Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

PAL PENTAZOCINE INJECTION 30mg/mL.

2. Qualitative and Quantitative Composition

Sr. No.	Ingredients	Specifications	Standard Quantity/ (mg/vial)	Reason for Inclusion
01	Pentazocine Lactate Eq. to Pentazocine (A)	BP	30.00	Opioid analgesic
02	Sodium Chloride (Inj. Grade)	BP	2.840	Tonicity agent
03	Lactic Acid (Inj.)	BP	0.013 ml	Acidifying agent
04	Sodium Acetate (Inj.) (AR Grade)	BP	1.000	Preservative
05	Disodium Edetate	BP	0.050	Chelating agent
06	Water For Injections	BP	Q.S. up to 1 ml	Solvent

Note:
(A)=Quantity of active ingredient is to be calculated on the basis of 100% potency and on anhydrous basis.

3. Pharmaceutical Form

Solution for Injection.
A clear colourless solution filled in ampoule.

4. Clinical Particulars

4.1 Therapeutic Indications

Pentazocine Injection is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Pentazocine Injection may also be used for preoperative or preanesthetic medication and as a supplement to surgical anesthesia.

4.2 Posology and method of administration

Posology
Adults*: Excluding Patients in Labor*.
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

Patients in Labor A single, intramuscular 30 mg dose has been most commonly administered. An intravenous 20 mg dose has given 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.

Pediatric Patients: ***Excluding Patients Less Than One Year Old.***
The recommended single parenteral dose as premedication for sedation is 0.5 mg/kg by intramuscular route. CAUTION: Pentazocine Injection should not be mixed in the same syringe with soluble barbiturates because precipitation will occur.

In the case of patients between 1 year and 12 years, the maximum single dose of parenteral Pentazocine should be calculated on the basis of 1mg/kg body weight intravenously.

Elderly

Elderly patients may be more sensitive to the analgesic effects of Pentazocine Injection than younger patients. Elderly patients generally should be started on low doses of Pentazocine Injection and observed closely.

4.3 Contraindications
• Patients who are hypersensitive to the active substance pentazocine lactate or other opioid analgesics or to any ingredient in the formulation.
• In patients with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).
• Patients with suspected surgical abdomen (e.g., acute appendicitis or pancreatitis).

4.4 Special warnings and precautions for use Addiction, Abuse, and Misuse

PENZITEN poses risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Each patient's risk should be assessed prior to prescribing PENZITEN, and all patients should be monitored regularly for the development of these behaviours or conditions. Like all opioids, PENZITEN is a potential drug of abuse and misuse, which can lead to overdose and death. Therefore, PENZITEN should be prescribed and handled with caution. Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. All patients receiving opioids should be routinely monitored for signs of misuse and abuse. Opioids, such as PENZITEN, should be used with particular care in patients with a history of alcohol and illicit/prescription drug abuse. However, concerns about abuse, addiction, and diversion should not prevent the proper management of pain. PENZITEN should be stored securely to avoid theft or misuse.

Life-threatening Respiratory Depression:

OVERDOSE:
Serious, life-threatening, or fatal respiratory depression may occur with use of PENZITEN. Infants exposed in-utero or through breast milk are at risk of life-threatening respiratory depression upon delivery or when nursed. Patients should be monitored for respiratory depression, especially during initiation of PENZITEN or following a dose increase. Further, instruct patients of the hazards related to taking opioids including fatal overdose. Respiratory depression from opioid use, if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the

patient's clinical status. Pentazocine should be used with extreme caution in patients with substantially decreased respiratory reserve, pre-existing respiratory depression, hypoxia or hypercapnia While serious, life threatening, or fatal respiratory depression can occur at any time during the use of PENZITEN, the risk is greatest during the initiation of therapy or following a dose increase. Patients should be closely monitored for respiratory depression when initiating therapy with PENZITEN and following dose increases. Life-threatening respiratory depression is more likely to occur in the elderly, cachectic, or debilitated patients because they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. To reduce the risk of respiratory depression, proper dosing and titration of PENZITEN are essential. Overestimating the PENZITEN dose when converting patients from another opioid product can result in a fatal overdose with the first dose. In these patients, the use of non-opioid analgesics should be considered, if feasible

Accidental Exposure
Accidental exposure of even one dose of PENZITEN, especially by children, can result in a fatal overdose of pentazocine. PENZITEN should be kept in a safe place, out of the sight and reach of children before, during and after use. PENZITEN should not be used in front of children, since they may copy these actions. PENZITEN should never be disposed of in trash. Disposal via a pharmacy take back program is recommended. Unused or expired PENZITEN should be properly disposed of as soon as it is no longer needed to prevent accidental exposure to others.

Neonatal Opioid Withdrawal Syndrome
Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life threatening. Neonatal opioid withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration, and severity of neonatal opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn. PENZITEN is not recommended to be used in pregnant women unless, in the judgement of the physician, the potential benefits outweigh the risks. If PENZITEN was used during pregnancy, special attention to NOWS is warranted.

Interaction with Alcohol
Caution should be observed when administering pentazocine to patients who have been or are taking alcohol. PENZITEN should be avoided as it may result in dangerous additive effects, causing serious injury or death. PENZITEN is an opioid with no approved use in the management of addictive disorders. Its proper usage in individuals with drug or alcohol dependence, either active or in remission is for the management of pain requiring opioid analgesia. Patients with a history of addiction to drugs or alcohol may be at higher risk of becoming addicted to PENZITEN; extreme caution and awareness are warranted to mitigate the risk.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.
Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol):
Pentazocine should be used with caution and in a reduced dosage during concomitant administration of other opioid analgesics, general anesthetics, phenothiazines and other tranquilizers, sedative-hypnotics, tricyclic antidepressants, antipsychotics, antihistamines, benzodiazepines, centrally-active anti-emetics and other CNS depressants. Respiratory depression, hypotension and profound sedation, coma or death may result. Observational studies have demonstrated that concomitant use of opioid analgesics and

benzodiazepines increases the risk of drug-related mortality compared to use of opioid analgesics alone. Because of similar pharmacological properties, it is reasonable to expect similar risk with the concomitant use of other CNS depressant drugs with opioid analgesics. If the decision is made to prescribe a benzodiazepine or other CNS depressant concomitantly with an opioid analgesic, prescribe the lowest effective dosages and minimum durations of concomitant use. In patients already receiving an opioid analgesic, prescribe a lower initial dose of the benzodiazepine or other CNS depressant than indicated in the absence of an opioid, and titrate based on clinical response. If an opioid analgesic is initiated in a patient already taking a benzodiazepine or other CNS depressant, prescribe a lower initial dose of the opioid analgesic, and titrate based on clinical response. Follow patients closely for signs and symptoms of respiratory depression and sedation. Advise both patients and caregivers about the risks of respiratory depression and sedation when PENZITEN is used with benzodiazepines or other CNS depressants (including alcohol and illicit drugs). Advise patients not to drive or operate heavy machinery until the effects of concomitant use of the benzodiazepine or other CNS depressant have been determined. Screen patients for risk of substance use disorders, including opioid abuse and misuse, and warn them of the risk for overdose and death associated with the use of additional CNS depressants including alcohol and illicit drugs. PENZITEN should not be administered to patients who have been or are consuming alcohol as it may increase the chance of experiencing dangerous side effects, including death. Severe pain antagonizes the subjective and respiratory depressant actions of opioid analgesics. Should pain suddenly subside, these effects may rapidly become manifest. There have been reported instances of the acute onset of hallucinations (usually visual), disorientation, and confusion in patients receiving therapeutic doses of PENZITEN. These manifestations have cleared spontaneously within hours upon discontinuation of the drug. The mechanism responsible for this reaction is not known. Patients demonstrating this reaction should be closely observed and if therapy with pentazocine is to be restarted, administration should proceed cautiously since the acute CNS manifestations may recur. Since CNS effects have been noted with the use of PENZITEN, ambulatory patients should be warned not to operate machinery, drive cars, or unnecessarily expose themselves to hazards. Caution should be observed in patients who are prone to convulsions; convulsions have occurred in a few such patients in association with the use of pentazocine, although no cause and effect relationship have been established. Reserve concomitant prescribing of PENZITEN and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

General

Patients should be instructed not to give PENZITEN (pentazocine lactate) to anyone other than for whom it was prescribed, as such inappropriate use may have severe medical consequences, including death. PENZITEN should be stored securely to avoid theft or misuse. PENZITEN should only be prescribed by persons knowledgeable in the continuous administration of potent opioids, in the management of patients receiving potent opioids for the treatment of pain, and in the detection and management of respiratory depression, including the use of opioid antagonists. PENZITEN should be administered as a supplement to surgical anesthesia only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids. Naloxone, resuscitative and intubation equipment and oxygen should be readily available. Patients should be cautioned not to consume alcohol while taking PENZITEN as it may increase the chance of experiencing serious adverse events, including death. Hyperalgesia that will not respond to a further dose increase of pentazocine can occur at particularly high doses. A pentazocine dose reduction or change in opioid may be required.

Dependence/Tolerance
As with other opioids, tolerance and physical dependence may develop upon repeated administration of PENZITEN and there is a potential for development of psychological dependence. Physical dependence and tolerance reflect the neuroadaptation of the opioid receptors to chronic exposure to an opioid, and are separate and distinct from abuse and addiction. Tolerance, as well as physical dependence, may develop upon repeated administration of opioids, and are not by themselves evidence of an addictive disorder or abuse. Patients on prolonged therapy should be tapered gradually from the drug if it is no longer required for pain control. Withdrawal symptoms may occur following abrupt discontinuation of therapy or upon administration of an opioid antagonist. Some of the symptoms that may be associated with abrupt withdrawal of an opioid analgesic include body aches, diarrhea, gooseflesh, loss of appetite, nausea, nervousness or restlessness, anxiety, runny nose, sneezing, tremors or shivering, stomach cramps, tachycardia, trouble with sleeping, unusual increase in sweating, palpitations, unexplained fever, weakness and yawning.

Endocrine
Adrenal Insufficiency: Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. Presentation of adrenal insufficiency may include non - specific symptoms and signs including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If adrenal insufficiency is suspected, confirm the diagnosis with diagnostic testing as soon as possible. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off of the opioid to allow adrenal function to recover and continue corticosteroid treatment until adrenal function recovers. Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency. The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency.

Gastrointestinal Effects
Pentazocine and other morphine-like opioids have been shown to decrease bowel motility. Pentazocine may obscure the diagnosis or clinical course of patients with acute abdominal Condition Peri-Operative Considerations.
The administration of analgesics in the peri-operative period should be managed by healthcare providers with adequate training and experience (e.g., by an anesthesiologist). PENZITEN is not indicated for pre-emptive analgesia (administration pre-operatively for the management of post-operative pain). In the case of planned chordotomy or other pain-relieving operations, patients should not be treated with PENZITEN for at least 24 hours before the operation and PENZITEN should not be used in the immediate post-operative period. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate. Thereafter, if PENZITEN is to be continued after the patient recovers from the postoperative period, a new dosage should be administered in accordance with the changed need for pain relief. The risk of withdrawal in opioid-tolerant patients should be addressed as clinically indicated. Pentazocine and other morphine-like opioids have been shown to decrease bowel motility. Ileus is a common post-operative complication, especially after intra-abdominal surgery with opioid analgesia. Caution should be taken to monitor for decreased bowel motility in post-operative patients receiving opioids. Standard supportive therapy should be implemented. PENZITEN should not be used in the early post-operative period (12 to 24 hours post-surgery) unless the patient is ambulatory and gastrointestinal function is normal.

4.5 Interaction with other medicinal products and other forms of interaction
Interaction with Benzodiazepines and Other Central Nervous System (CNS) Depressants:
Due to additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS

depressants (e.g. other opioids, sedatives/hypnotics, antidepressants, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, phenothiazines, neuroleptics, antihistamines, antiemetics, and alcohol) and beta-blockers, increases the risk of respiratory depression, profound sedation, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients closely for signs of respiratory depression and sedation (see WARNINGS AND PRECAUTIONS, Neurologic, Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol) and Psychomotor Impairment). PENZITEN should not be consumed with alcohol as it may increase the chance of experiencing dangerous side effects.

Drug-Drug Interactions
Concomitant use of monoamine oxidase inhibitors (MAOIs) with pentazocine may cause CNS excitation and hypertension through their respective effects on catecholamines. Caution should, therefore, be observed in administering pentazocine to patients who are currently receiving MAOIs or who have received them within the preceding 14 days. Pentazocine can antagonize the effects of opiate agonists such as diamorphine, morphine, and heroin and is itself antagonized by naloxone. Because pentazocine has narcotic antagonist activity, it may provoke withdrawal symptoms if given to narcotic addicts. It should be given with caution to patients recently being treated with large doses of narcotics. Coadministration of pentazocine with a serotonergic agent, such as a Selective Serotonin Reuptake Inhibitor or a Serotonin Norepinephrine Re-uptake Inhibitor, may increase the risk of serotonin syndrome, a potentially life-threatening condition.

Compatibility with Other Drugs:
PENZITEN has been compatible with other concurrently administered medication, such as diazepoxides, phenothiazines, meprobamate, barbiturates, chloral hydrate, digitalis, digitoxin, aminophylline, antibiotics and oncolytic drugs. PENZITEN did not alter insulin requirements in five diabetic patients. PENZITEN should not be mixed in the same syringe with soluble barbiturates, chlordiazepoxide or diazepam since precipitation will occur.

Drug-Lifestyle Interactions
Tobacco smoking could enhance the metabolic clearance rate of pentazocine reducing the clinical effectiveness of a standard dose of pentazocine. The concomitant use of alcohol should be avoided.

4.6 Pregnancy and Lactation
Pregnancy Studies in human have not been conducted. PENZITEN crosses the placental barrier and is not recommended to be administered to pregnant women unless, in the judgement of the physician, potential benefits outweigh the risks. Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal Opioid Withdrawal Syndrome (NOWS), unlike opioid withdrawal syndrome in adults, may be life-threatening. Pregnant women using opioids should not discontinue their medication abruptly as this can cause pregnancy complication such as miscarriage or still-birth. Tapering should be slow and under medical supervision to avoid serious adverse events to the fetus.

Labour, Delivery and Nursing Women
Since opioids can cross the placental barrier and are excreted in breast milk, PENZITEN is not recommended to be used in nursing women and during labour and delivery unless, in the judgement of the physician, the potential benefits outweigh the risks. Life-threatening respiratory depression can occur in the infant if opioids are administered to the mother. Naloxone, a drug that counters the effects of opioids, should be readily available if PENZITEN is used in this population.

Fertility

Androgen deficiency

Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as low libido, erectile dysfunction, or infertility. Chronic use of opioids may influence the hypothalamic pituitary-gonadal axis, leading to androgen deficiency that may manifest as low libido, impotence, erectile dysfunction, amenorrhea, or infertility. The causal role of opioids in the clinical syndrome of hypogonadism is unknown because the various medical, physical, lifestyle, and psychological stressors that may influence gonadal hormone levels have not been adequately controlled for in studies conducted to date. Patients presenting with symptoms of androgen deficiency should undergo laboratory evaluation.

4.7 Effects on ability to drive and use machines

Pentazocine Injection may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of Pentazocine INJECTION and know how they will react to the medication

4.8 Undesirable effects

At normal therapeutic doses side effects are generally of a minor nature. The most frequent side effects are lightheadedness, dizziness, nausea and vomiting, sedation and sweating. The following side effects have also been reported.

Cardiovascular:

Transient hypertension, tachycardia, hypotension, circulatory depression.

Central and peripheral nervous system:

Hallucinations, disturbances of vision, headache, disorientation, mood changes, nightmares, insomnia, paraesthesia, syncope, euphoria, grand mal convulsions, raised intracranial pressure, confusion, tremor.

Dermatologic/Allergic:

Soft tissue induration, nodules, cutaneous depression at injection sites, ulceration (sloughing) and severe sclerosis of the skin and subcutaneous tissues (and, rarely, underlying muscle), sting on injection. Allergic reactions sometimes severe have been reported including oedema of the face or anaphylactic shock, flushed skin including facial plethora, dermatitis including pruritus, toxic epidermal necrolysis, erythema multiforme.

Gastrointestional:

Constipation, dry mouth, biliary tract spasm, abdominal pain.

Haematologic:

Depression of white blood cell count, especially granulocytes, which is usually reversible, moderate transient eosinophilia. Ophthalmic: Miosis

Respiratory:

Respiratory depression

Other: Urinary retention, muscle tremor, chills, alterations in rate or strength of uterine contractions during labour.

4.9 Overdose

For management of a suspected drug overdose, contact your regional Poison Control Centre.
Symptoms: The symptoms and clinical signs of pentazocine overdosage may resemble those of morphine or other opioids. They may include somnolence, respiratory depression, hypotension, hypertension, tachycardia, hallucinations or seizures. Circulatory failure and deepening coma may occur in more severe cases, particularly in patients who have also ingested other CNS depressants such as alcohol, sedative/hypnotics or antihistamines.

Treatment:

Adequate measures to maintain ventilation and general circulatory support should be employed. For respiratory depression due to overdosage or unusual sensitivity to pentazocine, parenteral naloxone is a specific and effective antagonist. Initial doses of 0.4 to 2.0 mg of naloxone are recommended, repeated at 2 to 3 minutes intervals if needed, up to a total of 10 mg. Anticonvulsant therapy may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Benzomorphan derivatives, ATC code: N02AD01

Mechanism of action

Pentazocine is a member of the benzazocine series of synthetic benzomorphans. It produces both analgesic (agonist) and narcotic antagonist effects. Following intramuscular injection, a dose of 30 mg pentazocine lactate is approximately equivalent to a 10 mg dose of morphine or a 75 to 100 mg dose of meperidine. Analgesia usually begins within 2 to 3 minutes after intravenous administration or 15 to 20 minutes after intramuscular or subcutaneous injection and lasts about 3 hours. Opiate antagonism: Pentazocine weakly antagonizes the analgesic effects of morphine, meperidine and phenazocine. In addition, it produces incomplete reversal of cardiovascular, respiratory and behavioral depression produced by morphine and meperidine. Pentazocine has about 1/50 the antagonistic activity of nalorphine.

Central Nervous System:

Pentazocine produces respiratory depression by direct action on brain stem respiratory centres. The respiratory depression involves both a reduction in the responsiveness of the brain stem centres to increases in CO2 tension and to electrical stimulation. Pentazocine depresses the cough reflex by direct effect on the cough centre in the medulla. Antitussive effects may occur with doses lower than those usually required for analgesia. Pentazocine causes miosis, even in total darkness. Pinpoint pupils are a sign of opioid overdose but are not pathognomonic (e.g., pontine lesions of hemorrhagic or ischemic origin may produce similar findings). Marked mydriasis rather than miosis may be seen with hypoxia in the setting of pentazocine overdose.

Gastrointestinal Tract and Other Smooth Muscle:

Pentazocine causes a reduction in motility associated with an increase in smooth muscle tone in the antrum of the stomach and duodenum. Digestion of food in the small intestine is delayed and propulsive contractions are decreased. Propulsive peristaltic waves in the colon are decreased, while tone may be increased to the point of spasm resulting in constipation. Other opioid-induced effects may include a reduction in gastric, biliary and pancreatic secretions, spasm of the sphincter of Oddi, and transient elevations in serum amylase.

Cardiovascular System:

Pentazocine may produce release of histamine with or without associated peripheral vasodilation.

Manifestations of histamine release and/or peripheral vasodilatation may include pruritus, flushing, red eyes, hyperhidrosis and/or orthostatic hypotension.

Endocrine System:
Opioids may influence the hypothalamic-pituitary-adrenal or -gonadal axes. Some changes that can be seen include an increase in serum prolactin, and decreases in plasma cortisol and testosterone. Clinical signs and symptoms may be manifest from these hormonal changes. Immune System: In vitro and animal studies indicate that opioids have a variety of effects on immune functions, depending on the context in which they are used. The clinical significance of these findings is unknown.

Concentration – Efficacy Relationships
Opioid pharmacologic effects of pentazocine appear to be dose related and include miosis, respiratory depression, mild increase in biliary pressure, decreased intestinal motility and sedation

5.2 Pharmacokinetic properties

Absorption/Metabolism:
Pentazocine is well absorbed after intramuscular or subcutaneous administration and is extensively metabolized in the liver.

Distribution/Excretion:
Peak plasma concentrations occur 15 minutes to 1 hour after intramuscular administration and the elimination half-life in plasma ranges between 2 and 5 hours. The metabolites are excreted by the kidney with only a small amount of unchanged drug excreted in the urine.

5.3 Preclinical safety data
Carcinogenesis Long-term animal studies to evaluate the carcinogenic potential of pentazocine have not been conducted. Mutagenesis Studies to evaluate the mutagenic potential of pentazocine have not been conducted. Impairment of Fertility Animal studies to evaluate the impact of pentazocine on fertility have not been conducted.

6. Pharmaceutical Particulars

6.1 List of Excipients
Sodium Chloride (Inj. Grade) BP/USP
Lactic Acid (Inj.) BP
Sodium Acetate (Inj.) (AR Grade) IH
Disodium Edetate BP (Inj.)
Water For Injections BP

6.2 Incompatibilities

None.

6.3 Shelf Life
36 months

6.4 Special Precautions for Storage
Store below 30°C. Protect from light.

6.5 Nature and Contents of Container

PKN PENTAAZOCINE INJECTION

A clear colourless solution filled in 1 ml ampoule. 1 ml glass ampoule with white auto cut ring. 10 ampoules are packed in blister pack using “LPL” logo printed paper foil with package insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Manufacturer / Applicant

Farbe Firma

Plot No 1508 , GIDC
Ankelshwar

Gujrat :- 393002

PAL-PHARMACEUTICAL INDUSTRIES LIMITED,
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