SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

PENTAZOCINE INJECTION BP

2. Qualitative and quantitative composition

Each ml contains:

Pentazocine Lactate BP Equivalent To
Pentazocine 30mg
Benzyl Alcohol USP 1.5%V/V
Water for Injection BP .....QS

Sr. No.	Ingredient	Label Claim (mg)	Qty (mg/ml)	Function
1.	Pentazocine BP	30.00	30.00	Analgesic
2.	Sodium chloride BP	-	2.80	Isotonic agent
3.	Benzyl alcohol USP	-	0.015	Preservative
4.	Lactic Acid BP	-	0.012	Solvent
5.	Water for Injection BP	-	Q.S.	Vehicle

3. Pharmaceutical forms

Liquid Injection.
A colorless or almost colorless solution.

4. Clinical Particulars

4.1 Therapeutic Indications

It is indicated in Moderate to severe pain.

4.2 Posology and Method of administration

Posology

Prior to starting treatment with opioids, a discussion should be held with patients to put in place a strategy for ending treatment with pentazocine hydrochloride in order to minimise the risk of addiction and drug withdrawal syndrome (see section 4.4).
Posology
The dosage is usually tailored to the individual patient and to the severity of the pain.
Adults
The usual recommended dosage is one to two 50mg capsules every three to four hours after meals.
The maximum daily dose is 600mg.
Elderly
Since impaired renal or hepatic function is often associated with ageing, elderly patients may require smaller doses of pentazocine.
Paediatric population
Not recommended for children under 12 years of age.

Method of administration

For oral use

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Pentazocine should not be administered to patients with established respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion
- Acute alcoholism
- Acute bronchial asthma
- Heart failure secondary to chronic lung disease
- Porphyria
- Raised intracranial pressure, head injuries or pathological brain conditions where clouding of the sensorium is undesirable

4.4 Special warning and precaution for use

Pentozocine can both depress as well as elevate blood pressure possibly through the release of endogenous catecholamines. Particular caution should be observed therefore in using it in the presence of phaeochromocytoma, in the acute phase following myocardial infarction when it may increase pulmonary and systemic arterial pressure and vascular resistance, and in other clinical situations where alterations of vascular resistance and blood pressure might be particularly undesirable.
Caution should be observed in patients with severe renal or hepatic impairment and in elderly patients, who may additionally be especially sensitive to the effects of opioids, as both conditions may lead to an increase in bioavailability of pentazocine and call for a reduction in dosage.
Administer with caution to patients previously on large doses of narcotics.
Patients already receiving MAOIs need to be cautious before taking opioids. Some opioids can cause CNS excitation or depression. Opioids can be taken after two weeks of MAOIs discontinuation.
Caution should be observed in patients who are prone to seizures and in the presence of other opioids or opioid-dependence since the weak opioid antagonistic effects of pentazocine may provoke withdrawal symptoms.
Caution should also be observed in patients with hypothyroidism, adrenocortical insufficiency, prostatic hypertrophy, and in patients with inflammatory or obstructive bowel disorders..
After long term treatment (> 3 months) with analgesics with use every second day or more frequently, headache may develop or aggravate. Headache caused by overuse of analgesics (MOH - medication-overuse headache) should not be treated by increasing the dose. In such cases the use of analgesics should be discontinued in consultation with a doctor.
Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs:
Concomitant use of pentazocine and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe pentazocine concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.
The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).
Drug dependence, tolerance and potential for abuse
For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g. major depression). Additional support and monitoring may be necessary when prescribing for patients at risk of opioid misuse.
A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained on-line, and past and present medical and psychiatric conditions.
Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of pain control as initially experienced. Patients may also supplement their treatment with additional pain relievers. These could be signs that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient.
Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.
Patients should be closely monitored for signs of misuse, abuse, or addiction.
The clinical need for analgesic treatment should be reviewed regularly.
Drug withdrawal syndrome
Prior to starting treatment with any opioids, a discussion should be held with patients to put in place a withdrawal strategy for ending treatment with pentazocine hydrochloride.
Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take weeks to months.
The opioid drug withdrawal syndrome is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.
If women take this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.
Hyperalgesia
Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain. This might be qualitatively and anatomically distinct from pain related to disease progression or to

breakthrough pain resulting from development of opioid tolerance. Pain associated with hyperalgesia tends to be more diffuse than the pre-existing pain and less defined in quality. Symptoms of hyperalgesia may resolve with a reduction of opioid dose.
Pentazocine Capsules contain lactose and sodium.
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
This medicine contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Monoamine oxidase inhibitors may enhance the opioid effects of pentazocine and the agents may interact through their respective effects on catecholamine breakdown and release.
Pentazocine, should not be used in patients who are receiving monoamine oxidase inhibitors or who have received them within the past 14 days (see section 4.4).
Agents with sedative action, including phenothiazines, tricyclic antidepressants and ethyl alcohol can enhance the central depressant effects of pentazocine which are opposed by respiratory stimulants such as doxapram.
Tobacco smoking appears to enhance the metabolic clearance rate of pentazocine reducing the clinical effectiveness of a standard dose of pentazocine.
Pentazocine can antagonise the effects of stronger opioid agonists such as diamorphine (heroin) and morphine, and may provoke withdrawal symptoms if given to narcotic addicts and is itself antagonised by naloxone.
Sedative medicines such as benzodiazepines or related drugs:
The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited

4.6 Fertility, pregnancy and lactation

Pregnancy
Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate.
If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.
Administration during labour may depress respiration in the neonate and an antidote for the child should be readily available.
Breast-feeding
Administration to nursing women is not recommended as pentazocine hydrochloride may be secreted in breast milk and may cause respiratory depression in the infant.

4.7 Effects on ability to drive and use machines

As pentazocine may produce sedation, dizziness and occasionally euphoria, so ambulant patients should be warned against the performance of potentially hazardous tasks such as driving a car or operating machinery; alcohol may potentiate the sedative effect.
This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:
• The medicine is likely to affect your ability to drive
• Do not drive until you know how the medicine affects you
• It is an offence to drive while under the influence of this medicine
• However, you would not be committing an offence (called 'statutory defence') if:
- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
- It was not affecting your ability to drive safely

4.8 Undesirable effects

In chronic usage, care should be exercised to avoid any unnecessary increase in dosage since prolonged use of high dosage of pentazocine may produce dependence.
At therapeutic doses, side effects are generally of a minor nature. Sedation and drowsiness, the most common effect, is less than that associated with morphine. The most frequent side effects are light-headedness, dizziness, nausea, vomiting, and sweating.
The following side effects have also been reported.

Blood and lymphatic system disorders: transient eosinophilia, agranulocytosis, depression of the white blood cells.
Immune system disorders: oedema of the face, flushing of the skin, including facial plethora, skin rashes, urticaria, dermatitis including pruritus, chills and allergic reactions.
Psychiatric disorders: Frequency unknown: drug dependence (see section 4.4).
Nervous system disorders: hallucinations may occur occasionally, dysphoria, headache, disorientation, mood changes, nightmares, insomnia, paraesthesia, syncope, euphoria, grand mal convulsions, raised intracranial pressure, confusion, muscle tremor, thought disturbances.
Eye disorders: miosis, disturbances of vision.
Cardiac disorders: tachycardia, bradycardia, palpitations.
Vascular disorders: transient hypertension, hypotension, circulatory depression.
Respiratory thoracic and mediastinal disorders: respiratory depression.
Gastrointestinal disorders: constipation, dry mouth, biliary tract spasm.
Skin and subcutaneous system disorders: toxic epidermal necrolysis.
Renal and urinary disorders: urinary retention, ureteric tract spasm.
Pregnancy, puerperium and perinatal conditions: alterations in rate or strength of uterine contractions.
Reproductive system and breast disorders: decreased libido or potency.
General disorders and administration site conditions: hypothermia. Uncommon: drug withdrawal syndrome.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Patients should be informed of the signs and symptoms of overdose, and to ensure that family and friends are also aware of these signs, and to seek immediate medical help if they occur.
The symptoms and clinical signs of pentazocine overdose will resemble those of morphine and other opioids. They may therefore include somnolence, respiratory depression, hypotension, hypertension, tachycardia, hallucinations, or seizures. Circulatory failure and deepening coma may occur in more severe cases, as may convulsions, particularly in patients who have also ingested other CNS depressants such as alcohol, sedatives/hypnotics or antihistamines. Adequate measures to maintain ventilation and general circulatory support should be employed and consideration given to gastric lavage and gastric aspiration.
For respiratory depression due to overdosage or unusual sensitivity to pentazocine, parenteral naloxone is a specific and effective antagonist. Initial dose of 0.4 to 2mg of naloxone are recommended, repeated at 2-3 minute intervals if needed, up to a total of 10mg. Anti-convulsant therapy may be necessary.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

General properties
Pharmacotherapeutic group: Benzomorphan derivatives
ATC code: N02AD01
Pentazocine is an opioid benzomorphan derivative analgesic with actions and uses similar to those of morphine. It also has antagonist activity. It has weak narcotic antagonist actions.
Prolonged use of high doses of pentazocine may produce dependence. It is subject to abuse.

5.2 Pharmacokinetic Properties

*A*bsorption
Pentazocine is absorbed from the gastrointestinal tract.
Distribution
Following administration by mouth, peak plasma concentrations are reached in 1-3 hours. After intramuscular injection, peak plasma concentrations are reached in 15 minutes to 1 hour.
Pentazocine diffuses across the placenta.
Biotransformation
Pentazocine is metabolised in the liver.
Elimination
Only a small proportion of the dose administered appears unchanged in the urine.

5.3 Preclinical Safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium Chloride
Benzyl alcohol
Lactic acid
Water for injection

6.2 Incompatibilities

Not known.

6.3 Shelf Life

36 months from the date of manufacturing

6.4 Special precautions for storage

Store at a temperature not exceeding 30ºC in a dry place. Protect from excess heat and moisture. Keep medicines out of reach of children.

6.5 Nature and contents of container

1 ml clear glass ampoule.

6.6 Special precautions for disposal and other handling

None

7. Marketing authorisation holder

Manufacturer:
STALLION LABORATORIES PVT.LTD.
block no. 10-13 ,sarkhej-bavla highway,
city :changodar-382 213,
Dist: Ahmedabad,
Gujarat State, India

Applicant
F-Dumsom Nigeria Ltd,
Ajao Estate, Lagos.

8. Marketing authorisation number(s)

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9. Date of first authorisation/renewal of the authorisation

---

10. Date of revision of the text

Stallion

NRx

FD
Pentazocine Injection BP

For I.M. / I.V. USE

10 X 1 ml

FD Pentazocine Injection BP

FD Pentazocine Injection BP

Composition:
Each ml contains:
Pentazocine Lactate BP Equivalent To
Pentazocine 30mg
Benzyl Alcohol USP 1.5%v/v
Water for Injection BP .....Q.S.

For Pharmacology, Indication, Contraindications and Dosage See Package Inserts.

Storage:
Store at a temperature not exceeding 30ºC in a dry place.
Protect from excess heat and moisture.
Keep medicines out of reach of children.

Marketed by: **F-DUMSOM NIG LTD, F-DUMSOM NIG LTD**
10 NWOBODOEZE STREET, AJAO ESTATE.
LAGOS 01 Lagos Nigeria.

Mfg. Lic. No.:G/28-A/4737-A
NAFDAC Reg. No.:

Batch No. :
Mfg. Date :
Exp. Date :

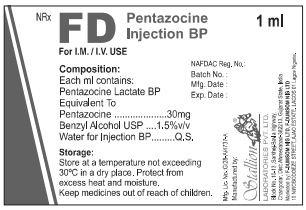
UVZ AREA

Manufactured by:
Stallion®
LABORATORIES PVT. LTD.
Block No. 10-13 ,Sarkhej-Bavla highway,
Changodar, Dist: Ahmedabad-382213,
Gujarat State, India

FD Pentazocine Injection BP

FD Pentazocine Injection BP

Dimension: 148 x 16 x 68 mm



Dimension: 30 x 20 mm

NRx

FD Pentazocine Injection BP

1 ml

For I.M. / I.V. USE

Composition:

Each ml contains:
Pentazocine Lactate BP
Equivalent To
Pentazocine 30mg
Benzyl Alcohol USP 1.5%v/v
Water for Injection BP.....Q.S.

Storage:

Store at a temperature not exceeding 30ºC in a dry place. Protect from excess heat and moisture.
Keep medicines out of reach of children.

NAFDAC Reg. No.:
Batch No. :
Mfg. Date :
Exp. Date :

Mfg. Lic. No.:G/28-A/4737-A
Manufactured by:
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LABORATORIES PVT. LTD.
Block No. 10-13 ,Sarkhej-Bavla highway,
Changodar, Dist: Ahmedabad-382213, Gujarat State, India
Marketed by: **F-DUMSOM NIG LTD, F-DUMSOM NIG LTD** Enyinnaya Ukpai
10 NWOBODOEZE STREET, AJAO ESTATE. LAGOS 01 Lagos Nigeria.

Front

NRx

FD Pentazocine Injection BP

Dosage Form:
Liquid Injection.

Product Description:
A colorless or almost colorless solution.

Composition:
Each ml contains:

Pentazocine Lactate BP Equivalent To Pentazocine	30mg
Benzyl Alcohol USP	1.5%v/v(Volume/Volume)
Water for Injection BP	Q.S.

Indications:
It is indicated in Moderate to severe pain.

Contraindications:
Children under three years of age: Since clinical experience in children is limited, administration to children is not recommended.
Pentazocine is contra-indicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretions. It is also contra-indicated in acute alcoholism, after biliary operations, in heart failure due to chronic lung disease.
Pentazocine should be given with caution to patients prone to seizures. In cases of liver disease or cirrhosis there is an enhanced availability and the dose should be decreased. May precipitate withdrawal symptoms in patients who have recently used narcotic analgesics.
Pentazocine should be used with care in patients with increased intracranial pressure and/or head injuries, or in patients with porphyria.

Dosage and Administration:
Prior to starting treatment with opioids, a discussion should be held with patients to put in place a strategy for ending treatment with pentazocine hydrochloride in order to minimise the risk of addiction and drug withdrawal syndrome.
Posology
The dosage is usually tailored to the individual patient and to the severity of the pain.
Adults
The usual recommended dosage is one to two 50mg capsules every three to four hours after meals. The maximum daily dose is 600mg.
Elderly
Since impaired renal or hepatic function is often associated with ageing, elderly patients may require smaller doses of pentazocine.
Paediatric population
Not recommended for children under 12 years of age.

Method of administration
For oral use

Adverse reactions:
In chronic usage, care should be exercised to avoid any unnecessary increase in dosage since prolonged use of high dosage of pentazocine may produce dependence.
At therapeutic doses, side effects are generally of a minor nature. Sedation and drowsiness, the most common effect, is less than that associated with morphine. The most frequent side effects are light-headedness, dizziness, nausea, vomiting, and sweating.
The following side effects have also been reported.
Blood and lymphatic system disorders: transient eosinophilia, agranulocytosis, depression of the white blood cells.
Immune system disorders: oedema of the face, flushing of the skin, including facial plethora, skin rashes, urticaria, dermatitis including pruritus, chills and allergic reactions.
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Cardiac disorders: tachycardia, bradycardia, palpitations.
Vascular disorders: transient hypertension, hypotension, circulatory depression.
Respiratory thoracic and mediastinal disorders: respiratory depression.
Gastrointestinal disorders: constipation, dry mouth, biliary tract spasm.
Skin and subcutaneous system disorders: toxic epidermal necrolysis.
Renal and urinary disorders: urinary retention, ureteric tract spasm.
Pregnancy, puerperium and perinatal conditions: alterations in rate or strength of uterine contractions.
Reproductive system and breast disorders: decreased libido or potency.
General disorders and administration site conditions: hypothermia. Uncommon: drug withdrawal syndrome.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Drug Interactions:
Monoamine oxidase inhibitors may enhance the opioid effects of pentazocine and the agents may interact through their respective effects on catecholamine breakdown and release.
Pentazocine, should not be used in patients who are receiving monoamine oxidase inhibitors or who have received them within the past 14 days.
Agents with sedative action, including phenothiazines, tricyclic antidepressants and ethyl alcohol can enhance the central depressant effects of pentazocine which are opposed by respiratory stimulants such as doxapram.
Tobacco smoking appears to enhance the metabolic clearance rate of pentazocine reducing the clinical effectiveness of a standard dose of pentazocine.
Pentazocine can antagonise the effects of stronger opioid agonists such as diamorphine (heroin) and morphine, and may provoke withdrawal symptoms if given to narcotic addicts and is itself antagonised by naloxone.
Sedative medicines such as benzodiazepines or related drugs:
The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited.

Pregnancy and Lactation:
Pregnancy
There is no epidemiological evidence for the safety of pentazocine in human pregnancy (other than during labour), but it has been widely used for many years without apparent ill consequences. In rodents, harmful effects in the foetus have been observed but only at doses high enough to cause maternal toxicity. Pentazocine can rapidly cross the placental barrier and enter the foetal circulation and has the potential to cause opioid effects including central depression and abstinence syndrome in the foetus and newborn infant. It does not appear to have significant adverse effects on uterine function at parturition. Nonetheless, careful consideration should be given to the use of pentazocine during pregnancy, particularly during the first trimester, or at term. Special attention should be paid to clinical monitoring of the newborn, particularly premature infants, if pentazocine has been used during labour.
Lactation
Pentazocine is excreted in very small amounts in breast milk. Caution should therefore be observed in administering pentazocine to breast-feeding mothers, particularly of infants at risk.

Back

Precaution/Warnings:
Pentozocine can both depress as well as elevate blood pressure possibly through the release of endogenous catecholamines. Particular caution should be observed therefore in using it in the presence of phaeochromocytoma, in the acute phase following myocardial infarction when it may increase pulmonary and systemic arterial pressure and vascular resistance, and in other clinical situations where alterations of vascular resistance and blood pressure might be particularly undesirable.
Caution should be observed in patients with severe renal or hepatic impairment and in elderly patients, who may additionally be especially sensitive to the effects of opioids, as both conditions may lead to an increase in bioavailability of pentazocine and call for a reduction in dosage.
Administer with caution to patients previously on large doses of narcotics.
Patients already receiving MAOIs need to be cautious before taking opioids. Some opioids can cause CNS excitation or depression. Opioids can be taken after two weeks of MAOIs discontinuation.
Caution should be observed in patients who are prone to seizures and in the presence of other opioids or opioid-dependence since the weak opioid antagonistic effects of pentazocine may provoke withdrawal symptoms.
Caution should also be observed in patients with hypothyroidism, adrenocortical insufficiency, prostatic hypertrophy, and in patients with inflammatory or obstructive bowel disorders..
After long term treatment (> 3 months) with analgesics with use every second day or more frequently, headache may develop or aggravate. Headache caused by overuse of analgesics (MOH - medication-overuse headache) should not be treated by increasing the dose. In such cases the use of analgesics should be discontinued in consultation with a doctor.
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Concomitant use of pentazocine and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe pentazocine concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.
The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms.

Drug dependence, tolerance and potential for abuse
For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g. major depression).
Additional support and monitoring may be necessary when prescribing for patients at risk of opioid misuse.
A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained on-line, and past and present medical and psychiatric conditions.
Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of pain control as initially experienced. Patients may also supplement their treatment with additional pain relievers. These could be signs that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient.
Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.
Patients should be closely monitored for signs of misuse, abuse, or addiction.
The clinical need for analgesic treatment should be reviewed regularly.

Drug withdrawal syndrome
Prior to starting treatment with any opioids, a discussion should be held with patients to put in place a withdrawal strategy for ending treatment with pentazocine hydrochloride.
Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take weeks to months.
The opioid drug withdrawal syndrome is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.
If women take this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.

Hyperalgesia
Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain. This might be qualitatively and anatomically distinct from pain related to disease progression or to breakthrough pain resulting from development of opioid tolerance. Pain associated with hyperalgesia tends to be more diffuse than the pre-existing pain and less defined in quality. Symptoms of hyperalgesia may resolve with a reduction of opioid dose.
Pentazocine Capsules contain lactose and sodium.
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
This medicine contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially 'sodium-free'.

Overdose and Treatments:
The symptoms and clinical signs of pentazocine overdose will resemble those of morphine and other opioids. They may therefore 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, sedatives / hypnotics, or antihistamines. Adequate measures to maintain ventilation and general circulatory support should be employed. Gastric lavage and gastric aspiration should be considered where appropriate. 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 2.0mg of naloxone are recommended, repeated at 2-3 minute intervals if needed, up to a total of 10mg. Anti-convulsant therapy may be necessary.

Packing:
1 ml clear glass ampoule.

Shelf-life:
36 months

Storage condition:
Store at a temperature not exceeding 30°C in a dry place. Protect from excess heat and moisture. Keep medicines out of reach of children.

Manufactured by:
Stallion®
LABORATORIES PVT. LTD.
Block No. 10-13 ,Sarkhej-Bavla highway,
Changodar, Dist: Ahmedabad-382213,
Gujarat State, India

Marketed by: **F-DUMSOM NIG LTD, F-DUMSOM NIG LTD**
10 NWOBODOEZE STREET, AJAO ESTATE.
LAGOS 01 Lagos Nigeria.

Dimension: 90 x 240 mm