

Paracetamol/caffeine/Codeine (32 tab.)
Size - 297 x 210 mm
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GSM paper : NLT 60gsm

Paracetamol/caffeine/Codeine (32 tab.)
Size - 297 x 210 mm
OPP inventory code & artwork representation as
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Customer: Fannin PL 20417/0064
Product Name: Codosolve 8mg/500mg/30mg Effervescent Tablets
Change: Codosolve - Brand Review CCRF 19032
Code: BXP064BPB
Colour: Pantone Black C
Size: 297 x 210mm Proof: 2
Date: 09 Jul 19 SCY (AWG)

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PATIENT INFORMATION LEAFLET

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

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

Read all of this leaflet carefully because it contains important information for you.

- 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.
- Keep this leaflet. You may need to read it again.

In this leaflet:

1. What Codosolve Effervescent Tablets are and what they are used for
2. Before you take Codosolve Effervescent Tablets
3. How to take Codosolve Effervescent Tablets
4. Possible side effects
5. How to store Codosolve Effervescent Tablets
6. Further information

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

Codosolve 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.

2. 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. If you take a painkiller for headaches for more than three days it can make them worse.

Do not take Codosolve 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, Further Information).
- are **taking or have recently taken any other paracetamol or codeine containing products.**
- If you are under 12 years:
For pain relief in children and adolescents (0-18 years of age) after **removal of their tonsils or adenoids** due to **obstructive sleep apnoea syndrome**
- This medicine is not recommended in children and adolescents between 12 and 18 years who have breathing problems.
- If you know that you **metabolise very rapidly codeine into morphine**

Take special care with Codosolve Effervescent Tablets

Please see your doctor before you take Codosolve Effervescent Tablets if you:

- **have severe liver or kidney disease**, including alcoholic liver disease.

- have **bowel problems** including blockage of the bowel.
- have had an **operation to remove your gall bladder**.

If your headaches become persistent, see your doctor.

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. 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)
- blood thinning medicines (anticoagulants) 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 Codosolve Effervescent Tablets.

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

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

Taking your medicine with food and drink

Codosolve 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.

Fertility, pregnancy and breast-feeding

Please see your doctor before you take this medicine if you are pregnant or likely to become pregnant. 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 Codosolve 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 paracetamol, codeine, caffeine 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 Codosolve 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. advice.

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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.

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 Codosolve 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, 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**
- **difficulty in urination**

The following side effects have also been reported:

- constipation
- dry mouth
- worsening of headache
- drowsiness

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- 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

Do not store your tablets above 25°C. Store in the original package. Do not take this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

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

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

6. FURTHER INFORMATION

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

Codosolve 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:

Fannin (UK) Limited, DCC Vital, Westminster Industrial Estate, Repton Road, Measham, DE12 7DT, England.

Manufacturer responsible for batch release:

Fannin (UK) Limited, DCC Vital, Westminster Industrial Estate, Repton Road, Measham, DE12 7DT, England.

This information is available in alternative formats upon request.

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This leaflet was last revised in June 2019.

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10 mm free space for Laetus Pharmacode System