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 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

Pentazocine belongs to a group of medicines called opioid analgesics. These are strong painkillers that are used to relieve moderate to severe pain.

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 swelling
- 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 Pentazocine if you:
- Are taking a monoamine oxidase inhibitor (MAO, 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 pain 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
- 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 have, have recently taken or might take any other medicines, especially any of the following:
- Other strong pain killers (e.g. morphine, diamorphine, naloxone)
- Phenothiazines (used to treat mental disorders, e.g. chlorpromazine, thioridazine)
- Monoamine oxidase inhibitors (see Warnings and precautions)
- Doxapram (used to stimulate breathing)

Pentazocine with alcohol
Do not drink alcohol whilst taking this medicine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 metabisulphite, which may rarely cause severe hypersensitivity reactions and bronchospasm

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.

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: 474614
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 take your capsules more often or for longer than your doctor advises. Too much Pentazocine can be habit forming. This is called dependence. If you stop taking your medicine suddenly it can cause withdrawal effects such as sweating, fever, weakness and muscular pains. Your doctor will help stop your medicine gradually to avoid you having these withdrawal symptoms.

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 (neutropenia).
- 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:
- light-headedness, dizziness - feeling sick, vomiting, constipation - feeling drowsy - sedation - fainting - sweating - headache - dry mouth - pins and needles - ureretic 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 impotence (failure to maintain an erection) - hypothermia (low body temperature).

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. 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.

Blisters 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, sodium hydrogen carbonate, sodium starch glycolate, magnesium stearate, colloidan anhydrous, silica, magnesium stearate, croscarmellose sodium. The capsule shell contains yellow iron oxide (E172), red 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 'P50' 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 are marketed.

Marketing Authorisation Holder

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

Manufacturer:

Mylan Laboratories Ireland Limited, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

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