



MercuryPharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zapain[®] 30mg/500mg Capsules

(Codeine Phosphate/Paracetamol)

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 Capsules throughout the rest of this leaflet.

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

Zapain Capsules 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 pain killers.

Zapain Capsules are used for the relief of severe pain. Zapain Capsules 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 such as paracetamol or ibuprofen alone.

2. BEFORE YOU TAKE ZAPAIN CAPSULES

Zapain Capsules should not be taken longer than as directed by your doctor. Taking codeine (an active ingredient of Zapain Capsules) regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the capsules.

If a pain killer is used too long for headaches, it can make them worse.

Do not take Zapain Capsules if

- you know that you are allergic to paracetamol or codeine, or any of the other ingredients (refer to section 6 below)
- you suffer from severe kidney or liver disease
- you know that you metabolise very rapidly codeine into morphine
- you are breast feeding
- you suffer from asthma or any other breathing problems, for example chronic bronchitis or emphysema
- you have just had a head injury or suffer from increased pressure on the brain
- you drink a lot of alcohol, or have done in the past
- you have recently had an operation to your gall bladder
- you have diarrhoea.

Do not use Zapain Capsules for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Zapain Capsules may cause obstructive sleep apnoea syndrome (sleep disruption due to respiratory pauses). Zapain Capsules should not be taken by children under 12 years of age.

Take special care and tell your doctor or pharmacist before taking Zapain Capsules if

- you are elderly or weak
- you have any stomach pains or other sudden problems in your abdomen (belly)
- you have an underactive thyroid gland
- you have kidney or liver problems, because the dose might need to be lower
- you have myasthenia gravis (muscle weakness, weakness of facial muscles including the eye muscles and difficulty in swallowing)
- you have a disease of the biliary tract
- you are suffering from decreased brain activity
- you are suffering from inflammation or obstruction of bowel
- you have experienced asthma or allergic reaction to aspirin
- you have problems with your adrenal glands (Addison's disease)
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)
- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs such as phenelzine, moclobemide or isocarboxazid are medicines used to treat depression.
- you feel you have taken Zapain Capsules for a long time. You may develop a dependence on Zapain Capsules which may be harmful.

Warnings and precautions

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Children and adolescents

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome (sleep disruption due to respiratory pauses).

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines interact with each other and this can alter their effect. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- MAOIs used to treat depression, taken within the last 14 days (refer to "take special care" in section 2 above)
- sedatives and sleeping tablets, e.g. temazepam and diazepam
- phenothiazines (medicines that calm your mood) or tricyclic antidepressants (e.g. amitriptyline)
- antipsychotics (e.g. clozapine)
- muscle relaxants (e.g. baclofen or diazepam)
- antihypertensive drugs, diuretics (water pills)
- medicines for irregular heart beats (mexiletine, quinine or quinidine)
- drugs used to dry fluids in the mouth and lungs known as anticholinergics
- medicines to treat sickness (metoclopramide, domperidone)
- medicines used to treat problems of the stomach, gall bladder, heart burn or sickness, (e.g. cimetidine, colestyramine)
- aspirin, other painkillers and strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants such as warfarin)
- medicines used to treat fits (phenytoin, phenobarbital, carbamazepine)
- antitubercular medicine (Rifampicin)
- herbal medicines containing St. John's wort (hypericum)
- patients should not take any other paracetamol containing medicines whilst taking Zapain Capsules. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

Zapain Capsules can interfere with some laboratory tests used for determining some diseases.

Taking Zapain Capsules with food and drink

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

Pregnancy and breast-feeding

Zapain Capsules should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born. Do not take codeine while you are breast feeding. Codeine and morphine passes into breast milk. Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

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

3. HOW TO TAKE ZAPAIN CAPSULES

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

Dose

The usual dosage is one or two capsules every four hours as needed. You should not take more than 8 Capsules in 24 hours. Children aged 12 years of above should take one capsule every 6 hours, as needed. Do not take more than 6 capsules in 24 hours. If you feel the effect of Zapain Capsules 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.

Zapain Capsules should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Zapain Capsules should not be taken with any other paracetamol containing product.

If you take more Zapain Capsules than you should

Immediate 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.

If you forget to take Zapain Capsules

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.

If you stop taking Zapain Capsules

Zapain Capsules can become habit forming. This is called dependence, if you stop taking your medicine suddenly it can cause symptoms such as restlessness and irritability. Your doctor will stop your capsules gradually to avoid you having these withdrawal symptoms. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zapain Capsules 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
- vision problems, headache
- slow heart rate
- slow or weak breathing, difficulty in breathing
- difficulty in passing urine, inability to empty the bladder
- allergic reactions such as skin irritation, swelling, rash, itching, swelling of face
- severe allergic reactions such as sloughing of skin, hypotension
- severe pain in the stomach with nausea and vomiting due to inflammation of pancreas(pancreatitis)
- changes in blood cells, such as low number of cells which fight infection and of cells which are involved in blood clotting resulting in tiredness, bruising easily.

Regular prolonged use of codeine is known to lead to addiction. Also, diminution in the physiological response to a drug that occurs after continued use, necessitating larger doses to produce a given response there might a need for higher dose. Symptoms of restlessness and irritability may result when treatment is then stopped.

Long-term usage of high doses of codeine + paracetamol can be rarely associated with sensorineural hearing loss.

Prolonged use of a pain killer for headaches can make them worse.

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 CAPSULES

Keep out of the reach and sight of children.

Do not use Zapain Capsules after the expiry date which is stated on the carton.

Keep this medicine in a dry place.

Do not store above 25°C.

Protect from light.

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

6. FURTHER INFORMATION

What Zapain Capsules contain

- The active substances are Paracetamol, 500mg and Codeine Phosphate, 30mg.
- The other ingredients are maize starch, sodium lauryl sulphate, talc, magnesium stearate, croscarmellose sodium, gelatin, titanium dioxide E171, erythrosine E127 and red iron oxide E172.

What Zapain Capsules look like and contents of the pack

Zapain Capsules are available in aluminium blister packs or plastic containers with child resistant lids of 56, 100 or 112 capsules.

Marketing Authorisation Holder

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