← Fold from here Talk to your doctor straight away if you 6. Contents of the pack and Package Leaflet: Information for the patient notice the following serious side effects: Paracetamol & Codeine 500mg/8mg other information **Very rare** (may affect up to 1 in 10,000 people): What Paracetamol & Codeine Effervescent **Effervescent Tablets** Severe stomach pain, which may reach through to vour back. This could be a sign of inflammation Tablets contain codeine phosphate hemihydrate and paracetamol The active substances of Paracetamol & Codeine of the pancreas (pancreatitis). Effervescent Tablets are codeine phosphate Not known (frequency cannot be estimated from Read all of this leaflet carefully before you start using this medicine because it contains hemihydrate and paracetamol. Each tablet important information for you. contains 8 mg of codeine phosphate hemihydrate • A serious condition that can make blood more and 500 mg of paracetamol. acidic (called metabolic acidosis), in patients with Important things you should know about 2. What you need to know before The other ingredients are citric acid, sorbitol severe illness using paracetamol (see section 2). Paracetamol & Codeine 500mg/8mg (E420), sodium hydrogen carbonate, povidone, you take Paracetamol & Tell your doctor or pharmacist if any of the **Effervescent Tablets** simeticone, sodium carbonate, saccharin sodium, following side effects get serious or last • This medicine can only be used for the short **Codeine Effervescent Tablets** macrogol 6000. longer than a few days: term treatment of acute, moderate pain • This medicine contains codeine which can **What Paracetamol & Codeine Effervescent** such as headaches, migraine, neuralgia, **Not known** (frequency cannot be estimated from cause addiction if you take it continuously for Tablets look like and contents of the pack toothache, painful menstrual periods and more than three days. This can give you Paracetamol & Codeine Effervescent Tablets are Constipation rheumatic pain which is not relieved by withdrawal symptoms from the medicine white to off-white, round, flat, bevelled edge paracetamol, ibuprofen or aspirin alone. Feeling sick (nausea), being sick (vomiting), dry when you stop taking it. You should only take this product for a tablets, plain on both sides. The diameter of the • This medicine contains paracetamol. Do not tablet is approximately 25.4 mm. maximum of three days at a time. If you • Dizziness, light-headedness, drowsiness, take anything else containing paracetamol need to take it for longer than three days They come in Surlyn strip packs containing 24 or confusion while taking this medicine. you should see your doctor or pharmacist Feeling overly happy (euphoria) 32 tablets. Not all pack sizes may be marketed. • If you take a painkiller for headaches for more for advice. • A feeling of unease or dissatisfaction than three days it can make them worse. This medicine contains codeine which can **Marketing Authorisation Holder and** Excessive constriction (shrinking) of the pupil of cause addiction if you take it continuously Warnings and precautions for more than three days. This can give you • Difficulty in passing water (urine) **Marketing Authorisation Holder:** Do not take Paracetamol & Codeine withdrawal symptoms from the medicine • Becoming dependent on codeine Effervescent Tablets and tell your doctor if: Accord, Barnstaple, EX32 8NS, UK ▶ You get infections or bruise more easily than when you stop taking it. You are allergic to codeine phosphate Manufacturer: usual. This could be because of a blood problem If you take this medicine for headaches for hemihydrate, paracetamol, or any of the other Accord Healthcare Limited, more than three days it can make them (such as agranulocytosis, neutropenia or ingredients of this medicine (listed in Section 6). Sage House, 319 Pinner Road, thrombocytopenia). Signs of an allergic reaction include a rash and The name of your medicine is Paracetamol & How do I know if I am addicted? Harrow, HA1 4HF, breathing problems. There can also be swelling of Codeine 500mg/8mg Effervescent Tablets (called If you take this medicine according to the the leas, arms, face, throat or tonque United Kingdom Paracetamol & Codeine Effervescent Tablets • You are taking medicines to treat depression called instructions on the pack it is unlikely that you will Distributed by The Boots Company PLC, throughout this leaflet). become addicted to the medicine. However, if MAOIs (Monoamine Oxidase Inhibitors) or have Nottingham, NG2 3AA. • Keep this leaflet. You may need to read it again. the following apply to you it is important that you taken them in the last 2 weeks. MAOIs are This leaflet was last revised in January 2025. • If you have any further questions, ask your doctor talk to your doctor: medicines such as moclobemide, phenelzine, or pharmacist ▶ You need to take the medicine for longer periods tranylcypromine (see 'Other medicines and If you get any side effects, talk to your doctor. Paracetamol & Codeine Effervescent Tablets') pharmacist or nurse. This includes any possible • The person going to take the tablets is under 12 • You need to take more than the recommended side effects not listed in this leaflet. See section 4. years of age. Paracetamol & Codeine Effervescent | dose • You are using the medicine for reasons other than Tablets must not be given to children under 12 What is in this leaflet prescribed 11. What Paracetamol & Codeine Effervescent When you stop taking the medicine you feel • You are under 18 years of age and have had your Tablets are and what they are used for unwell, but you feel better once taking the tonsils or adenoids removed due to obstructive 2. What you need to know before you take medicine again. sleep apnoea syndrome Paracetamol & Codeine Effervescent Tablets You know that you metabolise very rapidly codeine 3. How to take Paracetamol & Codeine Reporting of side effects into morphine Effervescent Tablets If you get any side effects, talk to your doctor, • You are breast-feeding or planning to breast-feed. 4. Possible side effects pharmacist or nurse. This includes any possible Do not take Paracetamol & Codeine 5. How to store Paracetamol & Codeine side effects not listed in this leaflet. You can also Effervescent Tablets if any of the above Effervescent Tablets report side effects directly via the Yellow Card applies to you. If you are not sure, talk to your 6. Contents of the pack and other information Scheme Website: www.mhra.gov.uk/yellowcard doctor or pharmacist before taking or search for MHRA Yellow Card in the Google Paracetamol & Codeine Effervescent Tablets. 1. What Paracetamol & Codeine Play or Apple App Store. **Effervescent Tablets are and** By reporting side effects you can help provide more information on the safety of this medicine. what they are used for Paracetamol & Codeine Effervescent Tablets 5. How to store Paracetamol & contain codeine phosphate hemihydrate and Codeine Effervescent Tablets paracetamol. Codeine belongs to a group of medicines called opioid analgesics which act to Keep this medicine out of the sight and reach of relieve pain. Paracetamol & Codeine Effervescent Tablets are used in adults and children over 12 Do not take this medicine after the expiry date years of age for the short term treatment of acute shown on the pack. The expiry date refers to the moderate pain caused by headaches, migraine. last day of that month. toothache, neuralgia, period pain and rheumatic Do not store above 25°C pains when other painkillers such as paracetamol, Store in the original package in order to protect ibuprofen or aspirin alone have not worked. Wait from moisture. at least 4 hours after you last took other painkillers Do not throw away any medicines via wastewater before taking this medicine. or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment Back side Front side

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Take special care and check with your

- doctor before taking Paracetamol & Codeine Effervescent Tablets if: • You have severe kidney or liver problems
- You have a liver problem caused by alcohol • 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 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 are elderly You suffer from seizures
- If you are not sure if any of the above apply to
- you, talk to your doctor or pharmacist before taking this medicine. **During treatment with Paracetamol &**

Codeine Effervescent Tablets, tell your doctor straight away if: • You have severe illnesses, including severe renal

impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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.

Children and adolescents over 12 years of age

Use in children and adolescents after surgery Paracetamol & Codeine Effervescent Tablets should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea

Use in children with breathing problems Paracetamol & Codeine Effervescent Tablets are not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children. This medicine is not recommended in adolescents over 12 years-old with breathing

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Other medicines and Paracetamol & **Codeine Effervescent Tablets**

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 I 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 Paracetamol & Codeine Effervescent Tablets. Concomitant use of Paracetamol & Codeine Effervescent 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 Paracetamol & Codeine Effervescent 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.

Paracetamol & Codeine Effervescent Tablets contain paracetamol. Do not take anything else containing paracetamol while taking this medicine.

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 any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Paracetamol & Codeine Effervescent Tablets can affect the way some other medicines work or other medicines can affect the way Paracetamol & Codeine Effervescent Tablets work.

• Medicines used to thin the blood such as warfarin • Chloramphenicol - an antibiotic used for

infections • Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see

section 2) Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)

Colestyramine - for lowering blood cholesterol

• The oral contraceptive pill. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

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Paracetamol & Codeine Effervescent Tablets with alcohol You should not drink alcohol while you are taking these tablets. This is because Paracetamol & Codeine Effervescent Tablets 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. • You are planning to breast-feed. Do not take Paracetamol & Codeine Effervescent Tablets while you are breast-feeding. Codeine passes

into breast milk. **Driving and using machines**

- This medicine 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 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. Paracetamol & Codeine Effervescent Tablets contain sodium and sorbitol **Sodium:** The maximum recommended daily dose of this medicinal product contains

3348.8 mg sodium (found in table salt). This is equivalent to 167.44% of the adult recommended maximum daily dietary intake for Talk to your pharmacist or doctor if you need

Paracetamol & Codeine Effervescent Tablets on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

Sorbitol (E420): This medicine contains 100 mg sorbitol in each tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Paracetamol & **Codeine Effervescent**

Always take this medicine exactly as described in this leaflet, or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

 Do not take for more than three days. If you need to use this medicine for more than three days you should speak to your doctor or pharmacist. Do not take more than the recommended

 Dissolve the effervescent tablets in a glass of water before taking.

hours when necessary up to a maximum of 8 tablets in 24 hours. Children aged 16 to 18 years: 1 to 2 tablets every 6 hours when necessary up to a maximum

Adults and the elderly: 2 tablets every 4 to 6

of 4 doses in 24 hours. Children aged 12 to 15 years: 1 tablet every 6 hours when necessary up to a maximum of 4 doses in 24 hours.

Children under 12 years: Paracetamol & Codeine Effervescent Tablets should not be given I to children below 12 years of age due to the risk of severe breathing problems.

If you take more Paracetamol & Codeine Effervescent Tablets 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 forget to take Paracetamol & Codeine **Effervescent Tablets**

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 for adults and 6 hours for children and adolescents aged 12 to 18 years. If you stop taking Paracetamol & Codeine Effervescent Tablets This medicine contains codeine and can cause addiction if you take it continuously for more than I 3 days. When you stop taking it you may get

doctor or pharmacist if you think you are suffering from withdrawal symptoms.

4. Possible side effects

withdrawal symptoms. You should talk to your

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 Paracetamol & Codeine Effervescent

• 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 Paracetamol & Codeine**

Effervescent Tablets and see a doctor or go to a hospital straight away if: **Very rare** (may affect up to 1 in 10,000 people):

 You get serious skin reactions. **Not known** (frequency cannot be estimated from the available data):

 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 Paracetamol & Codeine Effervescent

You have a fit (seizure)

• You have difficulty breathing and you feel dizzy.

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