Procaterol Hydrochloride Hemihydrate

Ventpro

5 mcg/mL Syrup

BRONCHODILATOR

FORMULATION
Each mL contains:
Procaterol (as Hydrochloride Hemihydrate) …….....5 mcg

PHARMACOLOGY
Procaterol hydrochloride is a direct-acting sympathomimetic with predominantly beta-adrenoreceptor stimulant activity selective to $beta_2$ receptors (a $beta_2$ agonist). It has properties similar to those of salbutamol and it is used as a bronchodilator in the management of reversible airways obstruction, as in asthma or in some patients with chronic obstructive pulmonary disease.
Characteristics:
1. Potent bronchodilating effect
   The bronchodilating action of procaterol hydrochloride is comparable to isoproterenol and more potent than that of salbutamol.
2. Long duration of action
   Procaterol hydrochloride has longer duration of action than isoproterenol and salbutamol.
3. High selectivity for $beta_2$-adrenergic receptors
   Procaterol hydrochloride has no adverse reactions to cardiovascular system. Compared to Isoproterenol and Salbutamol, this drug has higher affinity for the $beta_2$ - adrenergic receptor on cardiovascular system and trachea.
4. Anti-allergic action
   Procaterol hydrochloride has a strong ability of inhibition on the release of histamine which induces asthma.
5. Secretion effect on trachea
   This drug can promote tracheal cilia hyperplasia that will induce a significant impact on tracheal secretions.

INDICATIONS
Relief of dyspnea and other symptoms caused by respiratory obstructive disturbance in the following diseases: bronchial asthma, chronic bronchitis, and pulmonary emphysema.

DOSAGE AND ADMINISTRATION
The usual adult dosage is 10 mL of Procaterol syrup (50 mcg of procaterol hydrochloride) once before bed or twice (in the morning and before bed) a day by the oral route. The dosage in children 6 years of age or older is 5 mL of Procaterol syrup (25 mcg of procaterol hydrochloride) once before bed or twice (in the morning and before bed) a day by the oral route. The dosage in children less than 6 years of age is 0.25 mL of Procaterol syrup (1.25 mcg of procaterol hydrochloride) per kg body weight once before bed or twice (in the morning or before bed) or three times (in the morning, in the early afternoon, and before bed) a day by the oral route.

The dosage may be adjusted according to the patient's age and severity of symptoms.
Standard volume of a single dose of procaterol hydrochloride for children younger than 6 years old:
Less than 1 year old: 2-3 mL (Procaterol HCl 10-15 mcg)
1-3 years old: 3-4 mL (Procaterol HCl 15-20 mcg)
3-6 years old: 4-5 mL (Procaterol HCl 20-25 mcg)
Or as prescribed by the physician.

CONTRAINDICATIONS
Contraindicated in patients who are hypersensitive to any component of this product.

PRECAUTIONS

1. This drug should be carefully administered in patients with hyperthyroidism, hypertension, heart disease, diabetes mellitus, during pregnancy or suspected pregnancy.
2. Palpitation and tachycardia, facial flushing, tinnitus, headache, gastric discomfort, dry mouth, generalized fatigue and skin rash etc. symptoms will occur occasionally.
3. The combined use of this drug with Epinephrine, Isoproterenol or Catecholamine may cause arrhythmias. Co-administration should be avoided.
4. This drug tends to inhibit skin reactions in allergen tests. The drug should be withdrawn 12 hours prior to such tests.
5. If the desired therapeutic effect of procaterol syrup has not been achieved at the recommended dose, the drug should be discontinued
6. Continuous administration of excessive amounts of this drug may cause cardiac arrhythmia and cardiac arrest. Special care should therefore be taken not to exceed the recommended dose of this drug.

ADVERSE REACTIONS
Shock, anaphylactoid reaction may occur. Patient should therefore be closely monitored. If abnormal findings are observed, the drug should be discontinued and appropriate measures taken.
Significant decreases in serum potassium levels have been reported in patients receiving procaterol hydrochloride. If xanthine derivatives, corticosteroids, or diuretics are co-administered with this drug in patients with severe asthma, extreme care is necessary to minimize the possibility of aggravating the decrease in serum potassium levels induced by ß2-adrenergic agonists. Serum potassium levels should be closely monitored in hypoxic patients, in view of the possible aggravation of cardiac arrhythmias secondary to a decrease in serum potassium levels.

USE DURING PREGNANCY OR LACTATION
The drug should be administered to pregnant or possibly pregnant women only if the expected therapeutic benefit is thought to outweigh any possible risk. (The safety of this drug during pregnancy has not been established). Nursing should be interrupted before starting treatment with the drug. (Rat studies showed that procaterol hydrochloride is excreted in breast milk).

STORE AT TEMPERATURES NOT EXCEEDING 25ºC.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY
Pink HDPE Bottle with white plastic cap x 30 mL (Box of 1's)

Manufactured by :
CENTER LABORATORIES INC.
No.2, Shijian Rd., Hukou Township,
Hsinchu County 303, Taiwan (R.O.C.)

Imported by :
OEP PHILIPPINES, INC.
Rm 606 6/F SEDCCO I Bldg., cor. Rada & Legaspi Sts.,
Legaspi Village, Makati City

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