

**Package leaflet: Information for the patient**

# Pentazocine 50 mg capsules, hard

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

**1. What Pentazocine is and what it is used for**

This medicine has been prescribed for you for relieve of moderate to severe pain.

It contains Pentazocine hydrochloride which belongs to a class of medicines called opioids, which are ‘pain relivers’.

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 and when it is appropriate to stop, how to do this safely.

**2. What you need to know before you take Pentazocine**

**Do not take Pentazocine if you:**

- Are allergic to pentazocine, or any of the other ingredients of this medicine (listed in section 6)
- Have breathing problems for example, respiratory depression and/or shallow breathing (which may lead to blue lips), chronic bronchitis (coughing up a lot of phlegm) or asthma
- Have a history of alcohol abuse
- Are recovering from a head injury, or you have a condition which causes increased pressure on the brain. Symptoms include severe headaches, being sick, drowsiness or blurred vision
- Have heart failure or suffer from breathlessness and swollen ankles
- Have porphyria (a genetic disease that can cause skin blisters, abdominal pain and brain or nervous system disorders).

**Warnings and precautions**

Talk to your doctor or pharmacist 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 of pentazocine capsules 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 and when it is appropriate to stop, 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 or pharmacist before taking Pentazocine if you:

- Are taking a monoamine oxidase inhibitor (MAOI, a medicine used for depression e.g. phenelzine, isocarboxazid) or you have taken one within the last 14 days. Treatment with Pentazocine should only be started 2 weeks after discontinuing treatment with an MAOI
- Have a rare tumour of the adrenal glands called a phaeochromocytoma. This may cause headaches, sweating, palpitations, flushing of the face and pains in the chest or stomach
- Have recently had a heart attack
- Have high blood pressure
- Have severe kidney or liver disease, or you are elderly. You may need a lower dose
- Have epilepsy
- Have a history of drug abuse, or you are addicted to opiate pain killers such as morphine or diamorphine
- Are being treated for an underactive thyroid gland
- Have a condition which affects your adrenal glands
- Have an enlarged prostate gland and have difficulty urinating
- Suffer from an inflamed bowel or other gut disorders
- Suffer from swelling (inflammation) of the gallbladder (cholecystitis)
- Suffer from inflammation if the pancreas (pancreatitis)
- Suffer from unexplained stomach pain
- Are a smoker (the effect of Pentazocine may be decreased)
- Have been regularly taking other pain relieving medicines for longer than three months, especially if you are suffering from headaches or headaches have become worse.

**Other medicines and Pentazocine**  
**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially any of the following:**

- 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.

**Pentazocine with food and alcohol**

- These capsules should be taken after meals
- Do not drink alcohol whilst taking this medicine. If you drink alcohol whilst taking this medicine the sedative effect may be enhanced.

**Pregnancy and breast-feeding**

**Pregnancy**

Do not take pentazocine capsules 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 use pentazocine capsules 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 capsules while you are breastfeeding as pentazocine passes into breast milk and will affect your baby.

**Driving and using machines**

Pentazocine may cause sedation. If affected you should not drive or use machines.

The 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 contains sodium metabisulfite**, which may rarely cause severe hypersensitivity reactions and bronchospasm. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

### 3. How to take Pentazocine

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

Your doctor should have discussed with you, how long the course of capsules 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 capsules whole with a full glass of water. The capsules should be taken after meals. Do not chew or crush the capsules. Your doctor will decide how much Pentazocine you should take. This will depend on your condition and the severity of your pain.

The recommended dose is:

**Adults** - One 50 mg capsule every four hours. If more pain relief is needed your doctor may increase your dose to two 50 mg capsules every three to four hours. The maximum dose is 600 mg a day.

#### Use in children and adolescents

Other forms of this medicine may be more suitable for children, ask your doctor or pharmacist.

**Older people or patients with kidney or liver problems**- Your doctor may give you a lower dose.

#### If you take more Pentazocine than you should

Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining capsules with you. Signs of overdose include drowsiness, shallow breathing, low or high blood pressure, fast heartbeat, hallucinations (seeing things that are not there) coma or fits.

#### If you forget to take Pentazocine

Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Pentazocine

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, this medicine can cause side effects, although not everybody gets them. If they occur, they are likely to be mild. However, some may be serious and need medical attention.

#### If the following side effects occur, stop taking the capsules immediately and contact your doctor:

- sore throat, fever, severe chills and mouth ulcers. This can be due to a lack of white blood cells called granulocytes (agranulocytosis)
- swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing, skin rash or itchy flushed face (allergic reaction)
- blood changes such as a reduction in white blood cells which makes infection (with signs such as fever) more likely
- a serious skin reaction called toxic epidermal necrolysis. This is rare; symptoms include loss of the outer layers of skin and reddening of the skin.

#### Other possible side effects are:

- Dependence and addiction (see section 'How do I know if I am addicted?')
- light-headedness, dizziness
- feeling sick, vomiting, constipation
- feeling drowsy
- sedation
- fainting
- sweating
- headache
- dry mouth
- pins and needles
- ureteric or biliary tract spasm causing abdominal cramps
- urinary retention (difficulty passing water)
- itching or flushing of the skin
- rapid heartbeat or slower heartbeat
- feeling your heartbeat (palpitations)
- poor circulation
- increased pressure on the brain
- slow or shallow breathing
- collapse due to very low blood pressure

- short-lived hypertension (high blood pressure)
- altered contractions of the womb
- muscle tremor
- grand mal convulsions (seizures)
- mood changes, difficulties sleeping, nightmares, thought disturbances, disorientation, confusion, hallucinations (sensing things that are not real e.g. seeing things)
- extremes of feeling happy or sad
- eyesight changes
- chills
- lack of sexual desire and impotency (failure to maintain an erection)
- hypothermia (low body temperature)

#### Drug Withdrawal

When you stop taking pentazocine capsules, 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 capsules, 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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

#### Keep this medicine out of the sight and reach of children.

Store below 25°C.

Blister packs: Store in the original package in order to protect from light and moisture.

Bottle packs: Keep the bottle tightly closed in order to protect from light and moisture.

Do not use pentazocine after the expiry date which is stated on the container after 'EXP'. 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. Contents of the pack and other information

#### What Pentazocine Capsules contain

The active substance is pentazocine hydrochloride. Each capsule, hard contains 50 mg pentazocine hydrochloride.

The other ingredients are microcrystalline cellulose, pregelatinised maize starch, calcium hydrogen phosphate dihydrous sodium metabisulfite, sodium lauryl sulfate, colloidal anhydrous, silica, magnesium stearate, croscarmellose sodium. The capsule shell contains yellow iron oxide (E172), red iron oxide (E172), titanium dioxide (E171), black iron oxide (E172) and gelatine. The printing ink also contains Shellac and titanium dioxide

#### What Pentazocine Capsules look like and contents of the pack

Your medicine comes as a hard grey/orange capsule, marked 'PT50' on one side and 'G' on the other side printed in white ink.

Pentazocine is available in containers or blister packs of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180, and 500 capsules.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

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