

PRODUCT INFORMATION

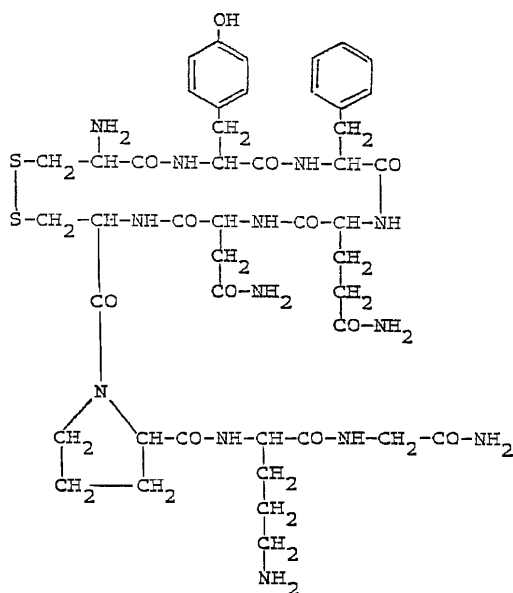
POR-8 FERRING[®]

Ornipressin

Description

POR-8 FERRING[®] is ornipressin (8-ornithine-vasopressin), a synthetic polypeptide with a molecular weight of 1042.2. It is closely related to synthetic vasopressin, and differs from that substance only by the substitution of ornithine for lysine in the side chain. It is available in sealed 1mL ampoules each containing 5 IU. The sterile solution is clear and pH is adjusted to 3.7.

POR-8 FERRING contains sodium acetate, sodium chloride, acetic acid and water for injections as excipients.



Cys-Try-Phe-Gln-Asn-Cys-Pro-Orn-Gly-NH₂

C₄₅H₆₃N₁₃O₁₂S₂

CAS No. 3397-23-7

Pharmacology

POR-8 FERRING[®] has a potent and specific constrictor effect on the microcirculation and veins which is equal to, if not greater than, that of vasopressin. It has antidiuretic activity but this is weak by comparison with vasopressin.

Topical administration or infiltration leads within 10 minutes to local ischaemia which usually lasts for 1 to 2 hours, and is not followed by reactive hyperaemia.

POR-8 FERRING[®] may be used with general anaesthetics which are usually not compatible with adrenaline, eg halothane, without fear of precipitating cardiac arrhythmias.

Indications

Local administration: to induce ischaemia and haemostasis at the site of an operation in various types of surgery where bleeding is a problem.

Plastic Surgery: Hair transplants, meloplasty, otoplasty, skin grafts, resection of tumours etc.

Obstetrics/Gynaecology: Vaginal repair, vaginal hysterectomy, cone biopsy of cervix, episiotomy, myomectomy.

ENT Surgery: Tonsillectomy, submucous resection of septum, myringoplasty etc.

Other types of surgery: Neurosurgery, orofacial surgery, surgery of head and neck, abdominal and rectal surgery, care of burns (excision of eschar).

Contraindications

Coronary heart disease, severe hypertension, toxemia 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 drug.

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

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 Reactions

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 WARNING. Generalised cyanosis,

circulatory collapse and proptosis have been observed but their relationship to POR-8 FERRING[®] is uncertain. Allergic skin reactions are rare.

Dose and Administration

POR-8 FERRING[®] should be diluted before use. Usually 5 I.U. (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 I.U., due to the possibility of systemic absorption.

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

For ENT surgery, somewhat more concentrated solutions, 5 I.U. 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.

Poisoning and 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.

Presentation and Packaging

Ampoules of 1 mL containing ornipressin – 5 I.U. per ampoule, 5.

Storage: POR-8 FERRING[®] should be stored in a refrigerator between 2° and 8°C. Do not freeze.

Schedule 4

TGA Approved 7 October 2003

Ferring Pharmaceuticals Pty Ltd
Suite 2B, Level 2, 802 Pacific Highway, Gordon, NSW 2072