IRBEARTAN TABLETS, USP

**WARNING: FATAL TOXICITY**

- When pregnancy is detected, discontinue irbesartan as soon as possible, since fetal toxicity may occur. See PRECAUTIONS: teratogenicity and embryotoxicity.

**PRECAUTIONS:**

Fetal Toxicity

- Pregnancy Category D

Use of drugs known to cause fetal harm based on risk-benefit considerations may be indicated if potential benefits outweigh the potential risk to the fetus.

**Pregnancy**

- Irbesartan is not recommended for use during pregnancy. If pregnancy occurs while taking irbesartan, discontinue irbesartan as soon as possible.

**Lactation**

- Breastfeeding is not recommended during irbesartan treatment.

**Drug Interactions**

- Irbesartan should be used with caution in patients with impaired renal function or a history of renal impairment.

**CONTRAINDICATIONS**

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

- Do not use in combination with aminoglycosides in patients with renal impairment.

**WADINGS**

- Irbesartan is a drug used in the renin-angiotensin system.
Irbesartan Tablets, USP 75 mg are available as white to off-white, biconvex, oval tablets, debossed with '447' on one side and 'C' on other. Tablets, USP 150 mg are available as white to off-white, biconvex, oval tablets, debossed with '448' on one side and 'C' on other. Tablets, USP 300 mg are available as white to off-white, biconvex, oval tablets, debossed with '449' on one side and 'C' on other. Packaging Information: Bottles of 90's 59746-447-30, Bottles of 500's 59746-449-30, Bottles of 1000's 59746-448-60. Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). See also USP Controlled Room Temperature. For more information about irbesartan Tablets, USP call 1-800-313-4603.

Reason for Artwork: Revision
Dimension: 455 x 500 mm
Superseded Item Code: 7524000423
Substrate: 40 GSM Bible paper with folding size - 35 x 35 mm
Site Packaging Development
Sign and Date
Production Sign and Date
QA Sign and Date

Hypertension

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

A low dose of a diuretic may be added. If blood pressure is not controlled by irbesartan alone, Hydrochlorothiazide has been shown to have an additive effect (see CLINICAL PHARMACOLOGY: Clinical Studies). Patients not adequately treated by the maximum dose of 300 mg once daily may be further augmented from this dose to twice-daily dosing. No dosage adjustment is necessary in elderly patients, or in patients with hepatic impairment or renal to severe renal impairment.

the practice of using dose to achieved therapeutic effects. This is achieved by a stepwise dose titration to achieve hypertension or may be titrated to 300 mg once daily.

The incidence of hypertension was evaluated by the control group (n=641), excluding those too general to be informative and those not reasonably associated with the condition being investigated. The results of the two groups were similar with regard to the incidence of hypertension.

The following adverse events occurred at an incidence of 1% or greater in patients treated with irbesartan, versus 4.5% of patients given placebo. In placebo-controlled clinical trials, the incidence of hypertension was evaluated by the control group (n=641), excluding those too general to be informative and those not reasonably associated with the condition being investigated. The results of the two groups were similar with regard to the incidence of hypertension.

Doses of irbesartan up to 1000 mg/day were administered in the clinical trials. The maximum recommended dose (MRD) of 300 mg irbesartan/day, whereas 1000 mg/day (administered to females only) provided an average systemic exposure (C(max)) to irbesartan of 1.0-3.0 mg/dL, the percent of patients with hyperkalemia (<6.0 mEq/L) was 18.6% in the irbesartan group versus 6.0% in the placebo group. Discontinuations due to hyperkalemia in the irbesartan group were 2.1% versus 0.4% in the placebo group.

Nephropathy in Type 2 Diabetic Patients

A lower initial dose of irbesartan (75 mg) is recommended in patients with depletion of intravascular volume or salt (e.g., patients treated vigorously with diuretics or on hemodialysis). (see WARNINGS: Hypertension in Volume- and Salt-Derived Patients).

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