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 30/500 Effervescent Tablets contain
- The active substances of Co-codamol 30/500 Effervescent Tablets are codeine phosphate and paracetamol. Each tablet contains 30mg of codeine phosphate and 500mg of paracetamol
- The other ingredients are sodium bicarbonate, anhydrous citric acid, anhydrous sodium carbonate, sorbitol powder, saccharin sodium, povidone, dimeticone and sodium lauryl sulphate

What Co-codamol 30/500 Effervescent Tablets look like and contents of pack
Co-codamol 30/500 Effervescent Tablets are white bevelled-edge tablets, scored on one face. They are supplied in cartons of 100 tablets.

The Marketing Authorisation Holder is
Winthrop Pharmaceuticals, PO Box 611, Guildford, Surrey, GU1 4YS, UK.
The Manufacturer is
Fawdon Manufacturing Centre, Edgefield Avenue, Fawdon, Newcastle upon Tyne, NE3 3TT, UK.
This leaflet was last updated in November 2010.

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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 on the shelf.

Do not take this medicine and tell your doctor or pharmacist if you are taking the following:
- 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, tranylcypromine

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 tablets. This is because co-codamol can change the way alcohol affects you.

Pregnancy and breast-feeding
Talk to your doctor before taking these tablets if:
- You are pregnant, think you may be pregnant or plan to get pregnant
- 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, diarrhoea, decreased or lack of appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

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 tablets
- Sodium: There is slighting of sodium per effervescent tablet. This may be harmful to people on a low sodium or low salt diet
- Sorbitol: This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine

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 effervescent tablets, taken together
- Dissolve the effervescent tablets in at least half a glass of water before taking
- Wait at least 4 hours before taking another dose
- Do not take more than 8 effervescent tablets 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
- 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
- Remember to take any remaining tablets 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 tablets.

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

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, it affects less than 1 in 10,000 people
**Important information about some of the ingredients of your co-codamol tablets**

- **Sodium:** There is 388mg of sodium per effervescent tablet. This may be harmful to people on a low sodium or low salt diet.
- **Sorbitol:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

**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 for longer than your doctor tells you to.
- The usual dose of co-codamol is 2 effervescent tablets, taken together.
- Dissolve the effervescent tablets in at least half a glass of water before taking.
- Wait at least 4 hours before taking another dose.
- Do not take more than 8 effervescent tablets in any 24-hour period.
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- 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.
- Remember to take any remaining tablets 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.

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- 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 tablets.

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

- You are pregnant, think you may be pregnant or plan to get pregnant.
- 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

**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 tablets

- **Sodium:** There is 388mg of sodium per effervescent tablet. This may be harmful to people on a low sodium or low salt diet.
- **Sorbitol:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

**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 for longer than your doctor tells you to.
- The usual dose of co-codamol is 2 effervescent tablets, taken together.
- Dissolve the effervescent tablets in at least half a glass of water before taking.
- Wait at least 4 hours before taking another dose.
- Do not take more than 8 effervescent tablets 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:

- 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.
- Remember to take any remaining tablets 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 tablets.

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

- You are pregnant, think you may be pregnant or plan to get pregnant.
- 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

**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.
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 30/500 Effervescent Tablets contain**

- The active substances of Co-codamol 30/500 Effervescent Tablets are codeine phosphate and paracetamol. Each tablet contains 30mg of codeine phosphate and 500mg of paracetamol.
- The other ingredients are sodium bicarbonate, anhydrous citric acid, anhydrous sodium carbonate, sorbitol powder, saccharin sodium, povidone, dimeticone and sodium lauryl sulphate.

**What Co-codamol 30/500 Effervescent Tablets look like and contents of pack**

Co-codamol 30/500 Effervescent Tablets are white bevelled-edge tablets, scored on one face. They are supplied in cartons of 100 tablets.

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The Manufacturer is

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**PATIENT INFORMATION LEAFLET**

**CO-CODAMOL 30/500 EFFERVESCENT TABLET**

**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 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.
- 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**

The name of your medicine is Co-codamol 30/500 Effervescent Tablets (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.
- Do not take codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
- 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 lips, face, throat or tongue.
  - You have severe asthma attacks or severe breathing problems.
  - You have 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 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 and tranylcypromine.
  - You are an alcoholic.
  - The person going to take the tablets is under 12 years of age. Co-codamol must not be given to children under 12 years of age.

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.

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**Winthrop Pharmaceuticals**

**Brand:** LLET CO-CODAMOL 30 500 EFF

**Category:** LEAFLET

**Argus Code:** 264

**Spec No:** 30309406

**Supersedes:** 30309405

**Core Spec No:** 60101300

**Ticket No:** 283480

**Core Spec No:** 60101300

**Barcode:** N/A

**Mag:** N/A

**Win/RFL Ref:** RFL 024

**Fonts:** Helvetica

**Krafts: 1 of 2**

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**Winthrop Pharmacist/Medical Affairs**

Approved: Yes

Date: Signature:

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**Winthrop Regulatory Affairs**

Approved: Yes

Date: Signature:

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**Signature:**