Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 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 Dispersible Co-codaprin tablets are and what they are used for
2. What you need to know before you take Dispersible Co-codaprin tablets
3. How to take Dispersible Co-codaprin tablets
4. Possible side effects
5. How to store Dispersible Co-codaprin tablets
6. Contents of the pack and other information

1. What Dispersible Co-codaprin tablets are and what they are used for

Dispersible Co-codaprin tablets belong to a group of medicines which have analgesic (pain relief), anti-inflammatory (reduce inflammation) and anti-pyretic (reduce temperature) properties. These tablets may be used for the relief of:

- headache, toothache, migraine, neuralgia (nerve pain), sore throat or period pains.
- symptoms of influenza, feverishness, rheumatic pains, sciatica (nerve pain of the leg/back), lumbago (lower back pain), fibrositis (muscular rheumatism), muscular aches and pains.

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 such as paracetamol.

2. What you need to know before you take Dispersible Co-codaprin tablets

Do not take Dispersible Co-codaprin tablets if you:

- are allergic to aspirin, codeine, other opioids, salicylates or non-steroidal anti-inflammatory drugs (NSAIDs) or other ingredients in the medicine (listed in section 6). You may have developed difficulty breathing, a runny nose, itchy skin or swelling after taking aspirin or a NSAID previously (see section 6)
- have a stomach ulcer or a history of ulcers or indigestion
- have diarrhoea caused by poisoning or severe bloody diarrhoea (pseudomembranous colitis)
- have difficulty breathing, or other chronic lung disease
- have nasal polyps associated with asthma or are having an asthma attack.
- have haemophilia or other blood clotting disorder or are taking medicines to thin the blood.
- are in the last three months of pregnancy
- are breastfeeding
- are known to metabolise codeine into morphine very rapidly.
are a child or adolescent (up to 18 years) and have recently undergone removal of your tonsils or adenoids due to obstructive sleep apnoea syndrome.

Important warnings
Do not take if you or your child is under 12 years old. There is a possible association between aspirin and Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor e.g. for Kawasaki’s disease.

Warnings and Precautions
Talk to your doctor or pharmacist before taking Dispersible Co-codaprin tablets if you:

• have asthma or allergies
• have heart, liver or kidney problems or gout
• have diseased adrenal glands (Addison’s disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma)
• have inflammatory bowel disease
• have gall bladder disease or gall stones
• have recently had surgery on your gastro-intestinal tract or urinary system
• have an enlarged prostate gland
• have epilepsy or suffered head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
• have an underactive or overactive thyroid gland
• have muscle weakness (myasthenia gravis)
• have low blood pressure, are dehydrated or are in shock
• have suffered from alcoholism, drug abuse or dependence or mental illness
• have anaemia or suffer from a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD) this can cause episodes of anaemia after eating certain foods such as fava beans (favism)
• have systemic lupus erythematosus (SLE) or other connective tissue disease.
• are pregnant or planning to become pregnant.

After taking Dispersible Co-codaprin tablets:
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.

Other warnings:
• do not take for longer than directed by your prescriber
• 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.

Use in children with breathing problems
Dispersible Co-codaprin is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.
Co-codaprin is not recommended in adolescents with compromised respiratory function for the treatment of cold.

**Other medicines and Disperible Co-codaprin tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- ciprofloxacin (antibacterial medicine)
- Monoamine Oxidase Inhibitors (MAOIs, e.g. moclobemide), Selective Serotonin Re-uptake Inhibitors (SSRIs) to treat depression
- medicines to prevent blood clotting such as warfarin, dipyridamole and heparin
- cyclizine, metoclopramide or domperidone (to prevent sickness)
- guanethidine or diuretics ("water tablets") e.g. spironolactone, furosemide, acetazolamide (to treat high blood pressure)
- mexiletine (to treat irregular heartbeats)
- loperamide or kaolin (to treat diarrhoea)
- selegiline (for Parkinson’s disease)
- phenytoin or sodium valproate (to treat epilepsy)
- cimetidine (to treat stomach ulcers)
- atropine or hyoscine (to reduce stomach muscle spasm)
- cisapride (to treat gastro-oesophageal reflux disease)
- medicines which affect the nervous system such as sleeping tablets, diazepam and hydroxyzine (for anxiety), amitriptyline (for depression) and medicines to treat mental illness
- muscle relaxants
- buprenorphine and naltrexone (to treat drug addiction) or naloxone (for breathing problems caused by opioids)
- medicines which make your urine more alkaline such as antacids, citrates
- probenecid, sulfinpyrazone (to treat gout)
- methotrexate (to treat some cancers, psoriasis and rheumatic disease)
- antidiabetics
- corticosteroids (to suppress the immune system)
- mifepristone (to induce abortion)
- other non-steroidal anti-inflammatory drugs - NSAIDs for pain and inflammation (eg ibuprofen or naproxen)
- medicines which can cause hearing problems (vancomycin).

Concomitant use of Dispersible Co-codaprin tablets 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 Dispersible Co-codaprin tablets 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.

**Food, drink and alcohol**

Avoid alcohol whilst taking this medicine.
Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Avoid taking Dispersible Co-codaprin tablets during pregnancy especially in the last three months or during labour.
Do not use during breast-feeding as aspirin, codeine and morphine pass into breast milk.
Aspirin should not be given to women wishing to become pregnant, speak to your doctor or pharmacist before taking this medicine.

Driving and using machines
Dispersible Co-codaprin tablets may cause dizziness, blurred vision or the inability to think clearly. Make sure you are not affected before you drive or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
· Do not drive or use machines while taking this medicine until you are sure you are not affected.
· 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.

Surgery and tests
If you need to have an operation including having your teeth removed or blood and urine tests, tell your doctor or dentist you are taking this medicine.

3. How to take Dispersible Co-codaprin tablets
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist, if you are not sure.
After meals, disperse the tablet(s) in a glass of water and drink.

Doses:
Adults, including the elderly: The recommended dose is 1 or 2 tablets every 4 hours, if you need to, up to 4 times in 24 hours.
Children aged 16 to 18 years: The recommended dose is one or two tablets, every 6 hours, if you need to.
Don’t take more than 8 tablets in 24 hours.
Do not take more than the amount recommended.
If symptoms do not go away, talk to your doctor.
Do not take this medicine for more than 3 days.
If you do not get effective pain relief during this time, consult your doctor for advice
Do not give to children under 16 years, unless on the advice of a doctor.
Do not give to children under 12 years old

If you take more than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include ringing in the ears, a spinning sensation, fast or slow breathing rate, coma, fever, heart or kidney failure, clammy skin, fits, confusion, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow heart beat.

**If you forget to take the tablets**
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time. Do not take more than one dose in any 4 hour period.

**If you stop taking the tablets**
If you stop taking the tablets you may develop tremor, difficulty sleeping, feeling or being sick, sweating and increased heart or breathing rate or blood pressure. Talk to your doctor before you stop taking the tablets and follow their advice.

4. **Possible side effects**
Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Dispersible Co-codaprin tablets and contact your doctor at once** if you experience signs of:
- an allergic reaction such as: runny nose, itchy skin, swelling of the face, lips, throat or tongue, worsening of asthma, increased sweating, redness or flushed face.
- high levels of morphine in the body: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

**Tell your doctor if you notice any of the following side effects** or notice any other effects not listed:
- **Gastrointestinal system** - stomach ulcers or bleeding which can be severe (you may develop bloody or black tarry stools, severe stomach pain and vomit blood), stomach irritation (mild stomach pain, heartburn and feeling sick), constipation, feeling or being sick, loss of appetite, dry mouth, problems with food passing through the guts, abdominal pain (may be caused by spasm of the bile ducts) and inflammation of the liver.
- **Heart** - slow heart rate, palpitations, low blood pressure.
- **Blood** - anaemia, changes in numbers and types of blood cells. If you have an increase in number of nose bleeds or notice that you bruise more easily or have more infections talk to your doctor.
- **Urinary system** - difficulty urinating, low abdominal pain (may be caused by spasm of the urinary system)
- **Ears and eyes** - ringing or buzzing in the ear, blurred or double vision, narrowing of the pupil.
- **Nervous system** - confusion, drowsiness, spinning sensation, dizziness, mood changes, hallucinations, restlessness, excitation, fits, headache, difficulty sleeping, nightmares, mental dullness, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), tolerance (medicine has less effect) withdrawal symptoms (tremor, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick) if the medicine is stopped too quickly.
- **Other effects** - trembling, unusual tiredness or weakness, malaise, low body temperature.
- **Salicylism** - if you take large doses for a long time you may develop these signs of: dizziness, ringing or buzzing in the ear, deafness, sweating, feeling or being sick, headache and confusion.

**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 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 Dispersible Co-codaprin tablets**

Keep out of the sight and reach of children.

Keep the tablets in a cool dry place, protected from light, tightly stoppered.

Do not use after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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. **Contents of the pack and other information**

**What Dispersible Co-codaprin tablets contain**

- The active substances (the ingredients that make the tablets work) are 8mg of codeine phosphate and 400mg aspirin (also known as acetylsalicylic acid).
- The other ingredients are calcium carbonate, cetrimide, maize starch, saccharin sodium, silica, citric acid (E330).

**What Dispersible Co-codaprin tablets look like and contents of the pack**

Dispersible Co-codaprin are white uncoated tablets.

Pack sizes are 100 tablets.

**Marketing Authorisation Holder and manufacturer**

Actavis UK Limited, (Trading style: Actavis), Whiddon Valley, Barnstaple, N Devon, EX32 8NS

This leaflet was last revised in August 2018