

PATIENT INFORMATION LEAFLET

Co-codamol 30mg/500mg CAPSULES

Codeine Phosphate and 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 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
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

In this leaflet:

1. What co-codamol is and what it is used for
2. Before you take co-codamol
3. How to take co-codamol
4. Possible side effects
5. How to store co-codamol
6. Further information

1. WHAT CO-CODAMOL IS AND WHAT IT IS USED FOR

The name of your medicine is Co-codamol 30mg/500mg Capsules (called co-codamol throughout this leaflet). Co-codamol contains two different medicines called codeine phosphate and paracetamol. It belongs to a group of medicines called analgesics (painkillers) and is used to treat severe pain.

2. BEFORE YOU TAKE CO-CODAMOL

Important things you should know about co-codamol

- Do not take for longer than your doctor tells you to
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the capsules
- Taking a painkiller for headaches too often or for too long can make them worse

Do not take co-codamol and tell your doctor if:

- You are allergic (hypersensitive) to codeine, paracetamol or any of the other ingredients in your medicine (listed in Section 6: Further information)
Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue
- You have severe asthma attacks or severe breathing problems
- You have recently had a head injury
- You have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred vision
- You have recently had an operation on your liver, gallbladder or bile duct (biliary tract)
- You are taking medicine to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypamine (see 'Taking other medicines')
- You are an alcoholic
- The person going to take the capsules is under 12 years of age. Co-codamol must not be given to children under 12 years of age

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Do not take co-codamol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking co-codamol.

Take special care and check with your doctor before taking co-codamol if:

- You have severe kidney or liver problems
- You have problems passing water or prostate problems
- You have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel
- You are elderly

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because co-codamol can affect the way some other medicines work. Also, some other medicines can affect the way co-codamol works.

While taking co-codamol you should not take any other medicines which contain paracetamol.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Do not take this medicine, and tell your doctor, if you are taking

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypamine

Tell your doctor if you are taking any of the following medicines:

- Medicines which make you drowsy or sleepy (CNS depressants)
- Medicines used to thin the blood such as warfarin
- Chloramphenicol - an antibiotic used for infections
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Colestyramine - for lowering blood cholesterol levels
- The oral contraceptive pill

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking co-codamol.

Taking co-codamol with food and drink

You should not drink alcohol while you are taking these capsules. This is because taking co-codamol can change the way alcohol affects you.

Pregnancy and breast-feeding

Talk to your doctor before taking these capsules if:

- You are pregnant, think you may be pregnant or plan to get pregnant
- You are breast-feeding or planning to breast-feed

Usually it is safe to take co-codamol while breast feeding as the levels of the active ingredients of this medicine in breast milk are too low to cause your baby any problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels in their breast milk. If any of the following side effects develop in you or your baby, stop taking this medicine and seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

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Driving and using machines

You may feel dizzy or sleepy while taking co-codamol. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of your co-codamol capsules

Azorubine: This may cause allergic reactions.

Changing or stopping treatment

Chronic usage of co-codamol may lead to tolerance and dependence. If you have taken regular daily doses of co-codamol for a long time, do not increase the dose or suddenly stop treatment without discussing this with your doctor.

3. HOW TO TAKE CO-CODAMOL

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

- Do not take more than the recommended dose
- Do not take for longer than your doctor tells you to

Adults and children over 12

- The usual dose of co-codamol is 2 capsules, taken together
- Take this medicine by mouth
- Swallow the capsules whole with a drink of water
- Wait at least 4 hours before taking another dose
- Do not take more than 8 capsules in any 24-hour period
- Elderly people may be prescribed a lower dose

Children

Co-codamol should not be given to children under 12 years of age.

If you take more co-codamol than you should

- Tell your doctor or go to your nearest hospital casualty department straight away - even if you feel well. This is because of the risk of delayed, serious liver damage
- Remember to take any remaining capsules and the pack with you. This is so the doctor knows what you have taken

If you have forgotten to take co-codamol

If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take two doses at or near the same time. Remember to leave at least 4 hours between doses.

4. POSSIBLE SIDE EFFECTS

As with all medicines, co-codamol can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Important side-effects you should know about co-codamol

- Taking a painkiller for headaches too often or for too long can make them worse.
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the capsules

Stop taking co-codamol and see a doctor or go to a hospital straight away if:

- You have difficulty in breathing or you feel dizzy
 - You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria)
- This may mean you are having an **allergic reaction** to co-codamol

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Talk to your doctor straight away if you notice the following serious side effect:

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- Constipation
- Feeling sick (nausea), being sick (vomiting)
- Dizziness, light-headedness, drowsiness, confusion
- Difficulty in passing water
- Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)

If any of the side effects gets serious, lasts longer than a few days or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CO-CODAMOL

Keep this medicine in a safe place out of the reach and sight of children.

Do not use this medicine after the expiry date shown on the pack.

Store your medicine in the original packaging in order to protect from moisture.

Do not store above 25°C.

Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

6. FURTHER INFORMATION

What Co-codamol 30mg/500mg Capsules contain

- The active substances of Co-codamol 30mg/500mg Capsules are codeine phosphate and paracetamol. Each tablet contains 30mg of codeine phosphate and 500mg of paracetamol
- The other ingredients are, maize starch, indigotine (E132), azorubine (E122), titanium dioxide (E171), gelatin, black iron oxide (E172), shellac, propylene glycol, talc and magnesium stearate.

What Co-codamol 30mg/500mg Capsules look like and contents of pack

Co-codamol 30mg/500mg Capsules are grey and purple printed with the word 'SOLPADOL' in black ink.

They come in cartons of 100 capsules.

The Marketing Authorisation Holder is

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK.

The Manufacturer is

FAMAR HEALTH CARE SERVICES MADRID, S.A.U.

Avda. Leganés, 62

Alcorcón 28923 (Madrid)

Spain

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|---|--|------------------------------------|--|---|--|
| Product Description: CO-CODAMOL 30/500 mg | | | | Pantone Black  | |
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| Country: UK | | Folder n°: 844486 | | | |
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