Omsis®

30mg Injection

(Pentazocine)

COMPOSITION:
Each ml contains:
Pentazocine BP 30mg

CLINICAL PHARMACOLOGY:
Analgesia usually occurs within 15 to 20 minutes after intramuscular or subcutaneous injection and within 2 to 3 minutes after intravenous injection. Pentazocine weakly antagonizes the analgesic effects of morphine, meperidine, and phenazocine; in addition, it produces incomplete reversal of cardiovascular, respiratory, and behavioral depression induced by morphine and meperidine. It also has sedative activity. Elderly patients exhibited a longer mean elimination half-life, a lower mean total plasma clearance, and a larger mean area under the concentration-time curve than younger patients

INDICATIONS AND USAGE:
Relief of moderate-to-severe pain; has also been used as a sedative prior to surgery and as a supplement to surgical anesthesia

CONTRAINDICATIONS:
Pentazocine should not be administered to patients who are hypersensitive to it

WARNINGS / PRECAUTIONS:
Concerns related to adverse effects
CNS depression: May cause CNS depression, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (e.g. Operating machinery or driving)
Injection-site reactions: Severe sclerosis has occurred at the injection-site following multiple injections; avoid subcutaneous use unless absolutely necessary; rotate sites of injection
Hypotension: May cause hypotension; use with caution in patients with hypovolemia, cardiovascular disease (Including acute MI), or drugs which may exaggerate hypotensive effects (Including phenothiazines or general anesthetics)

Disease-related concerns
Abdominal conditions: May obscure diagnosis or clinical course of patients with acute abdominal conditions
Adrenal insufficiency: Use with caution in patients with adrenal insufficiency, including Addison's disease
Biliary tract impairment: Use with caution in patients with biliary tract dysfunction; acute pancreatitis may cause constriction of sphincter of Oddi
CNS depression / coma: Use with caution in patients with CNS depression or coma
Drug abuse: Use with caution in patients with a history of drug abuse or acute alcoholism; potential for drug dependency exists. Tolerance, psychological and physical dependence may occur with prolonged use
Ethanol use: Use with caution due to the potential for increased risk of CNS depressant effects
Head trauma: Use with extreme caution in patients with head injury, intracranial lesions, or elevated intracranial pressure; exaggerated elevation of ICP may occur
Hepatic impairment: Use with caution in patients with hepatic dysfunction
Prostatic hyperplasia / urinary stricture: Use with caution in patients with prostatic hyperplasia and / or urinary stricture
Renal impairment: Use with caution in patients with renal dysfunction
Respiratory disease: Use with caution in patients with pre-existing respiratory compromise (Hypoxia and / or hypercapnia), COPD or other obstructive pulmonary disease. Critical respiratory depression may occur, even at therapeutic dosages
Seizures: Use with caution in patients with a history of seizure disorders
Thyroid dysfunction: Use with caution in patients with thyroid dysfunction

Concurrent drug therapy issues
Sedatives: Effects may be potentiated when used with other sedative drugs or ethanol

Special populations
Debilitated patients: Use with caution in debilitated patients; there is a greater potential for critical respiratory depression, even at therapeutic dosages
Elderly: Use with caution in the elderly; may be more sensitive to adverse effects. Decrease initial dose
Paediatrics: Safety and efficacy have not been established in children <1 year of age

Other warnings / precautions
Withdrawal: Concurrent use of agonist / antagonist analgesics may precipitate withdrawal symptoms and / or reduced analgesic efficacy in patients following prolonged therapy with Mu-opioid agonists. Abrupt discontinuation following prolonged use may also lead to withdrawal symptoms; tapering the dose for decrease risk of withdrawal symptoms

ADVERSE REACTIONS:
Cardiovascular: Circulatory depression, facial edema, flushing, hypotension, shock, syncope, tachycardia
Central nervous system: Chills, CNS depression, confusion, disorientation, dizziness, drowsiness, euphoria, excitement, hallucinations, headache, insomnia, irritability, lightheadedness, malaise, nightmares, sedation
Dermatologic: Dermatitis, erythema multiforme, pruritus, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria
Gastrointestinal: Abdominal distress, anorexia, constipation, diarrhoea, nausea, vomiting, xerostomia
Genitourinary: Urinary retention
Hematologic: Decreased WBCs, eosinophilia
Local: Tissue damage and irritation with I.M./S.C. use
Neuromuscular & skeletal: Paresthesia, tremor, weakness
Ocular: Blurred vision, miosis

180 mm

150mm

Otic: Tinnitus
Respiratory: Dyspnea, respiratory depression (Rare)

Miscellaneous: Anaphylaxis, diaphoresis, physical and psychological dependence
Concurrent drug therapy issues: Sedatives: Effects may be potentiated when used with other sedative drugs or ethanol

DOSAGE AND ADMINISTRATION:
Adults
The recommended single dose is 30mg by I.M., I.V. or S.C. route and may be repeated every 3 to 4 hours. It should not exceed 360mg in a day
Elderly patients
Started on low doses of pentazocine and observed closely. The S.C. route of administration should be used only when clearly needed. The drug should be administered intramuscularly when frequent injections are needed
Patients in labor: 30mg I.M. is recommended as single dose. 20mg I.V. can give adequate pain relief to some patients in labor when contractions become regular, and this dose may be given two or three times at two to three-hour intervals, as needed
Paediatric patients (Above one year old): The recommended single parenteral dose as premedication for sedation is 0.5 mg/kg I.M.

CAUTION: Pentazocine should not be mixed in the same syringe with soluble barbiturates because precipitation will occur

OR
As directed by the physician

OVERDOSAGE:
Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated. Assisted or controlled ventilation should also be considered. For respiratory depression due to over-dosage or unusual sensitivity to pentazocine, parenteral naloxone is a specific and effective antagonist

PRESENTATION:
Omsis® 30mg injection in pack of 5's

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Caution: Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particle(s)

اومسس ۳۰ ملی گرام انجکشن
(پینٹازوسن)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ہدایات: بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی
تنبیہ: انجکشن کے ایک ہونے، دُھندلا ہونے یا اس میں کوئی غیر حل پزیر شے نظر
آنے کی صورت میں ہرگز استعمال نہ کریں

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
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180 mm
150mm