FRONT

PATIENT INFORMATION LEAFLET

CO-CODAMOL 8/500 TABLETS
Codeine Phosphate and Paracetamol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.
Keep this leaflet. You may need to read it again. If you have further questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
What is in this leaflet:

1. What co-codamol is and what it is used for
2. What you need to know before you take co-codamol
3. How to take co-codamol
4. Possible side effects
5. How to store co-codamol
6. Contents of the pack and other information

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

The name of your medicine is Co-codamol 8/500 Tablets (called co-codamol throughout this leaflet). This medicine has been prescribed for you for the relief of most painful conditions such as headache including migraine, toothache, neuralgia, period pain, pain caused by rheumatism and arthritis and to relieve the symptoms of colds, flu and sore throats. Co-codamol contains two different medicines called codeine and paracetamol. Codeine belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Co-codamol 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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-CODAMOL

Important things you should know about co-codamol
- **Do not take for longer than your doctor tells you to**
- **This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.**
- **Taking a painkiller for headaches too often or for too long can make them worse**

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.
Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.
Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.
Warnings and precautions
Do not take co-codamol 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, tranylcypromine
- 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
- 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
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome
- You know you metabolise very rapidly codeine into morphine
- You are breastfeeding or planning to breastfeed

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 are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- You feel you need to take more co-codamol to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever
- 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.
- You have a condition called myasthenia gravis which weakens the muscles
- You suffer from hypothyroidism
- You have a disease of the adrenal gland called Addison's disease
- You are taking a benzodiazepine
- You suffer from seizures

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine and relieves pain and symptoms of cold. 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 or relieve their cold. 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.
Children and adolescents
Use in children and adolescents after surgery
Co-codamol should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.
Use in children and adolescents with breathing problems
Co-codamol is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.
Co-codamol is not recommended in adolescents over 12 years of age with breathing problems for the treatment of colds.
If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking co-codamol.
Other medicines and co-codamol
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.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking or have taken within the last two weeks:
- monoamine oxidase inhibitors (MAOIs) such as moclobemide and phenelzine used in the treatment of depression
- medicines which make you drowsy or sleepy (CNS depressants and benzodiazepines) such as medicines used to treat anxiety or anaesthetics.
- medicines for depression such as dosulepin, mirtazapine (Tricyclic) or chlorpromazine (phenothiazines)
- medicines known as tranquillisers, or hypnotics
- sleeping tablets, sedatives and some antihistamines

You may experience more drowsiness if you take these medicines with co-codamol.
Concomitant use of co-codamol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe co-codamol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
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.
Tell your doctor or pharmacist if you are taking:
- Flucloxacillin (an antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Tell your doctor or pharmacist if you are taking any other medicines:
- 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.

BACK

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking co-codamol.
Pregnancy and breast-feeding
- Do not take co-codamol if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.
- If you use co-codamol during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
- Do not take co-codamol while you are breastfeeding as codeine passes into breast milk and will affect your baby.

If necessary, co-codamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.
Driving and using machines
Co-codamol can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive whilst 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 whilst taking this medicine.

3. HOW TO TAKE CO-CODAMOL

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.
Always take co-codamol exactly as your doctor has told you. 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**
- **Swallow the tablets whole with a drink of water**

Adults: 2 tablets every 4 to 6 hours when necessary up to a maximum of 8 tablets in 24 hours.
Use in children aged 16 to 18 years: 1 to 2 tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.
Use in children aged 12 to 15 years: 1 tablet every 6 hours when necessary to a maximum of 4 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.
Children: Co-codamol should not be given to children under 12 years of age due to the risk of severe breathing problems.
If you take more co-codamol than you should
- 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.
- 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, do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.
If you stop taking co-codamol
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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.
- Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

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
- You get serious skin reactions. Very rare cases have been reported
- You have a fit (seizure)
- You have difficulty breathing and you feel dizzy

Talk to your doctor straight away if you notice any of the following serious side effects:
- 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), dry mouth
- Dizziness, light-headedness, drowsiness, confusion
- Feeling overly happy (euphoria)
- A feeling of unease or dissatisfaction
- Excessive constriction (shrinking) of the pupil of your eye
- 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.

Drug Withdrawal
When you stop taking co-codamol, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.
How do I know if I am addicted?
If you notice any of the following signs whilst taking co-codamol, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.
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 CO-CODAMOL

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
Store your medicine in the original packaging in order to protect from moisture. Do not store above 25°C.
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Co-codamol 8/500 Tablets contain
- The active substances are codeine phosphate and paracetamol. Each tablet contains 8mg of codeine phosphate and 500mg of paracetamol.
- The other ingredients are maize starch, povidone, potassium sorbate, microcrystalline cellulose, stearic acid, magnesium stearate, talc, pregelatinised starch and purified water.

What Co-codamol 8/500 Tablets look like and contents of the pack
Flat white tablets, marked S/4 on one side. They come in cartons of 50 and 100 tablets.
The Marketing Authorisation Holder is:
Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK
The Manufacturer is:
Zentiva Pharma UK Limited, Office 136-152, Austen House, Station View Units A-J, Guildford, GU1 4AR, UK
or
Zentiva Pharma UK Limited, First Floor, Andrews House, College Road, Guildford, GU1 4QB. United Kingdom
This leaflet was updated in February 2023

[556066] [1065036740]
ZEN-01202523-19tt-UK-EX
CO-CODAMOL 8/500 TABS
-50's &100's pack-

SANOFI
Artwork Approval History Reference No. : V.F. # 103911028
REGULATORY
PACKAGING
QUALITY
Design Unit

Artwork Number	:	ZEN-01202523-19tt-UK-EX		
Version Number	:	1	Date	: 15.02.23
Edition Number	:	19	Colours	
Product	:	Co-codamol 8/500 Tablets	1. Black	
Artwork Type	:	Leaflet - 100's		
Dimensions(mm)	:	140 x 480 mm		
Folded size	:	140 x 30 mm		
Plant PM Code	:	1065036740		
Market local code	:	556066		
Machine	:	IC-150-C/ CAM		
Minimum font size	:	8 pt	Braille	:
Pharma Code No	:	12025	Non-Varnish zones:	
EAN bar Code No	:	NA	Outline	: