

Pentazocine 25mg Tablets

(Pentazocine Hydrochloride)

This medicine contains pentazocine hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Pentazocine tablets are and what they are used for**
- 2 What you need to know before you take Pentazocine tablets**
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- 4 Possible side effects**
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1 What Pentazocine tablets are and what they are used for

This medicine has been prescribed for you for relief of moderate to severe pain. It contains pentazocine hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'.

This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor should have explained how long you will be taking it for, when it is appropriate to stop and how to do this safely.

2 What you need to know before you take Pentazocine tablets

Do not take Pentazocine tablets if you:

- are **allergic** (hypersensitive) to Pentazocine, analgesics or to any of the other ingredients of this medicine (listed in section 6)
- suffer from **heart problems** due to **lung disease**
- suffer from any **brain conditions** (including raised pressure in the skull) or **head injury**
- suffer from **asthma, lung disease** or have **breathing difficulties**, especially if you have blue discoloration of the skin (cyanosis) or cough up a lot of phlegm
- suffer from **alcoholism** or are a **heavy drinker**
- have **porphyria** (a group of rare inherited or acquired disorders where there is a problem with the production of haem (used to make haemoglobin in red blood cells) within the body).

Warnings and precautions

- **taking a pain reliever regularly for a long time may lead to a dependence (addiction)**
- **taking a pain reliever too often or for too long can make headaches develop or worsen. Headaches caused by overuse of medicine should not be treated by increasing the dose.**

Talk to your doctor before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- feel you need to take more Pentazocine tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be taking it for, when it is appropriate to stop and how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Also talk to your doctor before taking Pentazocine tablets if you:

- suffer from phaeochromocytoma (untreated tumour of the adrenal gland)
- have suffered a recent heart attack
- have high blood pressure
- suffer from severe kidney or liver problems
- are elderly, as you may be especially sensitive to the effects of Pentazocine
- have a history of or suffer from fits or seizures
- take other analgesic medicines (See "Other medicines and Pentazocine")
- have an underactive thyroid gland (hypothyroidism)
- have a condition in which the adrenal glands do not produce adequate amounts of steroid hormones (adrenocortical insufficiency)
- suffer from inflammation (swelling) of the prostate (prostatic hypertrophy)
- suffer from inflammatory or obstructive bowel disorders
- suffer from swelling (inflammation) of the gallbladder (cholecystitis)
- suffer from inflammation of the pancreas (pancreatitis)
- suffer from unexplained stomach pain
- are taking medicines used to treat major depressive episodes, known as Monoamine Oxidase Inhibitors (MAOIs) (See "Other medicines and Pentazocine"). Treatment with Pentazocine should only be started 2 weeks after discontinuing treatment with an MAOI.

Other medicines and Pentazocine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Pentazocine:

- Antidepressant medicines known as Monoamine Oxidase Inhibitors (MAOI) in the past 2 weeks
- Medicines which make you sleepy including:
 - Phenothiazines such as trifluoperazine, used to treat anxiety, mental disorders, feeling and/or being sick (nausea, vomiting)
 - Tricyclic antidepressants, used to treat depression such as amitriptyline
 - Medicines used to improve breathing ability such as doxapram (respiratory stimulants)
- Tobacco smoking may decrease the effectiveness of Pentazocine
- Strong pain relievers such as diamorphine (heroin), morphine and naloxone.

Concomitant use of Pentazocine and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Pentazocine together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Taking Pentazocine tablets with food and drink and alcohol

- These tablets should be taken after meals.
- Do not drink alcohol while you are taking these tablets. If you drink alcohol whilst taking this medicine, the sedative effect may be enhanced.

Pregnancy and breast-feeding

Pregnancy

- Do not take Pentazocine tablets if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby.
- If you take Pentazocine tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding

Do not take Pentazocine tablets while you are breast-feeding as pentazocine hydrochloride passes into breast milk and will affect your baby.

Driving and using machines

Pentazocine tablets 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.

Pentazocine tablets contain lactose

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Pentazocine tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Swallow the tablets with **water, after meals.**

The recommended dose is:

- Adults: the usual starting dose is 2 tablets every four hours. Dosage should be within the range of 25-100mg every three to four hours.
- Children 6-12 years: 25mg every 3 to 4 hours as required
- Children under 6 years: not recommended
- Elderly: your doctor may give you a lower dose
- Patients with liver or kidney problems: your doctor may reduce your dose.

If you take more Pentazocine tablets than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include:

sleepiness or drowsiness (somnolence), slower or weaker breathing (respiratory depression), low/high blood pressure (hypotension/hypertension), faster heartbeat (tachycardia), seeing or hearing things that are not real (hallucinations), or fits (seizures, convulsions). Poor circulation and unconsciousness or coma may occur in more severe cases.

If you forget to take Pentazocine tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Pentazocine tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Pentazocine tablets can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- **Allergic reactions (swelling of the face, throat or tongue, difficulty breathing or dizziness)**
- **Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)**
- **Severe blistering of the skin, mouth, eyes and genitals (toxic epidermal necrolysis).**

Side effects (most frequent)

- Feeling sick (nausea) or being sick (vomiting)
- Feeling tired or drowsy
- Light-headedness
- Dizziness
- Sweating.

Other side effects (frequency not known)

- Dependence and addiction (see section 'How do I know if I am addicted?')

- High blood pressure (hypertension) or low blood pressure (hypotension)
- Slow heartbeat (bradycardia) or fast heartbeat (tachycardia)
- Feeling your heartbeat (palpitations)
- Poor circulation
- Seeing or hearing things that are not real (hallucinations) may occur occasionally
- Feeling depressed or discontented (dysphoria)
- Visual disturbances
- Headache
- Feeling disorientated
- Mood changes
- Nightmares
- Difficulty sleeping (insomnia)
- Tingling or numbness in the hands or feet (paraesthesia)
- Fainting (syncope)
- Intense feeling of well-being or elation (euphoria)
- Fits (seizures)
- Increased pressure in the skull
- Confusion
- Thought disturbances
- Reddening of the face (flushing)
- Skin rashes
- Skin rashes with the formation of wheals (urticaria)
- Skin rash or inflammation (dermatitis)
- Severe itching (pruritus)
- Constipation
- Dry mouth
- Pain in lower back or stomach (may be caused by a spasm of the ureter or bile duct)
- Depression of the white blood cell count, which is usually reversible
- Extremely small pupils of the eyes (miosis)
- Breathing more slowly or weakly than usual (respiratory depression)
- Muscle tremor
- Chills
- Low body temperature (hypothermia)
- Difficulty passing urine
- Changes in the rate or strength of uterine contractions during labour
- Lack of sexual desire (decreased libido).

Drug Withdrawal

When you stop taking Pentazocine tablets, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Pentazocine tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your doctor
- You feel you need to use more than the recommended dose

- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Pentazocine tablets

Keep out of the sight and reach of children. Store below 25°C in a dry place.

Do not use Pentazocine tablets after the expiry date stated on the label/carton/bottle. 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 to protect the environment.

6 Contents of the pack and other information

What Pentazocine tablets contain

- The active substance (the ingredient that makes the tablets work) is 25mg of pentazocine hydrochloride.
- The other ingredients are lactose, magnesium stearate, polyvidone, microcrystalline cellulose (E460), crospovidone.

What Pentazocine tablets look like and contents of the pack

Pentazocine tablets are white, circular, biconvex uncoated tablets impressed "C" and the identifying letters "PZ" on one face.

Pack sizes are 28 tablets.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstable, EX32 8NS, UK.

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