PRESCRIBING INFORMATION

[Pr] Isoproterenol Hydrochloride Injection USP

0.2 mg / mL (1 mL and 5 mL)

Sterile solution

Single dose container

Sympathomimetic

Marcan Pharmaceuticals Inc.
2 Gurdwara Road, Suite #112,
Ottawa, ON, K2E 1A2

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Control # 258691

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0.2 mg / mL

THERAPEUTIC CLASSIFICATION

Sympathomimetic

INDICATIONS

Symptomatic relief of bronchial asthma and in cases of emphysema, bronchitis and other chronic bronchopulmonary disorders in which bronchospasm is a complicating factor.

Injectable form is particularly suitable for the treatment and prevention of (1) Adams-Stokes syndrome and other episodes of heart-block, except when caused by ventricular tachycardia of fibrillation (2) cardiac arrest (3) carotid sinus hypersensitivity (4) ventricular tachycardia and fibrillation (5) laryngobronchospasm during anesthesia (6) as adjunctive therapy in shock.

CONTRAINDICATIONS

Patients with tachyarrhythmias; tachycardia of heart-block caused by digitalis intoxication; ventricular arrhythmias which require inotropic therapy and angina pectoris. Do not administer concomitantly with epinephrine. May be used alternately with epinephrine if indicated, provided a 4-hour interval elapses.

PRECAUTIONS

Use with caution in patients sensitive to sympathomimetic amines and in the presence of hypertension, cardiovascular disorders (including coronary artery disease and coronary insufficiency), diabetes, hyperthyroidism, in patients with a potential for cardiac arrhythmias and in those patients receiving MAO inhibitors. Potent inhalational anesthetics such as halothane may sensitize the myocardium to effects of sympathomimetic amines.

Rarely, patients have been reported to develop severe paradoxical airway resistance with repeated, excessive use of aerosol preparations containing sympathomimetic amines. The cause of this refractory state is unknown. It is advisable that in such instances the use of the aerosol be discontinued immediately and alternative therapy instituted, since in the reported cases the patients did not respond to other forms of therapy until the aerosol was withdrawn. Deaths have been reported following excessive use of aerosol preparations containing sympathomimetic amines, the exact cause of which is unknown. Cardiac arrest was noted in several instances.

Close supervision and careful adjustment of dosages are required when isoproterenol is given with tricyclic antidepressants, since the effect of the two drugs may be cumulative.

In neutral or alkaline solution, isoproterenol may become red on exposure to air. Accordingly, the saliva or sputum may appear pink or red in colour after oral inhalation of the drug. This is not harmful but should be explained to patients to allay possible apprehension or confusion with bleeding.

Isoproterenol injection, by increasing myocardial oxygen requirements while decreasing effective coronary perfusion, may have a deleterious effect on the injured or failing heart. Most experts discourage its use as the initial agent in treating cardiogenic shock following myocardial infarction. However, when a low arterial pressure has been elevated by other means, isoproterenol injection may produce beneficial hemodynamic and metabolic effects.

In a few patients, presumably with organic disease of the AV node and its branches, isoproterenol injection has paradoxically been reported to worsen heart block or to precipitate Adams-Stokes attacks during normal sinus rhythm or transient heart block.

Isoproterenol injection should generally be started at the lowest recommended dose. This may be gradually increased, if necessary, while carefully monitoring the patient. Doses sufficient to increase the heart rate to more than 130 beats/minute may increase the likelihood of inducing ventricular arrhythmias. Such increases in heart rate will also tend to increase cardiac work and oxygen requirements which may adversely affect the falling heart or the heart with a significant degree of arteriosclerosis.

Adequate filling of the intravascular compartment by suitable volume expanders is of primary importance in most cases of shock, and should precede the administration of vasoactive drugs. In patients with normal cardiac function determination of central venous pressure is a reliable guide during volume replacement. If evidence of hypoperfusion persists after adequate volume replacement, isoproterenol injection may be given.

In addition to the routine monitoring of systemic blood pressure, heart rate, urine flow, and the ECG, the response to therapy should also be monitored by frequent determination of the central venous pressure and blood gases. Patients in shock should be closely observed during isoproterenol hydrochloride injection administration. Determination of cardiac output and circulation time may also be helpful. Appropriate measures should be taken to ensure adequate ventilation. Careful attention should be paid to acid-base balance and to the correction of electrolyte disturbances. In cases of shock associated with bacteremia, suitable antimicrobial therapy is, of course, imperative.

ADVERSE EFFECTS

The following reactions to isoproterenol injection have been reported:
CNS: Nervousness, headache, dizziness.

Cardiovascular: Tachycardia, palpitations, angina, Adams-Stokes attacks, pulmonary edema, hypertension, hypotension, ventricular arrhythmias, tachyarrhythmias.

In a few patients, presumably with organic disease of the AV node and its branches, isoproterenol hydrochloride injection has been reported to precipitate Adams-Stokes seizures during normal sinus rhythm or transient heart block.

Other: Flushing of the skin, sweating, mild tremors, weakness, swelling of the parotids with prolonged use, nausea and vomiting.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

OVERDOSAGE: SYMPTOMS AND TREATMENT

In case of accidental overdosage as evidenced mainly by tachycardia or other arrhythmias, palpitations, angina, hypotension, or hypertension, reduce rate of administration or discontinue Isoproterenol Hydrochloride Injection until patient's condition stabilizes. Blood pressure, pulse, respiration, and ECG should be monitored.

It is not known whether isoproterenol is dialysable.

If you think you, or a person you are caring for, have taken too much Isoproterenol Hydrochloride Injection USP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

DOSAGE

Parenteral

Cardiac Disorders: SC or IM injection of 200 mcg (1 mL of 1:5000 solution, IV injection of 20 mcg (0.1 mL of 1:5000 solution). IV infusion of solution containing 1 mg in 200 mL of 5% glucose at a rate of 1 mL (5 mcg) per minute. Intracardiac injection of 20 mcg (0.1 mL of 1:5000 solution).

Laryngobronchospasm: IV injection from 10 to 20 mcg (0.5 to 1 mL of 1:50000 solution). To prepare 1:50000 solution dilute 1 mL of 1:5000 solution to 10 mL with 5% dextrose in water.

Adjunctive Therapy in Shock: IV Infusion of 1 mg in 500 mL of 5% dextrose in water administered (after initial 5 mL dose of solution) at a rate of 0.5 mcg to 5 mcg/minute.

Infusion rate (up to 30 mcg/minute in advanced shock) should be adjusted on the basis of heart rate, central venous pressure, systemic blood pressure and urine flow. If the heart rate exceeds 110 beats/minute, it may be advisable to decrease the infusion rate or temporarily discontinue the infusion.

SUPPLIED

Isoproterenol Hydrochloride Injection USP (0.2 mg/mL) is sterile aqueous solution.

Each mL of Isoproterenol Hydrochloride Injection USP (0.2 mg/mL) contains Isoproterenol hydrochloride 0.2 mg, edetate disodium 0.2 mg, sodium chloride 7 mg, sodium citrate dihydrate

2.07 mg, citric acid anhydrous 2.5 mg, hydrochloric acid/ sodium hydroxide to adjust pH and water for injection.

Isoproterenol Hydrochloride Injection USP (0.2 mg/mL) is available in single use 1 mL and 5 mL vial, boxes of 10.

1 mL Isoproterenol Hydrochloride Injection USP available in 2 mL clear glass vial stoppered with 13 mm dark grey rubber stopper & sealed with 13 mm Green MT flip off seal.

The 5 mL Isoproterenol Hydrochloride Injection USP available in 5 mL clear glass vial stoppered with 13 mm dark grey rubber stopper & sealed with 13 mm Green MT flip off seal.

The stopper is not made with natural rubber latex.

Store between 15 and 30°C. Protect from light. Discard unused portion. Keep out of reach and sight of children.

The injection is not to be used if the colour is pinkish or darker than slightly yellow or if it contains a precipitate.

MORE INFORMATION

If you want more information about Isoproterenol Hydrochloride Injection USP:

- Talk to your healthcare professional
- Find the full Prescribing Information that is prepared for healthcare professionals by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), the manufacturer's website www.marcanpharma.com, or by calling: 1-855-627-2261.

This leaflet was prepared by:

Marcan Pharmaceuticals Inc.
2 Gurdwara Road, Suite #112
Ottawa, ON K2E 1A2

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