

BXP064BPG

PATIENT INFORMATION LEAFLET

Codasolve 8mg/500mg/30mg Effervescent Tablets (Codeine, Paracetamol and Caffeine)

The name of this medicine is Codasolve 8mg/500mg/30mg Effervescent Tablets. This medicine will be referred to as Codasolve Effervescent Tablets throughout this leaflet.

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.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4.
- This medicine can only be used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice.
- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take this medicine for headaches for more than three days it can make them worse.

What is in this leaflet:

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

1. WHAT CODASOLVE EFFERVESCENT TABLETS ARE AND WHAT THEY ARE USED FOR

Codasolve Effervescent Tablets contain the active ingredients codeine phosphate hemihydrate 8 mg, paracetamol 500 mg and caffeine 30 mg.

This medicine can be used in patients over 12 years of age for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. They are used to relieve migraine, headache, dental pain, period pain, backache, rheumatic pain, strains and sprains, and sciatica.

Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Paracetamol is another analgesic to relieve pain. Caffeine acts to further help the effectiveness of paracetamol.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CODASOLVE EFFERVESCENT TABLETS

This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it. This medicine contains paracetamol.

Do not take anything else containing paracetamol while taking this medicine. If you take a painkiller for headaches for more than three days it can make them worse.

If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued. The diagnosis of medication overuse headache should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

Do not take Codasolve Effervescent Tablets:

- if you are allergic (hypersensitive) to paracetamol, codeine, caffeine, other opioid painkillers or any of the other ingredients in the tablets (these are listed in Section 6, Contents of the pack and other Information).
- if you are taking or have recently taken any other paracetamol or codeine containing products.
- if you know that you metabolise very rapidly codeine into morphine
- If you are pregnant or breast-feeding
- If you have respiratory depression or chronic constipation.

If you are under 12 years:

- **Not recommended for use in children under 12 years of age.**

If you are over 12 years:

- Not recommended in all paediatric patients (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome because of an increased risk of developing serious and life-threatening adverse reactions
- **Codasolve Effervescent Tablets are not recommended in children and adolescents between 12 and 18 years who have breathing problems.**

Other medicines and Codasolve Effervescent Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Certain medicines can interfere with the effectiveness of each other.

It is particularly important to tell your doctor or pharmacist before taking this medicine if you are also on:

- metoclopramide or domperidone (for sickness or stomach problems)
- colestyramine (used to treat high cholesterol)
- monoamine oxidase inhibitors (MAOIs) (used to treat depression)
- probenecid (used to treat gout and hyperuricemia)
- pregabalin and gabapentin (increased risk of respiratory depression)
- blood thinning medicines (anti coagulants) such as warfarin and you need to take a painkiller on a daily basis over a long period. However, you can take occasional doses of Codasolve Effervescent Tablets.

Do not take Codasolve Effervescent Tablets if you are taking or have recently taken any other paracetamol or codeine containing products.

It may still be alright for you to take Codasolve Effervescent Tablets and your doctor will be able to decide what is suitable for you.

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment, and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Pharmacode

Warnings and precautions

Talk to your doctor or pharmacist before taking Codasolve Effervescent Tablets:

- If you have severe liver or kidney disease, including alcoholic liver disease.
- If you have bowel problems including blockage of the bowel.
- If you have had an operation to remove your gall bladder.
- if your headaches become persistent, see your doctor.
- If you have hypotension or hypothyroidism
- If you have experienced a recent head injury or raised intracranial pressure
- If you have asthma and have been told by your doctor that you are sensitive to aspirin
- If you have Gilbert's Syndrome (familial non-haemolytic jaundice)
- if you are taking other medicines that can affect liver function
- if you have glucose-6-phosphatase dehydrogenase deficiency
- if you have haemolytic anaemia
- if you have glutathione deficiency
- if you are dehydrated
- if you have a poor diet such that the diet causes health problems
- if you weigh less than 50kg
- if you are elderly
- if you have a condition called myasthenia gravis which weakens the muscles

They may reduce your dose or increase the time interval between doses of your medicine.

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.**

Talk to your doctor or pharmacist before taking Codasolve Effervescent Tablets:

- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- if you feel you need to take more of Codasolve Effervescent 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.

Taking higher doses or more frequent doses of opioids, such as codeine (an active ingredient of this medicine), may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Rarely, increasing the dose of this medicine can make you more sensitive to pain.

If this happens, you need to speak to your doctor or pharmacist about your treatment. Please refer Section 3 'How to take Codasolve Effervescent Tablets' for information on correct dosages and time intervals.

Do not take this medicine continuously for longer than 3 days.

Pharmacode

Possible withdrawal effect:

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. If you become addicted, when you stop taking it you may get withdrawal symptoms. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling of being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. You should talk to your doctor if you think you are suffering from withdrawal symptoms.

Codasolve Effervescent Tablets with food and drink

Codasolve Effervescent Tablets should be dissolved in at least half a glass of water and can be taken with or without a meal.

You should avoid drinking too much coffee or tea when taking these tablets.

Pregnancy, breast-feeding and fertility

Do not take Codasolve Effervescent 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 Codasolve Effervescent Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated. Do not take Codasolve Effervescent Tablets while you are breastfeeding.

Codeine and Morphine passes into breast milk and will affect your baby.

Do not use whilst breast-feeding unless advised by your doctor.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machinery

This 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 taken to treat a medical or dental problem and
- You have taken it according to 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. Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: www.gov.uk/drug-driving-law

Important information about some of the ingredients of Codasolve Effervescent Tablets

Each of these tablets contains about 403.24 mg of sodium per tablet. This is equivalent to 20.2% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your pharmacist or doctor if you need Codasolve Effervescent Tablets on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

This medicine contains 4.5mg of aspartame in each Codasolve Effervescent Tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. HOW TO TAKE CODASOLVE EFFERVESCENT TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not take for more than 3 days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist for advice.

Do not take anything else containing paracetamol while taking this medicine.

Dosage:

Adults: One to two tablets dissolved in water not more frequently than every 4-6 hours when necessary to a maximum of 8 tablets in 24 hours.

Elderly: Same as adult dose. A reduced dose may be required.

Paediatric population:

Children aged 16-18 years: One to two tablets dissolved in water every 6 hours when necessary to a maximum of 8 tablets in 24 hours.

Children aged 12-15 years: One tablet dissolved in water every 6 hours when necessary to a maximum of 4 tablets in 24 hours.

Avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.

Not recommended for use in children under 12 years of age.

Not recommended for children and adolescents between 12 and 18 years who have breathing problems.

Method of Administration

For oral administration only. These tablets should be dissolved in at least half a glass of water before taking them. Stir before use. The solution should be drunk immediately after preparation. These tablets are meant to be dissolved first so don't try to swallow them whole.

If you take more Codasolve Effervescent Tablets than you should

If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**.

Remember to take the pack and any remaining tablets with you.

The most common symptoms of overdose are nausea (feeling sick), vomiting (being sick) and stomach pain. You may also notice a rapid heartbeat.

Talk to a doctor at once if you take too much of this medicine even if you feel well.

This is because too much paracetamol can cause delayed, serious liver damage.

Withdrawal symptoms

This medicine contains codeine and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get withdrawal symptoms.

You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

If you have any further questions about this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

If you get any of the following symptoms after taking these tablets, **you should contact your doctor immediately:**

- any sudden wheeziness, difficulty in breathing or dizziness, nervousness, irritability or restlessness, swelling of the eyelids, face, lips or throat.
- an acute allergic reaction (anaphylaxis) or swelling of the skin
- severe abdominal pain, nausea and vomiting if you have recently had your gall bladder removed
- unexplained bruising or bleeding
- nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin
- very rare cases of serious skin reactions have been reported (Skin rash or peeling or mouth ulcers)
- difficulty in urination or cloudy urine

The following side effects have also been reported:

- constipation
- dry mouth
- worsening of headache
- drowsiness
- itching
- sweating
- vomiting (not following gall bladder removal as above)

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

How do I know if I am addicted?

If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:

- You need to take the medicine for longer periods of time
- You need to take more than the recommended dose
- When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again.

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 directly via the yellow card scheme at 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 CODASOLVE EFFERVESCENT TABLETS

Keep all medicines out of the sight and reach of children.

Do not take this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C. Store in the original package.

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 Codasolve Effervescent Tablets contain:

The active ingredients are codeine phosphate hemihydrate, paracetamol and caffeine. Each tablet contains codeine phosphate hemihydrate 8 mg, paracetamol 500 mg and caffeine 30 mg.

The other ingredients are anhydrous citric acid, povidone, sodium hydrogen carbonate, sodium saccharin, anhydrous sodium carbonate, simeticone, polysorbate 80 and aspartame (E951).

What Codasolve Effervescent Tablets look like and the contents of the pack:

Codasolve Effervescent Tablets are white, circular, flat bevelled effervescent tablets, which are plain on both sides.

Your medicine is available in blister packs of 16, 24 or 32 tablets.

Marketing Authorisation Holder:

Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer responsible for batch release:

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, England.

This information is available in alternative formats upon request.

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