

PACKAGE LEAFLET: INFORMATION FOR THE USER
Paracetamol and Caffeine 500 mg/65 mg Effervescent Tablets
(paracetamol and caffeine)

The name of this medicine is Paracetamol and Caffeine 500 mg/65 mg Effervescent Tablets which will be referred to as Paracetamol and Caffeine Tablets throughout this leaflet.

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after Three days.

What is in this leaflet

1. What Paracetamol and Caffeine Tablets are and what they are used for
2. What you need to know before you take Paracetamol and Caffeine Tablets
3. How to take Paracetamol and Caffeine Tablets
4. Possible side effects
5. How to store Paracetamol and Caffeine Tablets
6. Contents of the pack and other Information

1. WHAT PARACETAMOL AND CAFFEINE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredients in your tablets are paracetamol and caffeine. Paracetamol is an analgesic and an antipyretic; it works by relieving pain and reducing body temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

Paracetamol and Caffeine tablets are used to treat headache, migraine, backache, rheumatic and muscle pain, toothache and period pain. They also relieve discomfort in colds, influenza, sore throats and help reduce temperature.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL AND CAFFEINE TABLETS

Do not take Paracetamol and Caffeine Tablets:

- If you are **allergic (hypersensitive)** to paracetamol, caffeine, or to any of the other ingredients (these are listed in section 6, Further Information)
- if you are taking **any other prescription or non-prescription medicines containing paracetamol** to treat pain, fever, symptoms of cold and flu or to aid sleep.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Paracetamol and Caffeine Tablets:

- if you are pregnant or breast-feeding
- if you are under 12 years of age
- if you have **kidney or liver disease**, including **alcoholic liver disease**
- if you need 1 or more tablets daily for a prolonged period, especially if you are on a controlled sodium diet or have phenylketonuria (decreased metabolism of phenylalanine)

- if you have been told by your doctor that you have an intolerance to some sugars
- if you are **underweight** or **malnourished**
- if you regularly drink **alcohol**
- if you have a severe infection as this may increase the risk of metabolic acidosis.
 - Signs of metabolic acidosis include: deep, rapid, difficult breathing - feeling sick (nausea), being sick (vomiting) - loss of appetite

During treatment with Parasolve® Extra 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).

Contact a doctor immediately if you get a combination of these symptoms. You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

Other medicines and Paracetamol and Caffeine Tablets

Talk to your doctor or pharmacist before taking this medicine if you are taking any prescribed medicines, in particular:

- metoclopramide or domperidone - for nausea (feeling sick) or vomiting (being sick)
- cholestyramine - used to treat high cholesterol.

If you take blood thinning medicines (anticoagulants e.g., warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding.

But you can still take occasional doses of Paracetamol and Caffeine Tablets at the same time as anticoagulants.

This product is not recommended if you are taking lithium.

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Paracetamol and Caffeine Tablets with food and drink

Paracetamol and Caffeine Tablets should be dissolved in a glass of water and can be taken with or without a meal.

This medicine contains caffeine, which is also found in tea, coffee, chocolate and some canned drinks. Taking too much caffeine can cause difficulty sleeping, shaking or a thumping sensation in the chest (palpitations). You must not drink tea, coffee, chocolate or canned drinks containing caffeine if you need to take this medicine.

Do not drink alcohol (e.g., wine, beer, spirits) whilst taking this medicine

Pregnancy, breast-feeding and fertility

Due to the caffeine content of this product, it should not be used if you are pregnant or breast feeding.

Driving and using machines

It is unlikely that Paracetamol and Caffeine Tablets will affect your ability to drive or operate machines.

Important information about some of the ingredients of Paracetamol and Caffeine Tablets

The maximum recommended daily dose of this medicinal product contains 3112mg sodium (found in table salt). This is equivalent to 155% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you need Paracetamol and Caffeine on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

This medicine contains **4.5mg aspartame** per one tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. HOW TO TAKE PARACETAMOL AND CAFFEINE 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.

If your symptoms continue or your headache becomes persistent, see your doctor.

Adults, the elderly and children aged 16 to 18 years:

One or two tablets every 4 to 6 hours when necessary up to a maximum of 8 tablets in 24 hours. (A reduced dose may be required in the elderly).

Children 12 to 15 years:

One tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

- **Do not take more frequently than every 4 hours.**
- **Do not take for longer than three days without consulting your doctor.**
- **Do not take more than the recommended dose.**
- **Do not give to children under 12 years.**
- **Avoid too much caffeine in drinks like coffee and tea.** High caffeine intake can cause **difficulty sleeping, shaking** and an **uncomfortable feeling in the chest.**

Method of Administration

For oral administration only. These tablets should be dissolved in a glass of water before taking them. These tablets are meant to be dissolved first so don't try to swallow them whole.

If you take more Paracetamol and Caffeine 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 the pack and any remaining tablets with you.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

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

Stop taking the medicine and tell your doctor immediately if you experience:

- **Allergic reactions** which may be severe such as skin rash and itching sometimes swelling of the mouth or face or shortness of breath
- **Skin rash or peeling or mouth ulcers**
- **Breathing problems.** These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained **bruising** or **bleeding**

- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

An adverse reaction with an unknown frequency may also occur:

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Possible caffeine-related side effects include: (when the recommended paracetamol-caffeine dose is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related side effects.)

- difficulty sleeping
- dizziness
- nervousness
- restlessness
- irritability
- anxiety
- palpitations
- stomach issues/abdominal disturbances

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 PARACETAMOL AND CAFFEINE TABLETS

Keep out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in the original package and protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracetamol and Caffeine 500 mg/65 mg Effervescent Tablets contain

- The active ingredients are paracetamol and caffeine. Each tablet contains 500 mg of paracetamol and 65 mg of caffeine.
- The other ingredients are: citric acid (anhydrous) (E330), povidone, saccharin sodium, sodium hydrogen carbonate (E500), sodium carbonate anhydrous, simeticone (E900), Polysorbate 80 (E433) and aspartame (E951).

What Paracetamol and Caffeine 500 mg/65 mg Effervescent Tablets look like and contents of the pack

Paracetamol and Caffeine 500 mg/65 mg Effervescent Tablets are white to off-white coloured circular flat bevelled tablets plain on both sides. Your medicine is available in packs of 24 tablets.

Marketing Authorisation Holder

Kent Pharma UK Limited 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer responsible for batch release

Kent Pharmaceuticals Limited, Unit 200, Westminster 42, Westminster Industrial Estate, Repton Road, Measham, Swadlincote, DE12 7DT, United Kingdom.

This information is available in alternative formats upon request.

This leaflet was last revised in October 2025.