Benprost

(Beraprost Sodium) Tablets, JP

بین پروسٹ

(بیراپروسٹ سوڈیم) ٹیبلیٹس

۲۰ مائیکروگرام

COMPOSTION:
Each film coated tablet contains:
Beraprost Sodium JP ... 20mcg.
[JP Specs.]

DESCRIPTION:
Benprost (Beraprost Sodium) is a novel oral preparation of a prostacyclin (PGI_2) derivative, Beraprost Sodium is chemically stable and shows excellent antiplatelet and blood flow-increasing effects, when administered orally. **Benprost** (Beraprost Sodium) is a synthetic analogue of epoprostenol (prostacyclin) that causes vasodilation and prevents platelet aggregation. It is given by mouth as the sodium salt in the management of pulmonary hypertension and peripheral vascular disease.

MECHANISM OF ACTION:
Similar to prostacyclin, beraprost sodium shows actions, e.g., antiplatelet and vasodilating action, by increasing intracellular concentrations of cAMP, by inhibiting of Ca^{2+} influx, or other modes, via prostacyclin receptors on platelets and vascular smooth muscle.

PHARMACOKINETICS:
Plasma concentration:
Plasma concentration of the unchanged form after single oral administration of beraprost sodium 100mcg to healthy adults reached the peak at about 1.4 hours after administration showing a value of 0.44 ng/ml. The biological half-life was approximately 1.1 hours.
Maximum plasma concentrations were 0.3-0.5ng/ml after three time a day, 10 day consecutive oral administration of Beraprost Sodium 50mcg. Therefore, no accumulability due to repeated administration was noted.

Urinary Excretion:
Urinary excretion of the unchanged form by 24 hours after single oral administration of Beraprost Sodium 50 mcg to healthy adult volunteers was 2.8mcg, while that of the β-oxidation product was 5.4mcg. Both the unchanged form and the β-oxidation product were excreted as glucuronide conjugates as well. The percentages of the free form in the unchanged form and the β-oxidation product in the urinary excretion were 14% and 70% respectively.

INDICATIONS:
Benprost (Beraprost Sodium) is an oral formulation of prostacyclin, for the treatment of pulmonary hypertension (PH) and peripheral vascular disease.

CONTRAINDICATIONS:
This product is contraindicated in the following patients.
Patients with hemorrhage (e.g., hemophilia, capillary fragility, upper gastrointestinal hemorrhage, urinary tract hemorrhage, hemoptysis, vitreous hemorrhage).
Pregnant woman or woman might to be pregnant.

DOSAGE:
In primary pulmonary hypertension, Beraprost Sodium is given in an initial dose of 60mcg daily in three divided doses; this may be increased gradually if necessary to 180mcg daily in three or four divided doses. For peripheral vascular disease a dose upto 120mcg daily in three divided doses is used.

Rev: 03-23/3

SIDE EFFECTS:
Adverse effects of Beraprost Sodium include headache, flushing, nausea, diarrhoea, and increased liver enzyme, bilirubin, and triglyceride concentrations.

CLINICALLY SIGNIFICANT ADVERSE REACTIONS:
Bleeding tendency (cerebral hemorrhage, hemorrhage of digestive tract, bleeding in ocular fundus).

WARNING & PRECAUTIONS:
Careful Administration: Benprost (Beraprost Sodium) tablets should be administered with caution in the following patients.
Patients on medication with anticoagulants or antiplatelet agents (e.g., aspirin and ticlopidine). It has a risk of enhancing the activity of anticoagulants and antiplatelet agents and of promoting bleeding tendency.
Patients in menstruation. It has a risk of promoting bleeding tendency.
Patients with bleeding tendency or diathesis thereof. It has a risk of promoting bleeding tendency.

Hepatic function disorders:
Since hepatic function disorders accompanied by jaundice and markedly increased GOT and GPT may occur, the patient should be kept under observation. Medication should be discontinued and appropriate treatments should be conducted, if such symptoms are observed.

Use in the Elderly:
Since the elderly often have lowered physiological functions, this product should be administered with caution.

Use during Pregnancy or Lactation:
Since safety in pregnant women has not been established, this product should not be administered to pregnant women.
Since beraprost sodium has been reported to be transferred in milk in animal experiments (rats), administration of this product to nursing mothers should be avoided. If use of this product is unavoidable, the nursing mother should discontinue breast-feeding.

Pediatric use:
Safety in children has not been established.

INSTRUCTIONS:
Store below 30° C.
Protect from heat, light and moisture.
Keep out of the reach of children.

PRESENTATION:
Benprost (Beraprost Sodium) Tablets 20mcg are available in pack of 10's

ہدایات:
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.
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