

Irbes[®]

Irbesartan Tablet

DESCRIPTION

Irbes[®] is a preparation of Irbesartan, an angiotensin II receptor antagonist used in the treatment of hypertension. Angiotensin II is the principal pressor agent of the renin-angiotensin system and also stimulates aldosterone synthesis and secretion by adrenal cortex, cardiac contraction, renal reabsorption of sodium and activity of the sympathetic nervous system. Irbesartan blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II by selectively binding to the angiotensin II receptor and thereby reduce blood pressure.

INDICATIONS

It is indicated only for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

DOSAGE AND ADMINISTRATION

Adult : 75 or 150 mg once a day.

The recommended initial dose is 150 mg once daily. Patients requiring further reduction in blood pressure should be titrated to 300 mg once daily.

No dosage adjustment is necessary in elderly patients, or in patients with hepatic impairment or mild to severe renal impairment.

Child: Safety and effectiveness in children have not been established.

CONTRAINDICATION

Hypersensitivity to any component of this product.

PRECAUTIONS

- Be careful during driving or operating machinery. Alcohol can make dizziness or light-headedness.
- Irbesartan should be avoided in pregnant and breastfeeding women. It may cause birth defects or other problems in the baby if taken during pregnancy.

USE IN PREGNANCY AND LACTATION

Pregnancy

When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to developing foetus. When pregnancy is detected, Irbesartan should be discontinued as soon as possible.

Nursing mothers

The excretion of Irbesartan in human breast milk has not been studied yet. Therefore, Irbesartan should not be used during breast-feeding.

SIDE EFFECTS

One of the main advantages of Irbesartan is the low incidence of adverse effects, especially cough, a common effect of ACE inhibitors which work on the same renin-angiotensin system.

Common side effects

Headache, dizziness or light-headedness, fatigue, nausea, and vomiting.

Less common

- Anxiety • Nervousness • Belching • Heartburn • Stomach discomfort
- Diarrhoea • Headache • Muscle or bone pain • Unusual tiredness

USE IN OLDER AND KIDNEY DISEASE

Older adults : Blood levels of irbesartan may be increased in the elderly patients and they may be more sensitive to the effects of irbesartan.

Kidney disease : Effects of irbesartan may be increased because of slower removal of medicine from the body.

Supportive measures

Life style is a major factor contributing to hypertension and with some modifications can help lowering the blood pressure.

Such measures include:

- Losing weight
- Avoiding smoking
- Reducing alcohol intake
- Reducing the amount of salt in the diet
- Practicing regular, mild (not strenuous) exercise such as walking, swimming etc.

DRUG INTERACTION

No significant drug interactions were found in interaction studies with hydrochlorothiazide, digoxin, warfarin and nifedipine. In vitro studies show a significant inhibition of the formation of irbesartan metabolites by the CYP2C9 inhibitors, sulphenazole, tolbutamide and nifedipine. The pharmacokinetics of irbesartan were not affected by co-administration of nifedipine or hydrochlorothiazide, in clinical studies.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Irbes[®] 75 Tablet: Box containing 5 strips of 10 tablets each. Each tablet contains Irbesartan USP 75 mg.

Irbes[®] 150 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Irbesartan USP 150 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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