

Paracetamol packinsert keylines front side (Fannin)
Size - 297 x 210 mm
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No printing area

9 mm Pharmacode

GSM paper : NLT 60gsm

Paracetamol packinsert keylines back side
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PATIENT INFORMATION LEAFLET PARACETAMOL EFFERVESCENT 500mg TABLETS

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

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription. However, you still need to use Paracetamol Effervescent carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after three days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paracetamol Effervescent is and what it is used for
2. Before you take Paracetamol Effervescent
3. How to take Paracetamol Effervescent
4. Possible side effects
5. How to store Paracetamol Effervescent
6. Further information

1. WHAT PARACETAMOL EFFERVESCENT IS AND WHAT IT IS USED FOR

The active ingredient in Paracetamol Effervescent is paracetamol. Paracetamol Effervescent is used to relieve pain, including muscular and rheumatic pains, headache, migraine, neuralgia (severe burning or stabbing pain following the line of a nerve), toothache, sore throat, period pains, aches and pains, discomfort associated with influenza (flu), feverishness and feverish colds.

2. BEFORE YOU TAKE PARACETAMOL EFFERVESCENT

Do not take Paracetamol Effervescent if you:

- are **allergic (hypersensitive)** to **paracetamol** or any of the **other ingredients** in the tablets (these are listed in Section 6, Further Information)
- are already taking **other medicines containing paracetamol**

Take special care with Paracetamol Effervescent if:

- you have kidney or liver problems, including alcoholic liver disease
- you have non-serious arthritis
- taking a painkiller for headaches too often or for too long can make them worse.

During treatment with Paracetamol Effervescent, tell your doctor straight away if: 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).

Taking other medicines

Do not take these tablets if you are already taking other medicines containing paracetamol.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Certain medicines can interfere with the effectiveness of each other. It is particularly important to tell your doctor or pharmacist before taking this medicine if you are also on:

- metoclopramide or domperidone (often taken for sickness or stomach problems)
- colestyramine (used to treat high cholesterol)
- blood thinning medicines (anticoagulants) such as warfarin
- chloramphenical an antibiotic to treat eye infections

It may still be all right for you to take Paracetamol Effervescent and your doctor will be able to decide what is suitable for you.

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).

Taking your medicine with food and drink

Paracetamol should be dissolved in at least half a glass of water and can be taken with or without a meal.

Pregnancy and breast-feeding

If necessary, Paracetamol 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 machinery

The effect of paracetamol on the ability to drive and operate machinery is not known. If you feel dizzy or drowsy do not drive or operate machinery.

Important information about some of the ingredients of Paracetamol Effervescent

The maximum recommended daily dose of this medicinal product contains 3504mg sodium (found in table salt). This is equivalent to 175% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Paracetamol Effervescent on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

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This medicine contains 20mg aspartame in each tablet of 500mg Paracetamol which is equivalent to 6.13mg/g. 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 EFFERVESCENT

Do not exceed the recommended doses. If painful symptoms are not relieved in a few days, consult your doctor.

Dosage

The usual doses for Paracetamol Effervescent are as follows:

Adults and children over 16 years:

Take 1 or 2 tablets up to 4 times a day, or as instructed by your doctor.

Children 12-15 years of age: One tablet maximum.

The dose should not be repeated more frequently than every 4 hours, and not more than 4 doses should be taken in any 24-hour period. Do not continue to take these tablets for more than 3 days unless instructed by your doctor.

Not recommended for children under 12 years of age.

Method of Administration

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

If you take more Paracetamol Effervescent 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 about this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Effervescent can cause side effects although not everybody gets them. If you get any of the following symptoms after taking these tablets, **you should contact your doctor immediately:**

- **any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat**
- **an acute allergic reaction (anaphylaxis) or swelling of the skin**

The following side effects have also been reported:

- Very rare cases of serious skin reactions have been reported.
- Very rare reports of blood problems, so if you notice unusual bleeding, you bruise more easily than normal, or you seem to be more susceptible to infections than usual, tell your doctor as soon as possible.
- Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems so tell your doctor if this happens to you) blood tests may show abnormal liver function.

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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).

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 PARACETAMOL EFFERVESCENT

Do not store your tablets above 25°C. Store in the original package and protect from moisture.

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

Keep all medicines out of the sight and reach of children.

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. FURTHER INFORMATION

What Paracetamol Effervescent 500mg Tablets contain:

The active ingredient is paracetamol. Each tablet contains 500 mg paracetamol.

The other ingredients are anhydrous citric acid (E330), povidone, sodium hydrogen carbonate (E500), saccharin sodium, anhydrous sodium carbonate, simeticone (E900), polysorbate 80 (E433), aspartame (E951) (a source of phenylalanine). Each tablet contains 438 mg of sodium.

What Paracetamol Effervescent 500mg Tablets look like and the contents of the pack: Paracetamol Effervescent 500mg Tablets are white, circular effervescent tablets.

Your medicine is available in blister packs of:

PL 51463/0031 - 24, 32, 60 and 100 tablets
PL 51463/0032 - 12, 16, 24, 28 and 30 tablets
(not all pack sizes may be marketed).

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, Repton Road, Measham, DE12 7DT, U.K.

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Customer: Kent Pharma UK Limited

Change: PRAC Update

Colour: Pantone Black C

Size: 297 x 210mm Proof: 1

Date: 22/01/25 Code: BXP065FUL

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System