

POR-8 FERRING

Ornipressin 5 IU/1ml injection

Presentation

Each ampoule of POR-8 FERRING contains 1 ml of 5 IU ornipressin (8-ornithine-vasopressin). The sterile solution is clear and pH is adjusted 3.7. The ampoule identification rings are blue on turquoise.

Uses

Actions

POR-8 FERRING is a synthetic polypeptide with a potent and specific constrictor effect on microcirculation and veins which is equal to, if not greater than, that of vasopressin; it also has antidiuretic activity, but this is weak by comparison with vasopressin. Topical application or infiltration leads within 10 minutes to local ischaemia which usually lasts for 1 to 2 hours without causing reactive hyperaemia.

POR-8 FERRING may be used with general anaesthetics which are usually not compatible with adrenaline; e.g. halothane, without fear of precipitating cardiac arrhythmias.

Pharmacokinetics

No data on pharmacokinetics available.

Indications

Local Administration

To induce ischaemia and haemostasis at the site of an operation.

ENT

Tonsillectomy, nasal septotomy, operations of the middle and inner ear.

Obstetrics/Gynaecology

Vaginal surgery, myomectomy, episiotomy, cone biopsy of cervix.

General Surgery

Surgery of the skin and extremities, plastic and cosmetic surgery, care of burns (excision of eschar).

Urology

Transurethral operations, prevent bleeding during and after prostatectomy, haemorrhagic cystitis.

Dosage and Administration

POR-8 FERRING should be diluted before use. Usually 5 IU (1 ampoule) is diluted in 30 mL of physiological saline. No data are available on the compatibility or stability of POR-8 FERRING when mixed with local anaesthetic solution. The diluted solution is administered by regional infiltration at the operation site.

The maximum permitted total dose for tissue infiltration is 5 IU, due to the possibility of systemic absorption.

For gynaecological surgery and laparotomies, more dilute solutions, e.g. 5 IU in 50 or 60 mL physiological saline are used.

For ENT surgery, somewhat more concentrated solutions, 5 IU in 20 ml physiological saline may be required.

Extemporaneous dilutions of POR-8 FERRING should be used on the day on which they are prepared.

Contraindications

- Coronary heart disease
- Severe hypertension
- Toxaemia of pregnancy
- Advanced arteriosclerosis
- Epilepsy

As an adjunct to local anaesthetics intended to be used in regions of terminal arteries e.g. fingers, and for spinal anaesthesia; hypersensitivity to the medicine.

POR-8 FERRING is contraindicated in pregnancy as animal tests have shown that it is teratogenic in high doses as is the case with vasopressin and the catecholamine vasoconstrictors. These effects appear to be mediated through a vasoconstrictor mechanism.

Warnings and Precautions

Warnings

In isolated cases, severe cardiovascular incidents associated with unmeasurable peripheral blood pressure have been reported. Since in such conditions peripheral resistance may be increased by POR-8 FERRING, caution is required when using additional vasoconstrictor agents.

Precautions

As is the case with adrenaline, some absorption may occur from local application leading to systemic vasoconstriction. A rise in blood pressure may occur in some patients. Caution is therefore indicated in conditions in which a rise in blood pressure would be medically undesirable. Anginal symptoms may be precipitated in patients with ischaemic heart disease.

Adverse Effects

POR-8 FERRING is generally well tolerated. Some patients may display facial or general pallor, but this is due to capillary constriction which in itself is harmless. Less common adverse reactions include a rise (or occasionally fall) in blood pressure, cardiac arrhythmias, anginal pain, increased perspiration and increased bowel motility. Absorption from local application may lead to alterations in heart rate, and isolated reports have been received of fibrillation and cardiac arrest in conjunction with other medication. See also **Warnings**. Generalised cyanosis, circulatory collapse and proptosis have been observed but their relationship to POR-8 FERRING is uncertain. Allergic skin reactions are rare.

Interactions

No data available.

Overdosage

The indications suggest that overdosage is highly improbable. However, toxic doses may cause gastrointestinal disturbances, increased bowel motility, hypertension, circulatory collapse, convulsions in predisposed patients, and sweating. Treatment is symptomatic. Circulation, electrolytes and fluids should be closely monitored.

Pharmaceutical Precautions

Store in a refrigerator between 2-8°C. Do not freeze. Shelf-life is 5 years.

Medicine Classification

Prescription Medicine.

Package Quantities

Each pack contains 5 ampoules of 1 ml.

Further Information

POR-8 (8-ornithine-vasopressin) is a synthetic polypeptide with a molecular weight of 1042.2.

Name and Address

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