

Paracetamol 500 mg Effervescent Tablets

Paracetamol

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

- This medicine is available without prescription. However, you still need to take Paracetamol Effervescent Tablets carefully to get the best result from it.
- 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 or pharmacist. 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 3 days.

What is in this leaflet

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1. What Paracetamol Effervescent Tablets are and what they are used for

Paracetamol Effervescent Tablets contain paracetamol, which is a mild pain killer and reduces the body temperature in fever. The tablets are recommended for use in treatment of mild to moderate pain and/or fever.

2. What you need to know before you take Paracetamol Effervescent Tablets

Do not take Paracetamol Effervescent Tablets if you:

- are allergic to paracetamol, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol Effervescent Tablets if you:

- are suffering from liver problems including liver problems due to excessive alcohol consumption
- gilbert's syndrome (mild jaundice)
- are suffering from kidney problems
- are suffering from dehydration and chronic malnutrition
- suffer from asthma and are sensitive to aspirin
- are taking any other paracetamol containing medicines
- have a fever that does not improve after taking this medicine
- have glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency)
- have haemolytic anaemia (abnormal breakdown of red blood cells).

During treatment with Paracetamol 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).

Other medicines and Paracetamol Effervescent Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those you have bought without a prescription.

Tell your doctor before you take Paracetamol Effervescent Tablets if you are taking:

- drugs to thin the blood (anti-coagulant drugs e.g. warfarin, other coumarins)
- medicines used to relieve sickness (e.g. metoclopramide, domperidone)
- medicines used to treat high cholesterol (cholestyramine)
- probenecid (medicine used to treat high levels of uric acid in the blood stream (gout))
- medicine to treat fever or mild pain (aspirin, salicylamide)
- barbiturates and tricyclic antidepressants (to treat depression)
- medicines used to treat epilepsy (lamotrigine)
- medicines to treat tuberculosis (isoniazid)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Effects of paracetamol on laboratory tests

Uric acid and blood sugar tests may be affected.

Paracetamol Effervescent Tablets with food and drink

This medicine may be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant see your doctor before you take Paracetamol Effervescent Tablets. Small amounts of paracetamol pass into breast milk. This medicine may be taken, as instructed (see section 3), by mothers who are breast-feeding. If necessary, Paracetamol Effervescent Tablets 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 if the pain and/or fever are not reduced or if you need to take the medicine more often.

Driving and using machines

Paracetamol has no influence on the ability to drive and use machines.

Paracetamol Effervescent Tablets contain sodium

This medicine contains 418.5 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 20.92 % of the recommended daily dietary intake of sodium for an adult. Talk to your pharmacist or doctor if you need 5 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Paracetamol Effervescent Tablets contain sorbitol

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 Effervescent Tablets

Method of Administration

Paracetamol 500 mg Effervescent Tablets are for oral administration. The tablet(s) should be placed in a full tumbler of water and allowed to dissolve completely before swallowing.

This presentation is reserved for use in adults and in adolescents aged 12 years and above.

Use in Children and adolescents:

Children below 12 years of age: Do not give to children younger than 12 years.

Adolescents of 12 to 15 years and weighing 41 to 50 kg: The recommended dose is one tablet to be taken every 4-6 hours when necessary to a maximum of

4 doses in 24 hours. Maximum single dose is 500 mg (1 effervescent tablet).

Adolescents of 16 to 18 years and weighing more than 50kg: As adults.

Adults and children 16 years and older:

The recommended dose is one or two tablets every 4-6 hours when necessary up to four times daily. Maximum dose of 8 tablets in 24 hours. Maximum single dose is 1 g (2 effervescent tablets)

If the pain persists for more than 5 days or the fever lasts for more than 3 days, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

Do not take more medicine than the label or leaflet tells you too.

If you take more Paracetamol 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.

If you forget to take Paracetamol Effervescent Tablets

If you forget to take a dose, take another as soon as you remember, unless it is almost time for your next dose. Remember to leave at least four hours between doses. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, Paracetamol Effervescent Tablets can cause side effects, although not everybody gets them.

Stop taking Paracetamol Effervescent Tablets and see your doctor immediately if you experience symptoms like:

Rare (may affect up to 1 in 1,000 people):

- swelling on the face, mouth, hands (angioedema).

Very rare (may affect up to 1 in 10,000 people):

- serious skin reactions causing rash, sores, severe blistering and peeling of the skin. Very rare cases have been reported.

Not known (frequency cannot be estimated from the available data):

- accumulation of fluid in the larynx including an itchy rash, throat swelling (severe allergic reaction).

Talk to your doctor straight away if you notice the following serious side effect:

Not known (frequency cannot be estimated from the available data):

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

Other side effects:

Rare (may affect up to 1 in 1,000 people):

Oedema (abnormal accumulation of fluid under the skin), abnormal vision, simple skin rash or urticaria (dark red rash on the skin), haemorrhage (bleeding), abdominal pain, diarrhoea, nausea, vomiting, dizziness, fever, reduction of irritability or agitation (sedation), platelet disorders (clotting disorders), stem cell disorders (disorders of the blood forming cell in the bone marrow), abnormal liver function, liver failure, hepatic necrosis (death of liver cells), jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, pruritus (itching), feeling lousy (malaise).

Very rare (may affect up to 1 in 10,000 people):

Hepatotoxicity (damage caused to the liver), thrombocytopenia (reduction in blood platelets, which increases the risk of bleeding or bruising), leucopenia (frequent infections due to poorly functioning white blood cells or decrease in white blood cells), neutropenia (reduced neutrophil count in blood), agranulocytosis (severe decrease in white blood cells which may lead to severe infections), haemolytic anaemia (abnormal breakdown of red blood cells, which may cause weakness or pale skin), hypoglycaemia (low levels of glucose in the blood), cloudy urine and kidney disorders.

Not known (frequency cannot be estimated from the available data):

Anaemia (decrease in red blood cells), problems with the way your kidneys work (kidney alteration), problems with the way

your liver works (liver alteration), haematuria (blood in urine), anuresis (inability to urinate), gastrointestinal effects, vertigo. There have been cases of difficulty breathing, wheezing, coughing, and shortness of breath with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs such as ibuprofen.

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.

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 Website: 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 Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after expiry date which is stated on the label, blister and carton after EXP. The expiry date refers to the last day of that month.
- In-use shelf life (polypropylene tube): Use within 1 month of first opening the tube.
- Store below 30°C. Keep the polypropylene tube tightly closed. Store in the original container to protect from moisture and light.
- Do not use this medicine if you notice visible signs of deterioration, like brown or black spots on the tablets, bulging of tablets or discoloration of the tablets.
- 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 protect the environment.

6. Contents of the pack and other information

What Paracetamol Effervescent Tablets contain

The active substance is paracetamol. Each effervescent tablet contains 500 mg of paracetamol.

The other ingredients are:

Anhydrous citric acid, Sodium hydrogen carbonate, Sorbitol E420, Sodium carbonate anhydrous, Povidone K25 (E1201), Simethicone, Saccharin sodium, Lemon flavour (containing maize maltodextrin, acacia gum (E 414), alpha-tocopherol (E 307), Macrogol 6000.

What Paracetamol Effervescent Tablets look like and contents of the pack

Paracetamol 500 mg Effervescent Tablets are white to off white round, flat, beveled edged plain on both sides.

Polypropylene tube pack:

The Effervescent Tablets are packed in white opaque plain polypropylene tube and white opaque tamper evident polyethylene cap with inbuilt desiccant containing 24 tablets, 20 tablets, 10 tablets or 8 tablets.

Pack size: 60 (3 x 20) tablets per carton, 20 (1 x 20) tablets per carton, 10 (1 x 10) tablets per carton, 16 (2 x 8) tablets per carton, 30 (3 x 10) tablets per carton, 24 (3 x 8) tablets per carton, 100 (5 x 20) tablets per carton and 24 (1 x 24) tablets per carton.

Pack size(s) for tube pack: 8, 10, 20 or 24 tablets in a tube.

Strip packs:

The Effervescent Tablets are also available in Paper/PE/ Aluminium/Surlyn Strip in following pack sizes.

Pack Size: 10, 16, 20, 24, 30, 32, 60 and 100 tablets per carton.

Pack size(s) for strip: 4 or 10 tablets in a strip.

Not all pack sizes may be marketed.

CAUTION for tube pack: Cap contains desiccant. Do not eat.

Marketing Authorisation Holder and Manufacturer

Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom.

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