

Package leaflet: Information for the user

Zapain® 30mg/500mg Capsules codeine phosphate/ paracetamol

This medicine contains codeine 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.

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

What is in this leaflet

1. What Zapain Capsules are and what they are used for
2. What you need to know before you take Zapain Capsules
3. How to take Zapain Capsules
4. Possible side effects
5. How to store Zapain Capsules
6. Contents of the pack and other information

1. What Zapain Capsules are and what they are used for

This medicine has been prescribed for you for the relief of severe pain. Zapain Capsules contain paracetamol and codeine. It contains codeine. Codeine belongs to a class of medicines called opioid, which are 'pain relievers'. It also contains Paracetamol which is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). 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.

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 prescriber 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 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 are allergic to paracetamol or codeine, or any of the other ingredients of this medicine (listed in section 6)
- 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.

Warnings and precautions

Talk to 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

Talk to your prescriber 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 Zapain 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 prescriber 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 prescriber 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 prescriber 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 prescriber 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.

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.

Other medicines and Zapain Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

Concomitant use of Zapain Capsules 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 Zapain Capsules 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.

Zapain Capsules with food, drink and alcohol

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

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.

Pregnancy

Do not take Zapain Capsules if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Zapain 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 Zapain Capsules while you are breastfeeding as codeine passes into breast milk and will affect your baby.

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.

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.

Zapain Capsules contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage, that is to say essentially 'sodium-free'.

3. How to take Zapain Capsules

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 prescriber 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.

The recommended dose is one or two capsules every four to six hours as required up to a maximum of 8 capsules in any 24 hour period.

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 with any other paracetamol containing product.

Use in children and adolescents

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

Children aged 12 – 15 years: the recommended dose is one capsule every 6 hours when necessary up to a maximum of 4 capsules in 24 hours.

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

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.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Zapain Capsules

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber 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.

Stop taking the medicine and seek immediate medical advice if you notice the following:

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:**Uncommon: may affect up to 1 in 100 people**

- Drug Withdrawal

When you stop taking Zapain 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

Not known: frequency cannot be estimated from the available data

- 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.
- dependence and addiction (see section “How do I know if I am addicted?”).

How do I know if I am addicted?

If you notice any of the following signs whilst taking Zapain Capsules, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- 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 prescriber.

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.

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 website: 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 Zapain Capsules

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP.

Keep this medicine in a dry place.

Do not store above 25°C.

Protect from light.

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 to protect the environment.

6. Contents of the pack and other 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 50, 56, 100 or 112 capsules.

Marketing Authorisation Holder

Mercury Pharmaceuticals Ltd.,

Dashwood House, 69 Old Broad Street, London, EC2M 1QS, UK.

Manufacturer

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