PATIENT INFORMATION LEAFLET

CO-CODAMOL EFFERVESCENT TABLETS 8/500 mg

The name of this medicine is Co-codamol Effervescent Tablets 8/500 mg, which will be referred to as Co-codamol 8/500 throughout this leaflet.

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

In this leaflet:
1. What Co-codamol 8/500 are and what they are used for
2. Before you take Co-codamol 8/500
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4. Possible side effects
5. How to store Co-codamol 8/500
6. Further information

1. WHAT CO-CODAMOL 8/500 ARE AND WHAT THEY ARE USED FOR

The active ingredients in Co-codamol 8/500 are paracetamol and codeine phosphate hemihydrate.

Codeine can be used in children over 12 years of age for short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

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.

Co-codamol 8/500 is used to relieve pain, including muscular and rheumatic pain, headache, migraine, neuralgia (severe burning or stabbing pain following the line of a nerve), toothache, sore throat, period pains, aches and pains, discomfort associated with influenza (flu), feverishness and feverish colds.

2. BEFORE YOU TAKE CO-CODAMOL 8/500

Do not take Co-codamol 8/500 if you:

- Know that you metabolise very rapidly codeine into morphine
- Are breast feeding
- Are a child under 12 years old
- Are allergic (hypersensitive) to paracetamol, codeine or any of the other ingredients in the tablets (these are listed in Section 6. Further information)
- Are already taking other medicines containing paracetamol
- Have a dependency to alcohol
- Suffer from acute asthma or other lung disease
- Have raised intracranial pressure or head injury
- Are on a low sodium diet
- Have bowel or prostate problems
- Are receiving monoamine oxidase inhibitor (MAOI) therapy

Talk to your doctor if you:

- Have liver or kidney problems

Take special care with Co-codamol 8/500 if you:

- Have an under-active thyroid gland
- Have a disease of the Adrenal gland called Addison’s disease.
- Have a condition which weakens the muscles called myasthenia gavis.
- Are elderly
- Feel weak
- Are debilitated
- Do not take for longer than directed by your prescriber.
- Taking codeine regularly for a long period of time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.

Taking Co-codamol tablets for too long can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.

Taking other medicines
Do not take these tablets if you are already taking other medicines containing paracetamol.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, as they may decrease or increase the effect of Co-codamol 8/500:

- Metadeparine or dornopar (often taken for sicknes or stomach problems)
- Colestyramine (for high blood lipid levels)
- Analgesics to reduce blood clotting (e.g. warfarin)
- MAO’s and CNS depressants such as sleeping tablets, sedatives and some antihistamines

It may still be all right for you to take Co-codamol 8/500 and your doctor will be able to decide what is suitable for you.

Taking your medicine with food and drink

Co-codamol 8/500 should be dissolved in at least half a glass of water and can be taken with or without a meal.

Pregnancy, breast-feeding and fertility

Although there is no evidence that these tablets cause any ill effects during pregnancy, your doctor should advise you about taking them if you are pregnant.

Do not take codeine while you are breast feeding. Codeine and morphine pass into breast milk.

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

Driving and using machinery
These tablets may make you feel dizzy or drowsy and if this happens do not drive or operate machinery.

Important information about some of the ingredients of Co-codamol 8/500
Each of these tablets contains about 438 mg of sodium and may interfere if you are on a low sodium diet.

This product also contains aspartame (a source of phenylalanine), which should not be given to anyone with phenylketonuria.
3. HOW TO TAKE CO-CODAMOL 8/500

Do not exceed the recommended doses. If painful symptoms are not relieved in a few days, consult your doctor.

Dosage
The usual doses for Co-codamol 8/500 are as follows:

Adults:
Should take 1 or 2 tablets dissolved in water every 4-6 hours, as needed. Do not take more than 8 tablets in 24 hours.

Children over 12 years:
Children aged 12 years and above should take 1 or 2 tablets dissolved in water every 6 hours, as needed. Do not take more than 8 tablets in 24 hours.

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.

Co-codamol 8/500 should not be taken by children below the age of 12 years, due to the risk of severe 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. These tablets are meant to be dissolved first so don't try to swallow them whole.

If you take more Co-codamol 8/500 than you should
Talk to your 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. Remember to take the pack and any remaining tablets with you.

If you are giving this medicine to a child, immediate medical advice should be sought in the event of overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

If you forget to take Co-codamol 8/500
If you forget to take one or more doses, take your next dose when you remember and then go on as prescribed. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-codamol 8/500 can cause side effects although not everybody 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.

The following effects have been reported:

- Mood changes
- Severe stomach pains (pancreatitis)
- Stomach pains
- Deafness
- Problems with the blood (thrombocytopenia and agranulocytosis). This is usually shown by tiredness, weakness, or unexplained bruising or bleeding. This side effect is very rare.
- Skin rashes
- Constipation
- Nausea, vomiting
- Light-headedness, dizziness
- Confusion
- Drowsiness

- Urinary retention
- Rarely pancreatitis (inflammation of the pancreas which may cause severe abdominal pain that can spread through to your back)

There have been very rare reports of blood problems, so if you notice unusual bleeding or you bruise easily, tell your doctor as soon as possible.

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

5. HOW TO STORE CO-CODAMOL 8/500

Do not store your tablets above 25°C. Store in a dry place and protect from light.

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 Co-codamol 8/500 mg Effervescent Tablets contain:
The active ingredients are paracetamol and codeine phosphate hemihydrate. Each tablet contains 500mg paracetamol and 8mg codeine phosphate hemihydrate.

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

What Co-Codamol 8/500 look like and the contents of the pack:
Co-codamol 8/500 mg Effervescent Tablets are white, circular, with a flat bevelled edge and plain on both sides. Your medicine is available in blister packs of 100 tablets.

Marketing Authorisation Holder:
Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough, Northamptonshire, NN8 6GT, UK.

Manufacturer responsible for batch release:
Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough, Northamptonshire, NN8 6GT, UK.

This leaflet was last approved in August 2014.
Packaging Development

Product Name: Co-codamol 8-500 PIL (POM)
Item Code: 6682 Q
Item: PIL
Date: 21-06-13 (21-10-13)

Coordinate: Kanchan
AVM: Atul
Software: Illustrator CS5
Fonts: Arial
Colours:
- BLUE WOOL TEST VALUE 5-8 LIGHT FASTENING DATA

Ink - Oil based inks from DIC/MICRO

- Spectro-Densitometer Delta-E reading (for colour: NOT MORE THAN dE2.5)
- Glossmeter reading (for white surface): NOT LESS THAN 80%

Supersedes / Reference:
Screen: # 150
Unwinding Direction:
Tuck flap: Side / Collar flap overlap: Caliper (Thickness) for Board:

Material:
- 42 GSM TFC Paper with plain perforated tear here tape.

Actual Size: 335 x 250mm
Print repeat length:
Grain Direction:
- Perpendicular to Crease / Perpendicular to Pasting Flap / Parallel to length

Actual Size: 335 x 250mm
Print repeat length:
Grain Direction:
- Perpendicular to Crease / Perpendicular to Pasting Flap / Parallel to length

Pharmaco Code: 221, mini
Design: Folded
Varnish:

Caliper (Thickness) for Board:

Pharmacy Code
2D Code
Barcode Code
Artwork
Spell check

Artwork Print Size:          actual           scaled
Path: F:atul/Pawan/Fannin/Co-codamol Effer Tab.Fannin/6682 Q Co-codamol 8-500 PIL Piggy Pack Fannin CODA Add change AXP029FUB (POM)
Checked by: Artist          Coordinator          Section Head          File Copied by:         File loaded in BCT HO

NOTE TO THE PRINTER:
- Return approved artwork along with the proof.
- The proof must be verified against the approved hardcopy, should be certified and signed by an authorised QA person. The unsigned proof will not be accepted.
- Colour scheme must be as approved by packaging development co-ordinator.
- Any deviation must be brought to the notice of packaging development co-ordinator immediately.
- For any clarification, please contact packaging development co-ordinator immediately.