in humans. However, daily doses of 900 mg for 8 weeks were well-tolerated. The most likely manifestations of overdosage are expected to be hypotension and tachycardia; bradycardia might also occur from overdose. As there is no specific information for

treatment of overdosage with Irbesartan, symptomatic and supportive treatment should be given.

Suggested measures include induction of emesis and/or gastric lavage. Activated charcoal may be useful. Patients should be closely monitored. Irbesartan is not removed by hemodialysis.

STORAGE: Store below 30°C.

SHELF LIFE: 24 months

PRESENTATION:

1. DYNACARD-150

(Irbesartan Tablets 150 mg)

Formula: Each film coated tablet contains:

Irbesartan Ph. Eur. 150 mg.

Packaging: 2 x 14 tablets, packed in a carton.

2. DYNACARD-300

(Irbesartan Tablets 300 mg)

Formula: Each film coated tablet contains:

Irbesartan Ph. Eur. 300 mg.

Packaging: 2 x 14 tablets, packed in a carton.

Manufactured by: **USV Private Limited**

H-13, 16, 16A, 17, 18, 19, 20, 21, E-22, O IDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman - 396210, India.

Product Registration Holder:

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11900 Bayan Lepas, Pulau Pinang.

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3015XXX 12/18



Size : 140 mm x 210 mm (L x H)