Read all of this leaflet carefully before you start taking this medicine. 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. 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 tell your doctor or pharmacist.

The product is known by the name above but will be referred to as Zapain Tablets throughout the rest of this leaflet.

In this leaflet:
1. What Zapain Tablets are and what they are used for
2. Before you take Zapain Tablets
3. How to take Zapain Tablets
4. Possible side effects
5. How to store Zapain Tablets
6. Further information

1. WHAT ZAPAIN TABLETS ARE AND WHAT THEY ARE USED FOR

Zapain Tablets contain paracetamol and codeine. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other painkillers, such as paracetamol or ibuprofen alone.

Zapain Tablets are used for the relief of severe pain. Zapain Tablets can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers.

2. BEFORE YOU TAKE ZAPAIN TABLETS

Do not take with any other paracetamol-containing products. Do not take for longer than directed by your prescriber. Do not use Zapain Tablets for pain relief in children and adolescents 0-18 years of age after removal of their tonsils or adenoids as Codeine in Zapain Tablets may cause obstructive sleep apnoea syndrome (sleep disruption due to respiratory pauses). They may be at increased risk of severe side effects in case of morphine toxicity.

If any of the following side effects, you must stop taking this medicine and seek immediate medical advice:

- you feel you have taken Zapain Tablets for a long time. You may develop a dependence on this medicine.
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed).
- you have problems with your adrenal glands (Addison’s disease).
- you have a disease of the biliary tract.
- you have myasthenia gravis (muscle weakness, weakness of facial muscles including the eye muscles and difficulty in swallowing).
- you have had a head injury or suffered from increased pressure on the brain.
- you have diarrhoea.
- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last 14 days (refer to “do not take if” in section 6 above).
- you drink a lot of alcohol, or have done in the past.
- you have diarrhoea.
- you have recently had an operation to your gall bladder.
- you have a disease of the biliary tract.
- you have liver, kidney disease, or cirrhosis.
- you have any stomach pains or other sudden problems in your abdomen (belly).
- you have myasthenia gravis.
- you have severe kidney or liver disease.
- you have diarrhoea.
- you have recently had an operation to remove your tonsils or adenoids.
- you have problems with your adrenal glands (Addison’s disease).
- you have diarrhoea.
- you have a disease of the biliary tract.
- you have liver, kidney disease, or cirrhosis.
- you have any stomach pains or other sudden problems in your abdomen (belly).
- you have myasthenia gravis.
- you have severe kidney or liver disease.
- you have diarrhoea.
- you have recently had an operation to remove your tonsils or adenoids.
- you have problems with your adrenal glands (Addison’s disease).
- you have diarrhoea.
- you have a disease of the biliary tract.
- you have liver, kidney disease, or cirrhosis.
- you have any stomach pains or other sudden problems in your abdomen (belly).
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- you have severe kidney or liver disease.
- you have diarrhoea.
- you have recently had an operation to remove your tonsils or adenoids.
- you have problems with your adrenal glands (Addison’s disease).
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- you have recently had an operation to remove your tonsils or adenoids.
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- you have recently had an operation to remove your tonsils or adenoids.
- you have problems with your adrenal glands (Addison’s disease).
- you have diarrhoea.
- you have a disease of the biliary tract.
- you have liver, kidney disease, or cirrhosis.
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- you have liver, kidney disease, or cirrhosis.
- you have any stomach pains or other sudden problems in your abdomen (belly).
- you have myasthenia gravis.
- you have severe kidney or liver disease.
- you have diarrhoea.
- you have recently had an operation to remove your tonsils or adenoids.
- you have problems with your adrenal glands (Addison’s disease).
- you have diarrhoea.
- you have a disease of the biliary tract.
**Taking Zapain Tablets with food and drink**

Do not drink alcohol whilst taking Zapain Tablets. Swallow the tablets with a glass of water. Do not bite or chew the tablets.

**Pregnancy and breastfeeding**

Zapain Tablets should not be used during pregnancy as they can affect the baby and cause breathing problems when the baby is born. Do not take codeine while you are breastfeeding. Codeine and morphine pass into breast milk.

Ask your doctor or pharmacist before taking any medicine.

**Driving and using machines**

Zapain Tablets may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision.

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.

**3. HOW TO TAKE ZAPAIN TABLETS**

Always take Zapain Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Dose**

Adults: The recommended dose is one or two tablets every four to six hours when needed, up to a maximum of 8 tablets in any 24 hour period.

If you feel the effect of Zapain Tablets is too strong or too weak or your symptoms persist, speak to your doctor or pharmacist. This medicine should not be taken for more than 3 days, if the pain does not improve after 3 days, talk to your doctor for advice.

A lower dosage may be needed if you are elderly or have other medical problems.

Check with your doctor about this.

Do not take with any other paracetamol-containing products.

**Use in children and adolescents**

Children aged 16-18 years: The recommended dose is one to two tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 12-15 years: The recommended dose is one tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

Zapain Tablets should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

If you take more Zapain Tablets than you should immediately medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Bring the remaining tablets and this leaflet with you so that the medical staff knows what you have taken.

If you forget to take Zapain Tablets

Do not take more than one dose at a time. If you forget to take a dose then take your next dose at the usual time. Never take two doses at the same time.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Zapain Tablets can cause side effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other possible side effects are:

- feeling sick (nausea) and being sick (vomiting)
- light headedness, dizziness, sleepiness
- stomach pains, constipation.

Lying down may help these effects if they happen.

Other side effects include:

- a feeling of extra well being, or depression
- liver damage, especially in heavy drinkers
- restlessness or irritability
- hearing loss
- changes in blood cells, such as low number of cells which fight infection and of cells which are involved in blood clotting.

If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

**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

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

**5. HOW TO STORE ZAPAIN TABLETS**

- keep this medicine out of the sight and reach of children
- do not use Zapain Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month
- keep this medicine in a dry place
- do not store above 25˚C
- protect from light.

Medicines should not be disposed of via wastewater. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**What Zapain Tablets contain**

- the active substances are paracetamol, 500mg and codeine phosphate, 30mg
- the other ingredients are maize starch, methyl cellulose, talc, calcium stearate, povidone, purified water, hypromellose and macrogol 3350.

**What Zapain Tablets look like and contents of the pack**

Zapain Tablets are caplet shaped white tablets.

Zapain Tablets are available in aluminium blister packs or plastic containers with child resistant lids of 56, 100 or 112 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Mercury Pharmaceuticals Ltd.

Capital House, 85 King William street, London EC4N 7BL, UK

**Manufactured By:**

Haupt Pharma, Wolfratshausen GmbH, Pfaffenriederstrasse 5, 80515, Wolfratshausen, Germany

This leaflet was revised in February 2018.

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