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MercuryPharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-codamol 30mg/500mg Tablets

Codeine Phosphate/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, 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 become 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 30/500 Tablets are and what they are used for
2. Before you take Co-codamol 30/500 Tablets
3. How to take Co-codamol 30/500 Tablets
4. Possible side effects
5. How to store Co-codamol 30/500 Tablets
6. Further information

1. WHAT CO-CODAMOL 30/500 TABLETS ARE AND WHAT THEY ARE USED FOR

Co-codamol 30/500 Tablets contain paracetamol and codeine. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). 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 pain killers.

Co-codamol 30/500 Tablets are used for the relief of severe pain. Co-codamol 30/500 Tablets can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

2. BEFORE YOU TAKE CO-CODAMOL 30/500 TABLETS

Do not take with any other paracetamol-containing products. Do not take for longer than directed by your prescriber. Do not use Co-codamol 30/500 Tablets for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Co-codamol 30/500 Tablets may cause obstructive sleep apnoea syndrome (sleep disruption due to respiratory pauses). 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. Taking a painkiller for headaches too often or for too long can make them worse.

Do not take Co-codamol 30/500 Tablets if:

- you know that you are allergic to paracetamol or codeine, or any of the other ingredients (refer to section 6 below)
- you suffer from severe kidney or liver disease
- you know that you metabolise very rapidly codeine into morphine
- you are breast-feeding
- you suffer from asthma or any other breathing problems, for example chronic bronchitis or emphysema
- you have just had a head injury or suffer from increased pressure on the brain
- you drink a lot of alcohol, or have done in the past
- you have recently had an operation to your gall bladder
- you have diarrhoea
- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs such as phenelzine, moclobemide or isocarboxazid are medicines used to treat depression.

Co-codamol 30/500 Tablets should not be taken by children under 12 years of age.

Take special care and tell your doctor or pharmacist before taking Co-codamol 30/500 Tablets if:

- you are elderly or weak
- you have any stomach pains or other sudden problems in your abdomen (belly)
- you have an underactive thyroid gland
- you have liver, kidney problems, because the dose might need to be lower
- you have myasthenia gravis (muscle weakness, weakness of facial muscles including the eye muscles and difficulty in swallowing)
- you have a disease of the biliary tract
- you have problems with your adrenal glands (Addison's disease)
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)
- you feel you have taken Co-codamol 30/500 Tablets for a long time. You may develop a dependence on Co-codamol 30/500 Tablets which may be harmful.

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.

Warnings and precautions

Children and adolescents

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome (sleep disruption due to respiratory pauses). They may be at increased risk of severe side effects in case of morphine toxicity.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

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. Some medicines interact with each other and this can alter their effect. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- MAOIs used to treat depression, taken within the last 14 days (refer to “do not take if” in section 2 above)
- sedatives and sleeping tablets, e.g. temazepam and diazepam
- phenothiazines (medicines that calm your mood) or tricyclic antidepressants
- antihypertensive drugs, diuretics (water pills)
- medicines for irregular heart beats (mexiletine, quinine or quinidine)
- drugs used to dry fluids in the mouth and lungs known as anticholinergics
- medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
- medicines used to treat problems of the stomach, gall bladder, heart burn or sickness (e.g. cimetidine, colestyramine)
- sodium oxybate used to treat sleepiness and sudden loss of muscle tone
- other strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants such as warfarin)
- patients should not take any other paracetamol containing medicines whilst taking Co-codamol 30/500 Tablets. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

Co-codamol 30/500 Tablets can interfere with some laboratory tests used for determining some diseases.

Taking Co-codamol 30/500 Tablets with food and drink

Do not drink alcohol whilst taking Co-codamol 30/500 Tablets. Swallow the tablets with a glass of water. Do not bite or chew the tablets.

Pregnancy and breast-feeding

Co-codamol 30/500 Tablets should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born. Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk.



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Version No:	100154/LF/027/07
Product Name:	Co-codamol 30mg/500mg Tablets
Pack Size:	100 Tablets
Component:	Leaflet
SKU:	100154
Market:	UK
Production Site:	Bristol
Revision No.:	2
Revision Date:	01/03/2017
Revised by:	PAT
CRF:	PR 8719

Dimension:	180 X 430 mm
Commodity No.:	N/A
Pharma Code:	N/A
Core Spec Ref:	N/A
DCMF:	N/A
Print Colours:	Black

Non-Print Colours: Cutter

Tech App. Date:	08/03/2017
Min. Font Size:	8.5 pt

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Signature

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Date

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Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

Co-codamol 30/500 Tablets may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision.

The 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 prescribed to treat a medical or dental problem and
 - you have taken it according to the instructions given by the prescriber or in 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.

3. HOW TO TAKE CO-CODAMOL 30/500 TABLETS

Always take Co-codamol 30/500 Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dose

Adults: The recommended dose is one or two tablets every four to six hours when needed, up to a maximum of 8 tablets in any 24 hour period.

If you feel the effect of Co-codamol 30/500 Tablets is too strong or too weak or your symptoms persist, speak to your doctor or pharmacist. 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.

A lower dosage may be needed if you are elderly or have other medical problems.

Check with your doctor about this.

Do not take with any other paracetamol-containing products.

Use in children and adolescents

Children aged 16-18 years: The recommended dose is one to two tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 12 – 15 years: The recommended dose is one tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

Co-codamol 30/500 Tablets should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

If you take more Co-codamol 30/500 Tablets 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. Bring the remaining tablets and this leaflet with you so that the medical staff knows what you have taken.

If you forget to take Co-codamol 30/500 Tablets

Do not take more than one dose at a time. If you forget to take a dose then take your next dose at the usual time. Never take two doses at the same time.

If you stop taking Co-codamol 30/500 Tablets

Co-codamol 30/500 Tablets can become habit forming. This is called dependence, if you stop taking your medicine suddenly it can cause symptoms such as restlessness and irritability. Your doctor will stop your tablets gradually to avoid you having these withdrawal symptoms. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-codamol 30/500 Tablets can cause side effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other possible side effects are:

- feeling sick (nausea) and being sick (vomiting)
- light headedness, dizziness, sleepiness
- stomach pains, constipation.

Lying down may help these effects if they happen.

Other side effects include:

- a feeling of extra well being, or depression
- liver damage, especially in heavy drinkers
- restlessness or irritability
- hearing loss
- changes in blood cells, such as low number of cells which fight infection and of cells which are involved in blood clotting.

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

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 30/500 TABLETS

- keep this medicine out of the sight and reach of children.
- do not use Co-codamol 30/500 Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month
- keep this medicine in a dry place
- do not store above 25 °C
- protect from light.

Medicines should not be disposed of via wastewater. 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 30/500 Tablets contain

- the active substances are paracetamol, 500mg and codeine phosphate, 30mg
- the other ingredients are maize starch, methyl cellulose, talc, calcium stearate, povidone, purified water, hypromellose and macrogol 3350.

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

Co-codamol 30/500 Tablets are caplet shaped white tablets.

Co-codamol 30/500 Tablets are available in aluminium blister packs or plastic containers with child resistant lids of 56, 100 or 112 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Mercury Pharmaceuticals Ltd,
Capital House, 85 King William Street,
London EC4N 7BL, UK

Manufactured By:

Bristol Laboratories Ltd.,
Laporte Way, Luton,
Bedfordshire, LU4 8WL, UK

This leaflet was revised in March 2017.

100154/LF/027/07



MercuryPharma

Version No:	100154/LF/027/07
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Pack Size:	100 Tablets
Component:	Leaflet
SKU:	100154
Market:	UK
Production Site:	Bristol
Revision No.:	2
Revision Date:	01/03/2017
Revised by:	PAT
CRF:	PR 8719

Dimension:	180 X 430 mm
Commodity No.:	N/A
Pharma Code:	N/A
Core Spec Ref:	N/A
DCMF:	N/A
Print Colours:	Black

Non-Print Colours: Cutter

Tech App. Date:	08/03/2017
Min. Font Size:	8.5 pt

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Co-codamol 30mg/500mg Tablets

Codeine Phosphate/Paracetamol

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In this leaflet:

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- How to take Co-codamol 30/500 Tablets
- Possible side effects
- How to store Co-codamol 30/500 Tablets
- Further information

1. WHAT CO-CODAMOL 30/500 TABLETS ARE AND WHAT THEY ARE USED FOR

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Do not take Co-codamol 30/500 Tablets if:

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- you suffer from severe kidney or liver disease
- you know that you metabolise very rapidly codeine into morphine
- you are breast-feeding
- you suffer from asthma or any other breathing problems, for example chronic bronchitis or emphysema
- you have just had a head injury or suffer from increased pressure on the brain
- you drink a lot of alcohol, or have done in the past
- you have recently had an operation to your gall bladder
- you have diarrhoea
- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs such as phenelzine, moclobemide or isocarboxazid are medicines used to treat depression.

Co-codamol 30/500 Tablets should not be taken by children under 12 years of age.

Take special care and tell your doctor or pharmacist before taking Co-codamol 30/500 Tablets if:

- you are elderly or weak
- you have any stomach pains or other sudden problems in your abdomen (belly)
- you have an underactive thyroid gland
- you have liver, kidney problems, because the dose might need to be lower
- you have myasthenia gravis (muscle weakness, weakness of facial muscles including the eye muscles and difficulty in swallowing)
- you have a disease of the biliary tract
- you have problems with your adrenal glands (Addison’s disease)
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)
- you feel you have taken Co-codamol 30/500 Tablets for a long time. You may develop a dependence on Co-codamol 30/500 Tablets which may be harmful.

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.

Warnings and precautions

Children and adolescents

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome (sleep disruption due to respiratory pauses). They may be at increased risk of severe side effects in case of morphine toxicity.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

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. Some medicines interact with each other and this can alter their effect. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

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- medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
- medicines used to treat problems of the stomach, gall bladder, heart burn or sickness (e.g. cimetidine, colestyramine)
- sodium oxybate used to treat sleepiness and sudden loss of muscle tone
- other strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants such as warfarin)
- patients should not take any other paracetamol containing medicines whilst taking Co-codamol 30/500 Tablets. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

Co-codamol 30/500 Tablets can interfere with some laboratory tests used for determining some diseases.

Taking Co-codamol 30/500 Tablets with food and drink

Do not drink alcohol whilst taking Co-codamol 30/500 Tablets. Swallow the tablets with a glass of water. Do not bite or chew the tablets.



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Version No: **100154/LF/219/02**
Product Name: **Co-codamol 30mg/500mg Tablets**
Pack Size: 100/112 tablets.
Component: Leaflet
SKU: 100154
Market: UK
Production Site: Famar
Revision No.: 3
Revision Date: 02/03/2017
Revised by: PAT
CRF: **PR 8719**

Dimension: 320 x 200 mm
Commodity No.: 2613802
Pharma Code: 182
Core Spec Ref: N/A
DCMF: N/A
Print Colours: Black

Non-Print Colours: **Cutter**

Tech App. Date: 07/03/2017
Min. Font Size: 8 pt

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Signature

Name

Date

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Pregnancy and breast-feeding

Co-codamol 30/500 Tablets should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born. Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk.

Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

Co-codamol 30/500 Tablets may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision.

The 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 prescribed to treat a medical or dental problem and
 - you have taken it according to the instructions given by the prescriber or in 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.

3. HOW TO TAKE CO-CODAMOL 30/500 TABLETS

Always take Co-codamol 30/500 Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dose

Adults: The recommended dose is one or two tablets every four to six hours when needed, up to a maximum of 8 tablets in any 24 hour period.

If you feel the effect of Co-codamol 30/500 Tablets is too strong or too weak or your symptoms persist, speak to your doctor or pharmacist.

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.

A lower dosage may be needed if you are elderly or have other medical problems.

Check with your doctor about this.

Do not take with any other paracetamol-containing products.

Use in children and adolescents

Children aged 16-18 years: The recommended dose is one to two tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 12-15 years: The recommended dose is one tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

Co-codamol 30/500 Tablets should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

If you take more Co-codamol 30/500 Tablets 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. Bring the remaining tablets and this leaflet with you so that the medical staff knows what you have taken.

If you forget to take Co-codamol 30/500 Tablets

Do not take more than one dose at a time. If you forget to take a dose then take your next dose at the usual time. Never take two doses at the same time.

If you stop taking Co-codamol 30/500 Tablets

Co-codamol 30/500 Tablets can become habit forming. This is called dependence, if you stop taking your medicine suddenly it can cause symptoms such as restlessness and irritability. Your doctor will stop your tablets gradually to avoid you having these withdrawal symptoms. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-codamol 30/500 Tablets can cause side effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

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Lying down may help these effects if they happen.

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Reporting of side effects:

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

5. HOW TO STORE CO-CODAMOL 30/500 TABLETS

- keep this medicine out of the sight and reach of children
- do not use Co-codamol 30/500 Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month
- keep this medicine in a dry place
- do not store above 25°C
- protect from light.

Medicines should not be disposed of via wastewater. 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 30/500 Tablets contain

- the active substances are paracetamol, 500mg and codeine phosphate, 30mg
- the other ingredients are maize starch, methyl cellulose, talc, calcium stearate, povidone, purified water, hypromellose and macrogol 3350.

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

Co-codamol 30/500 Tablets are caplet shaped white tablets.

Co-codamol 30/500 Tablets are available in aluminium blister packs or plastic containers with child resistant lids of 56, 100 or 112 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Mercury Pharmaceuticals Ltd.,
Capital House, 85 King William Street,
London EC4N 7BL, UK

Manufactured By:

FAMAR Italia
via Zambelletti, 25, 20021 Baranzate (MI)-Italy

This leaflet was revised in March 2017.
2613802 / IS-200-320-50D2

100154/LF/219/02



MercuryPharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Co-codamol 30mg/500mg Tablets

Codeine Phosphate/Paracetamol

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1. WHAT CO-CODAMOL 30/500 TABLETS ARE AND WHAT THEY ARE USED FOR

Co-codamol 30/500 Tablets contain paracetamol and codeine. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). 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 pain killers.

Co-codamol 30/500 Tablets are used for the relief of severe pain. Co-codamol 30/500 Tablets can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

2. BEFORE YOU TAKE CO-CODAMOL 30/500 TABLETS

Do not take with any other paracetamol-containing products. Do not take for longer than directed by your prescriber. Do not use Co-codamol 30/500 Tablets for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Co-codamol 30/500 may cause obstructive sleep apnoea syndrome (sleep disruption due to respiratory pauses). 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. Taking a painkiller for headaches too often or for too long can make them worse.

Do not take Co-codamol 30/500 Tablets if:

- you know that you are allergic to paracetamol or codeine, or any of the other ingredients (refer to section 6 below)
- you suffer from severe kidney or liver disease
- you know that you metabolise very rapidly codeine into morphine
- you are breast-feeding
- you suffer from asthma or any other breathing problems, for example chronic bronchitis or emphysema
- you have just had a head injury or suffer from increased pressure on the brain
- you drink a lot of alcohol, or have done in the past
- you have recently had an operation to your gall bladder
- you have diarrhoea
- you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs such as phenelzine, moclobemide or isocarboxazid are medicines used to treat depression.

Co-codamol 30/500 Tablets should not be taken by children under 12 years of age.

Take special care and tell your doctor or pharmacist before taking Co-codamol 30/500 Tablets if:

- you are elderly or weak
- you have any stomach pains or other sudden problems in your abdomen (belly)
- you have an underactive thyroid gland
- you have liver, kidney problems, because the dose might need to be lower
- you have myasthenia gravis (muscle weakness, weakness of facial muscles including the eye muscles and difficulty in swallowing)
- you have a disease of the biliary tract
- you have problems with your adrenal glands (Addison’s disease)
- you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)
- you feel you have taken Co-codamol 30/500 Tablets for a long time. You may develop a dependence on Co-codamol 30/500 Tablets which may be harmful.

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.

Warnings and precautions

Children and adolescents

Use in children and adolescents after surgery
Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome (sleep disruption due to respiratory pauses). They may be at increased risk of severe side effects in case of morphine toxicity.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

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. Some medicines interact with each other and this can alter their effect. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- MAOIs used to treat depression, taken within the last 14 days (refer to “do not take if” in section 2 above)
- sedatives and sleeping tablets, e.g. temazepam and diazepam
- phenothiazines (medicines that calm your mood) or tricyclic antidepressants
- antihypertensive drugs, diuretics (water pills)
- medicines for irregular heart beats (mexiletine, quinine or quinidine)
- drugs used to dry fluids in the mouth and lungs known as anticholinergics
- medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
- medicines used to treat problems of the stomach, gall bladder, heart burn or sickness (e.g. cimetidine, colestyramine)
- sodium oxybate used to treat sleepiness and sudden loss of muscle tone
- other strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants such as warfarin)
- patients should not take any other paracetamol containing medicines whilst taking Co-codamol 30/500 Tablets. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

Co-codamol 30/500 Tablets can interfere with some laboratory tests used for determining some diseases.



MercuryPharma

Version No:	100154/LF/056/07
Product Name:	Co-codamol 30mg/500mg Tablets
Pack Size:	100 Tablets
Component:	Leaflet
SKU:	100154
Market:	UK
Production Site:	Haupt
Revision No.:	3
Revision Date:	02/03/2017
Revised by:	PAT
CRF:	PR 8719

Dimension:	148 X 420 mm
Commodity No.:	722929 GB4
Pharma Code:	4352
Core Spec Ref:	N/A
DCMF:	N/A
Print Colours:	Black

Non-Print Colours: Cutter

Tech App. Date:	09/03/2017
Min. Font Size:	9 pt

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(Please strike off whichever NOT applicable)

Signature

Name

Date

Taking Co-codamol 30/500 Tablets with food and drink

Do not drink alcohol whilst taking Co-codamol 30/500 Tablets. Swallow the tablets with a glass of water. Do not bite or chew the tablets.

Pregnancy and breast-feeding

Co-codamol 30/500 Tablets should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born. Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk.

Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

Co-codamol 30/500 Tablets may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision.

The 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 prescribed to treat a medical or dental problem and
 - you have taken it according to the instructions given by the prescriber or in 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.

3. HOW TO TAKE CO-CODAMOL 30/500 TABLETS

Always take Co-codamol 30/500 Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dose

Adults: The recommended dose is one or two tablets every four to six hours when needed, up to a maximum of 8 tablets in any 24 hour period.

If you feel the effect of Co-codamol 30/500 Tablets is too strong or too weak or your symptoms persist, speak to your doctor or pharmacist. 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.

A lower dosage may be needed if you are elderly or have other medical problems.

Check with your doctor about this.

Do not take with any other paracetamol-containing products.

Use in children and adolescents

Children aged 16-18 years: The recommended dose is one to two tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 12–15 years: The recommended dose is one tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

Co-codamol 30/500 Tablets should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

If you take more Co-codamol 30/500 Tablets 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. Bring the remaining tablets and this leaflet with you so that the medical staff knows what you have taken.

If you forget to take Co-codamol 30/500 Tablets

Do not take more than one dose at a time. If you forget to take a dose then take your next dose at the usual time. Never take two doses at the same time.

If you stop taking Co-codamol 30/500 Tablets

Co-codamol 30/500 Tablets can become habit forming. This is called dependence, if you stop taking your medicine suddenly it can cause symptoms such as restlessness and irritability. Your doctor will stop your tablets gradually to avoid you having these withdrawal symptoms. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Co-codamol 30/500 Tablets can cause side effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other possible side effects are:

- feeling sick (nausea) and being sick (vomiting)
- light headedness, dizziness, sleepiness
- stomach pains, constipation.

Lying down may help these effects if they happen.

Other side effects include:

- a feeling of extra well being, or depression
- liver damage, especially in heavy drinkers
- restlessness or irritability
- hearing loss
- changes in blood cells, such as low number of cells which fight infection and of cells which are involved in blood clotting.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 30/500 TABLETS

- keep this medicine out of the sight and reach of children
- do not use Co-codamol 30/500 Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month
- keep this medicine in a dry place
- do not store above 25°C
- protect from light.

Medicines should not be disposed of via wastewater. 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 30/500 Tablets contain

- the active substances are paracetamol, 500mg and codeine phosphate, 30mg.
- the other ingredients are maize starch, methyl cellulose, talc, calcium stearate, povidone, purified water, hypromellose and macrogol 3350.

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

Co-codamol 30/500 Tablets are caplet shaped white tablets.

Co-codamol 30/500 Tablets are available in aluminium blister packs or plastic containers with child resistant lids of 56, 100 or 112 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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London EC4N 7BL, UK

Manufactured By:

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