Isosuprine Hydrochloride Tablets, USP
Rx Only

DESCRIPTION:
Each tabllet really contains Isosuprine Hydrochloride, USP with the following chemical structure:

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\text{C}_{24}\text{H}_{29}\text{NO}_2 \cdot \text{HCl}
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Quantitative Ingredient Information: Each tablet really contains 10 or 20 mg Isosuprine HCl.

Pharmacological Class: Peripheral VasoDilator

INDICATIONS:
Based on the review of this drug by the National Academy of Sciences-National Research Council, the FDA has classified the indications as follows:

Precisely Effective:
1. For the relief of symptoms associated with hemodynamic instability.
2. In peripheral vascular disease of arteriosclerotic obliterans, thromboangiitis obliterans (Buerger's disease) and Raynaud’s disease.

Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS:
There are no known contraindications to use when administered in recommended doses. Isosuprine Hydrochloride, USP should be given immediately postpartum or in the presence of arterial bleeding.

PRECAUTIONS:
Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS:
On rare occasions, administration of the drug has been associated with the occurrence of hypotension, tachycardia, chest pains, nausea, vomiting, dizziness, abdominal distress, and severe rash. If rash appears, the drug should be discontinued.

Although available evidence suggests a temporal association of these reactions with Isosuprine Hydrochloride, a causal relationship can be neither confirmed nor ruled out.

Beta Adrenergic receptor stimulants such as Isosuprine Hydrochloride have been used to inhibit pre-term labor.

Maternal and fetal tachycardia may occur under such use. Hypokalemia, hypoglycemia, hypoventilation, and bradycardia have been reported to occur in infants whose mothers received Isosuprine Hydrochloride. Pulmonary edema has been reported in mothers treated with beta stimulants. Isosuprine Hydrochloride is neither approved nor recommended for use in the treatment of premature labor.

DOSEAGE AND ADMINISTRATION:
Oral: 10 to 20 mg, three or four times daily.

HOW SUPPLIED:
Isosuprine HCl Tablets, USP 10 mg are white, round, bioequivalent tablet identified as "B10" debossed on one side and blunted on the other.

Bottle of 500 NDC 51290-450-05
Bottle of 1000 NDC 51290-450-10

Isosuprine HCl Tablets, USP 20 mg are white, round, bioequivalent tablet identified as "B20" debossed on one side and blunted on the other.

Bottle of 500 NDC 51290-455-05
Bottle of 1000 NDC 51290-455-10

COMPOSITION:
Isosuprine HCl Tablets, 10 mg and 20 mg. These tablets contain the following inactive ingredients: Cellulose (Vegetable), Magnesium Stearate (Vegetable).

Manufactured By:
ECI Pharmaceuticals, LLC
Fort Lauderdale, FL 33309

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