

## Package leaflet: Information for the patient

### Pentazocine 25 mg film-coated 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 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 (hypersensitive) 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

- **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 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 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 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
- 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
- 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.
- Have a history of or suffer from fits or seizures
- Suffer from swelling (inflammation) of the gallbladder (cholecystitis)
- Suffer from inflammation of the pancreas (pancreatitis)
- Suffer from unexplained stomach pain

##### 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:

- Other strong pain killers (e.g. morphine, diamorphine (heroin), naloxone)
- Phenothiazines (used to treat mental disorders, e.g. chlorpromazine, thioridazine)
- Monoamine oxidase inhibitors (see Warnings and precautions)
- Doxapram (used to stimulate breathing)
- Tobacco smoking
- Tricyclic antidepressants (used to treat depression, e.g. amitriptyline)

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.

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.

##### Pentazocine with alcohol

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 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 use 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 breastfeeding as pentazocine passes into breast milk and will affect your baby.

##### Driving and using machines

Pentazocine may cause sedation, dizziness and occasionally euphoria. 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 tablet, 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 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 whole with a full glass of water. The tablets should be taken after meals. Do not chew or crush the tablets.

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** - Two 25 mg tablets every four hours, after meals. If more pain relief is needed your doctor may increase your dose up to a maximum of four tablets every three to four hours after meals.

**Use in children and adolescents** - Children between the ages of 6 and 12 years old will usually be given one 25 mg tablet every 3 to 4 hours. This medicine is not recommended for children under 6 years old.

#### **Elderly patients 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 tablets with you. Signs of overdose include drowsiness, shallow breathing, low/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 tablets 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, dizziness (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 severe blistering, loss of the outer layers of skin, mouth, eyes and genitals and reddening of the skin.
- frequent wheezing, breathlessness, abdominal pain, diarrhea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)

#### **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 tired or drowsy
- 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
- palpitations
- 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)
- feeling depressed or discontented (dysphoria)
- tingling or numbness in the hands or feet (paraesthesia)
- thought disturbances
- skin rashes
- skin rashes with the formation of wheals (urticaria)
- skin rashes or inflammation (dermatitis)
- extremely small pupils of the eyes

#### **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 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 Tablets contain**

The active substance is pentazocine hydrochloride. Each tablet contains 25 mg pentazocine hydrochloride.

The other ingredients are microcrystalline cellulose, pregelatinised maize starch, calcium hydrogen phosphate, dihydrate sodium metabisulfite, sodium lauril sulfate, colloidal anhydrous silica, magnesium stearate, croscarmellose sodium. The coating contains hypromellose, titanium dioxide (E171), polyethylene glycol, carnauba wax.

#### **What Pentazocine Tablets look like and contents of the pack**

Your medicine comes as a white tablet marked with "PT" and "25" on one side and "G" on the reverse.

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 tablets

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Mylan,  
Potters Bar,  
Hertfordshire,  
EN6 1TL,  
United Kingdom.

#### **Manufacturer:**

Generics [UK] Limited,  
Potters Bar,  
Hertfordshire,  
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