

Aldorin[®]

Epalrestat film coated tablet

DESCRIPTION

Aldorin[®] is a preparation of epalrestat, which specifically inhibits aldose reductase and accumulation of sorbitol in the nerve; thereby improves subjective symptoms and nerve dysfunction in patients with diabetic peripheral neuropathy.

INDICATIONS

Aldorin[®] is indicated for the improvement of subjective symptoms (numbness and pain), abnormality of vibration sense and abnormal change in heartbeat associated with diabetic peripheral neuropathy (when high glycohemoglobin value is noted).

DOSAGE AND ADMINISTRATION

The usual adult dose is 1 tablet (50 mg) three times daily before each meal. The dosage may be adjusted according to the patient's age and symptoms.

USE IN PREGNANCY & LACTATION

The safety of epalrestat in pregnant women has not been established. The drug may be used in pregnant women or in women who may possibly be pregnant only if expected therapeutic benefits outweigh the possible risks associated with the treatment. Breast-feeding should be avoided during administration of epalrestat.

CONTRAINDICATIONS

The drug is contraindicated for patients with known hypersensitivity to epalrestat.

ADVERSE REACTIONS

Major adverse reactions are hepatic function abnormalities and thrombocytopenia. In cases of hepatic abnormalities drug should be discontinued immediately and appropriate measures should be taken. Other reactions may be malaise, headache, abdominal pain, nausea, hypersensitivity reaction etc.

PRECAUTION

The administration of **Aldorin[®]** should be considered to patients showing high glycohemoglobin values even after fundamental therapies for diabetes mellitus such as diet therapy, exercise therapy and treatment with an oral hypoglycemic agent, insulin etc. The efficacy of this product has not been established in patients with diabetic peripheral neuropathy with irreversible organic changes. The patient should be carefully monitored during the administration of this product. When the efficacy of this product is not observed even after 12 weeks of administration, other appropriate therapies should be taken.

PHARMACEUTICAL PRECAUTIONS

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

PACKAGING

Aldorin[®] Tablet:

Box containing 3 strips of 10 tablets each. Each film coated tablet contains Epalrestat INN 50 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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