1.3.1 Summary of Product Characteristics (SmPC):

Summary of Product Characteristics (SmPC) of Pentazocine Injection BP 30mg/ml has been enclosed in the following points:

BELCO PHARMA
515, Modern Industrial Estate, Bahadurgarh - 124507
Haryana (INDIA)

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medical product:
Pentazocine Injection BP 30mg/ml (Pilat)

2. Qualitative and Quantitative composition:

Composition:

Each mL Contains:

Pentazocine BP 30mg

(Present as Lactate)

Water for Injections BP q.s.

3. Dosage form: Injectable Solution.

4. Clinical particulars:

4.1 Therapeutic indication:

Pentazocine injection is used to relieve moderate to severe pain. It may also be used before surgery or with a general anesthetic (medicine that puts you to sleep). Pentazocine belongs to the group of medicines called narcotic analgesics (pain medicines). It acts on the central nervous system (CNS) to relieve pain. When a narcotic medicine is used for a long time, it may become habit-forming, causing mental or physical dependence. However, people who have continuing pain should not let the fear of dependence keep them from using narcotics to relieve their pain. Mental dependence (addiction) is not likely to occur when narcotics are used for this purpose. Physical dependence may lead to withdrawal side effects if treatment is stopped suddenly. However, severe withdrawal side effects can usually be prevented by gradually reducing the dose over a period of time before treatment is stopped completely.

4.2 Posology and method of administration:

Posology

The recommended single parenteral dose is 30 mg by intramuscular, subcutaneous, or intravenous route. This may be repeated every 3 to 4 hours. Doses in excess of 30 mg intravenously or 60 mg intramuscularly or subcutaneously are not recommended. Total daily dosage should not exceed 360 mg. Elderly patients may be more sensitive to the analgesic effects

of than younger patients. Elderly patients generally should be started on low doses of and observed closely. The subcutaneous route of administration should be used only when necessary because of possible severe tissue damage at injection sites. When frequent injections are needed, the drug should be administered intramuscularly. In addition, constant rotation of injection sites (e.g., the upper outer quadrants of the buttocks, mid-lateral aspects of the thighs, and the deltoid areas) is essential.

Method of administration:

Intramuscular Route:

The intramuscular route is frequently used for drugs dissolved in oily vehicles or for those in a microcrystalline formulation that are poorly soluble in water (e.g., procaine or penicillin G). Advantages include rapid absorption in many cases, often in under 30 min. Other advantages of the intramuscular route include the opportunity to inject a relatively large amount of solution and a reduction in pain and local irritation compared with subcutaneous injections. Potential complications include infections and nerve damage. The latter usually results from the choice of an incorrect site for injection.

Intravenous Route:

Medications must be given by an intravenous (IV) injection or infusion. This means they're sent directly into your vein using a needle or tube. In fact, the term "intravenous" means "into the vein."

With IV administration, a thin plastic tube called an IV catheter is inserted into your vein. The catheter allows your healthcare professional to give you multiple safe doses of medication without needing to poke you with a needle each time.

In most cases, you won't give yourself an intravenous medication. While you can take some infusion medications yourself at home, you'll likely receive your therapy from a healthcare professional.

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Route of Administration:

For I/M or I/V Use

Contraindications:

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, doctor may want to change the dose, or other precautions may be necessary. When you are receiving this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, doctor may change the dose or how often you use one or both of the medicines. Acepromazine, Acepromazine, Alfentanil, Alprazolam, Amifampridine.

Interaction with other medicinal products and other forms of interaction:

List of the products are as follows:

Amineptine	Aprepitant
Amiodarone	Armodafinil
Amitriptylinoxide	Buspirone
Amobarbital	Bupropione
Amoxapaine	Butabarbital
Amphetamine	Calcium Oxybate
Amprenavir	Cetirizine
Armodafinil	Chloral Hydrate

Fertility, pregnancy and lactation:

Animal studies during the early gestational period have shown neural tube defects at 4.4 times the maximum daily dose. Prolonged use of opioids during pregnancy for either medical or nonmedical use may cause physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth. Opioids cross the placenta and may produce respiratory depression in neonates (naloxone should be available for reversal of opioid-induced respiratory depression). There are no controlled data in human pregnancy.

Chronic opioid use may cause reduced fertility in males and females; it is unknown whether these effects on fertility are reversible.

This drug has been detected in human milk; newborn infants appear to be particularly sensitive to the effects of even small doses. Once a mother's milk comes in, it is best to provide pain control with nonnarcotic analgesics. The developmental and health benefits of breastfeeding should be considered along with the mother's need for this drug and any potential adverse effects on the breastfed infant or underlying maternal condition. Withdrawal symptoms may occur in breastfed infants when maternal administration of an opioid analgesic is stopped or when breastfeeding is stopped.

Undesirable effects:

Side effects that you should report to doctor or health care professional as soon as possible:

- allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- breathing problems
- confusion
- redness, blistering, peeling or loosening of the skin, including inside the mouth
- signs and symptoms of low blood pressure like dizziness; feeling faint or lightheaded, falls; unusually weak or tired
- trouble passing urine or change in the amount of urine

Side effects that usually do not require medical attention (report to doctor or health care professional if they continue or are bothersome):

- constipation

- dry mouth
- nausea, vomiting
- pain, redness, or irritation at site where injected
- tiredness

Overdose:

Pentazocine is a medicine used to treat moderate to severe pain. It is one of a number of chemicals called opioids or opiates, which were originally derived from the poppy plant and used for pain relief or their calming effects. Pentazocine overdose occurs when someone accidentally or intentionally takes more than the normal or recommended amount of this medicine.

A patient who ingested 1.5 g pentazocine developed status epilepticus, coma, respiratory depression, acidosis, profound hypotension, and ventricular arrhythmias. Although this patient survived after institution of general supportive measures, she did not respond to usual doses of naloxone. We describe the clinical symptoms and course of recovery of a patient with pentazocine overdose. Our case suggests that pentazocine overdose may require higher doses of naloxone (5 to 20 mg) than are customarily used for narcotic overdoses. Which given as follows:

Over dosage with opioids

By IV Injection: Child 1 Month-11years: Initially 100 micrograms/kg, if no response, repeat at intervals of 1 minute to a max. of 2mg, then review diagnosis further dose may be required if respiratory function worsen, doses can be given by subcutaneous or intramuscular routes but only if intravenous route is not feasible, intravenous administration has more rapid onset of the action.

Overdosage with opioids in a non-medical setting:

By Intramuscular Injection:

Adult: 400 micrograms every 2-3 minutes, each dose given in subsequent resuscitation cycles if patient not breathing normally, continue until consciousness regained, breathing normally, medical assistance available, or content of syringe used up, to be injected into deltoid region or anterolateral thigh.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pentazocine is a potent analgesic which when administered orally in a 50 mg dose appears equivalent in analgesic effect to 60 mg (1 grain) of codeine. Onset of significant analgesia usually occurs between 15 and 30 minutes after oral administration, and duration of action is usually three hours or longer. Onset and duration of action and the degree of pain relief are

related both to dose and the severity of pretreatment pain. Pentazocine weakly antagonizes the analgesic effects of morphine and meperidine; in addition, it produces incomplete reversal of cardiovascular, respiratory, and behavioral depression induced by morphine and meperidine. Pentazocine has about 1/50 the antagonistic activity of nalorphine. It also has sedative activity

Pharmacokinetics properties:

The pharmacokinetics of single and combined doses of pentazocine HCl (40 and 80 mg) and tripelennamine HCl (50 and 100 mg) were studied in six healthy drug abusers. After intramuscular administration of 40 or 80 mg pentazocine alone, mean peak plasma concentrations at 15 minutes were 102 and 227 ng/ml, respectively, and mean plasma t1/2 values were 4.6 and 5.3 hours, respectively. After intramuscular administration of 50 or 100 mg tripelennamine, mean plasma concentrations at 30 minutes were 105 and 194 ng/ml, respectively, and mean plasma t1/2 values were 2.9 and 4.4 hours, respectively. After concurrent administration of pentazocine with tripelennamine, plasma pentazocine and tripelennamine concentrations at all time points were not significantly different from those when pentazocine or tripelennamine was administered alone. Coadministration of pentazocine and tripelennamine had no effect on the distribution, elimination, and clearance of either pentazocine or tripelennamine. In conclusion, there did not appear to be a clinically significant metabolic interaction between pentazocine and tripelennamine.

List of excipients:
Pentazocine (Present as Lactate) BP
Lactic Acid BP
Sodium Chloride BP
Water for Injections BP

Incompatibilities:
Many injectable drugs cannot be mixed together in syringes or infusions. Some cannot be safely diluted in infusion bags. Incompatibility can involve precipitation, ionic reactions, and evolution of gas and denaturation of biological molecules. Knowledge of drug compatibility is needed before mixing drugs. Reference texts can provide information, but data are often unavailable for new drugs. If drugs are mixed together, the mixture should be inspected for precipitates, turbidity or changes in color, however not all incompatibilities are visible.

Shelf Life:
36 Months.

Special storage for precautions:
Store below 30˚C, Protect from Light.