



## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

# PENTAZOCINE INJECTION

Pentazocine 30mg/ml

### Read this leaflet carefully before you start taking this medicine:

- You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

### In this leaflet:

1. What Pentazocine Injection is and what it is used for
2. What you need to know before you are given Pentazocine Injection
3. How to take Pentazocine Injection
4. Possible side effects
5. How to store Pentazocine Injection
6. Contents of the pack and other information

## 1. WHAT PENTAZOCINE INJECTION IS AND WHAT IT IS USED

Pentazocine Injection is an opioid pain medication, sometimes called a narcotic. It works by changing the way the brain and nervous system respond to pain.

Pentazocine is used to treat moderate to severe pain in adults and children who are at least 12 years old. It is also used as part of anaesthesia for surgery. Pentazocine may also be used for purposes not listed in this medication guide.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN PENTAZOCINE INJECTION

Do not take Pentazocine injection if you are allergic to it or if you have:

- Severe breathing problems; or
- A stomach or bowel obstruction (including paralytic ileus).

You should not use Pentazocine unless you are already using a similar opioid medicine and are tolerant to it. Opioid medicines include Fentanyl, Hydrocodone, Morphine, Oxycodone, and many others. Ask your doctor if you are not sure you are opioid-tolerant.

To make sure Pentazocine is safe for you, tell your doctor if you have ever had:

- Any type of breathing problem or lung disease;
- Asthma or sulfite allergy;
- A head injury, brain tumor, or seizures;
- Blockage in your digestive tract (stomach or intestines);
- Alcoholism, drug addiction, or mental illness.
- Low blood pressure;
- High blood pressure, heart disease, or heart attack;
- Liver or kidney disease; or



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- Problems With Your Gallbladder or adrenal gland

### **Taking other medicines with Pentazocine injection**

Some medicines can interact with Pentazocine and cause a serious condition called Serotonin syndrome. Be sure your doctor knows if you also take stimulant medicine, herbal products, or medicine for depression, mental illness, Parkinson's disease, migraine headaches, serious infections, or prevention of nausea and vomiting. Ask your doctor before making any changes in how or when you take your medications.

### **Pregnancy and Breast-feeding**

#### **Pregnancy**

If you use Pentazocine Injection while you are pregnant, your baby could become dependent on the drug. This can cause life-threatening withdrawal symptoms in the baby after it is born. Babies born dependent on habit-forming medicine may need medical treatment for several weeks. Tell your doctor if you are pregnant or plan to become pregnant.

#### **Breast-feeding**

Pentazocine Injection can pass into breast milk and may cause drowsiness, breathing problems, or withdrawal symptoms in the nursing baby. Tell your doctor if you are breast-feeding.

### **Driving and using machines**

Pentazocine may cause sedation, dizziness and occasionally euphoria. Make sure you are not affected before you drive or operate machinery. This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence 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 or in the information provided with the medicine and - It was not affecting your ability to drive safely. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

## **3. HOW TO TAKE PENTAZOCINE INJECTION**

A healthcare provider will give you this injection. Never use Pentazocine in larger amounts, or for longer than prescribed.

### **Adults**

Pentazocine Injection may be administered subcutaneously, intramuscularly, or intravenously. The usual starting dose is 30mg to 60mg according to the severity. The dose should be adjusted according to response and repeated as necessary every three to four hours. A dose should not normally exceed 1mg/kg body weight SC or IM, or 0.5mg/kg iv. The maximum daily dose is 360mg.



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### Children

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.

Pentazocine Injection is not recommended for use in children under one year. Elderly Since impaired renal or hepatic function is often associated with ageing, elderly patients may require smaller doses of Pentazocine.

Pentazocine Injection is usually given only for a short time. Do not stop using Pentazocine suddenly after long-term use, or you could have unpleasant withdrawal symptoms. Ask your doctor how to safely stop using this medicine.

### What happens if I miss a dose?

Since Pentazocine is used for pain, you are not likely to miss a dose. Skip any missed dose if it is almost time for your next scheduled dose. Do not use extra medicine to make up the missed dose. If Pentazocine is given by a healthcare professional, you are not likely to miss a dose.

## 4. POSSIBLE SIDE EFFECTS

Get emergency medical help if you have signs of an allergic reaction: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Like other narcotic medicines, Pentazocine can slow your breathing. Death may occur if breathing becomes too weak. A person caring for you should seek emergency medical attention if you have slow breathing with long pauses, blue colored lips, or if you are hard to wake up.

Call your healthcare provider at once if you have:

- Noisy breathing, sighing, shallow breathing;
- A light-headed feeling, like you might pass out;
- Severe constipation;
- Pain, burning, irritation, or skin changes where the injection was given; or
- Low cortisol levels--nausea, vomiting, loss of appetite, dizziness, worsening tiredness or weakness.

Seek medical attention right away if you have symptoms of serotonin syndrome, such as: agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

Serious side effects may be more likely in older adults and those who are overweight, malnourished, or debilitated.

Long-term use of opioid medication may affect fertility (ability to have children) in men or women. It is not known whether opioid effects on fertility are permanent.

Common side effects may include:

- Dizziness, drowsiness;
- Constipation;



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- Nausea, vomiting; or
- Increased sweating.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

Tell your doctor or nurse if you experience the following side effects:

### **Rare (may affect up to 1 in 1,000 people)**

- A general feeling of being unwell (malaise)
- A drop in blood pressure.
- Changes in liver enzymes found during blood checks. Should this occur, inform your doctor as regular blood checks may be required later.

### **Very rare (may affect up to 1 in 10,000 people)**

- Other changes in laboratory test results which may result in regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells) can occur, possibly leading to bleeding from the nose or gums.

### **Not Known (frequency cannot be estimated from the available data)**

- Cases of redness of the skin, flushing, itching and abnormally rapid beating of the heart have been reported.
- Cases of pain and burning sensation at injection site have been reported.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, or healthcare provider: This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE PENTAZOCINE INJECTION**

- Keep all medicines out of the reach of children.
- Store below 30°C.
- Do not use this medicine after the expiry date 'Exp. Date' which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. FURTHER INFORMATION**

### **What Pentazocine Injection contains**

The active substance of Pentazocine Injection is Pentazocine. Each ml contains 30mg of Pentazocine.






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**What Pentazocine Injection looks like and contents of the pack**  
Pentazocine Injection as 10x1ml ampoules in a carton.

**SUPPLIER AND MANUFACTURER**

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