For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

HERDILAN SR

(Isoxsuprine Hydrochloride) Tablet

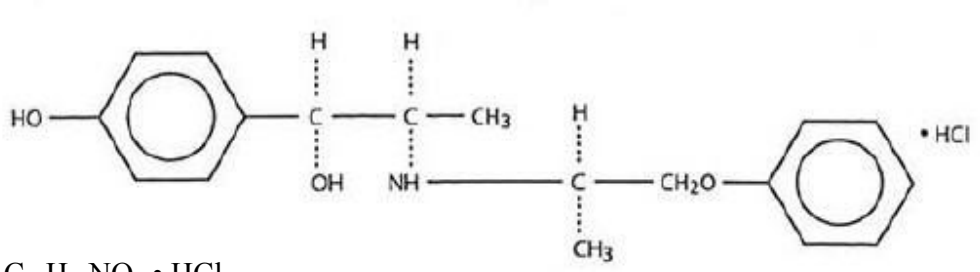
COMPOSITION

Each uncoated sustained release tablet contains:

Isoxsuprine Hydrochloride I.P…….. 40mg

DESCRIPTION

Each tablet contains Isoxsuprine Hydrochloride, USP with the following chemical structure:



$C_{18}H_{23}NO_3$ • HCl

p-Hydroxy-α[1-[(methyl-2-phenoxy-ethyl)amino]ethyl]benzyl alcohol hydrochloride.

CLINICAL PHARMACOLOGY

Mechanism of Action: Peripheral vasodilator

Pharmacodynamic: Isoxsuprine is a vasodilator that also stimulates beta-adrenergic receptors. It causes direct relaxation of vascular and uterine smooth muscle and its vasodilating action is greater on the arteries supplying skeletal muscles than on those supplying skin. Isoxsuprine also produces positive inotropic and chronotropic effects.

Pharmacokinetic

Isoxsuprine hydrochloride is well absorbed from the gastrointestinal tract. The peak plasma concentration occurs about 1 hour after an oral dose. A plasma half-life of about 1.5 hours has been reported. Isoxsuprine is excreted in the urine mainly as conjugates.

INDICATIONS

Isoxsuprine hydrochloride has been used to arrest premature labour, but drugs with a more selective action are now preferred. It has also been given in the treatment of cerebral and peripheral vascular disease.

1. For the relief of symptoms associated with cerebrovascular insufficiency.
2. In peripheral vascular disease of arteriosclerosis obliterans, thromboangitis obliterans (Buerger's disease) and Raynaud's disease.

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

CONTRAINDICATION

Isoxsuprine Hydrochloride, USP should not be given immediately postpartum or in the presence of arterial bleeding.

Isoxsuprine is contra-indicated after recent arterial haemorrhage. It should not be given immediately post partum, nor should it be used for premature labour if there is infection.

WARNINGS AND PRECAUTIONS

In women being treated for premature labour, the risk of pulmonary oedema means that extreme caution is required. beta agonists should be given with caution in hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT-interval prolongation,hypertension, and diabetes mellitus (especiallyon intravenous use—blood glucose should be monitored since ketoacidosis has been reported). Sympathomimetics should be used with caution in patients with cardiovascular disorders, who may have an increased susceptibility to their effects. Particular care is needed in patients with cardiac arrhythmias, ischaemic heart disease, or hypertension.

ADVERSE EFECTS

On rare occasion oral administration of the drug has been associated in time with the occurrence of hypotension, tachycardia, chest pain, 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 Isoxsuprine Hydrochloride, a causal relationship can be neither confirmed nor refuted.

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

Maternal and fetal tachycardia may occur under such use.

Hypocalcemia, hypoglycemia, hypotension and ileus have been reported to occur in infants whose mothers received Isoxsuprine Hydrochloride. Pulmonary edema has been reported in mothers treated with beta stimulants. Isoxsuprine Hydrochloride is neither approved nor recommended for use in the treatment of premature labor.

Isoxsuprine may cause transient flushing, hypotension, tachycardia, rashes, and gastrointestinal disturbances. Maternal pulmonary oedema and fetal tachycardia have been reported after intravenous use in premature labour.

DOSAGES AND ADMINISTRATION

Tablets to be swallosed whole, not to be crushed or chewed.

For use as a vasodilator, isoxsuprine hydrochloride is given by mouth in doses 40mg once or twice daily

USE IN SPECIAL POPULATION

Pregnancy

Ileus was found to be more common in the offspring of mothers who received isoxsuprine than in matched controls. The incidence of respiratory distress syndrome also rose as the isoxsuprine concentration in cord blood exceeded 10 nanograms/mL; likewise the incidence of hypocalcaemia and hypotension rose progressively with increasing concentrations. The cord concentrations correlated inversely with the drug-free interval before delivery and it was suggested that with frequent assessment of uterine response it should be possible to avoid delivering infants at a time when they have high plasma-isoxsuprine concentrations.

In another study of the association between ruptured membranes, beta-adrenergic therapy, and respiratory distress syndrome, it was found that both therapy with isoxsuprine and premature rupture of membranes were individually associated with a lowered incidence of respiratory distress syndrome, but when present together they resulted in an increased risk of respiratory distress syndrome. It was suggested that

therapy with beta-adrenergic drugs including isoxsuprine should be restricted to patients with intact membranes.

Pediatric Use

Safety and effectiveness in pediatric patients has not been established.

Expiry date.

Do not use later than the date of expiry

Storage.

Store below 25°C in a dry place. Protect from light.

Presentation.

HERDILAN-SR is available as Blister (alu alu) pack of 10 tablets

MARKETED BY:

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