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Package leaflet: Information for the user



Paracetamol 500mg Effervescent Tablets

Paracetamol

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 3 days.
- The full name of this medicine is Paracetamol 500mg Effervescent Tablets but within the leaflet it will be referred to as Paracetamol Effervescent Tablets.

What is in this leaflet

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

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)
- are below 12 years of age.

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before taking Paracetamol Effervescent Tablets if you:
- are suffering from liver problems including liver problems due to excessive alcohol consumption
 - have 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-phosphatodehydrogenase deficiency (enzyme deficiency)
 - have hemolytic anemia (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 important warnings

Taking painkillers for headaches too often or for too long can make them worse.

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

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

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.

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.

Important information about some of the ingredients of Paracetamol Effervescent Tablets

Paracetamol Effervescent Tablets contain sodium
This medicine contains 418.5mg 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 (E420)

This medicine contains 100mg of 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

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

Place the tablet(s) in a full glass of water and allow to dissolve completely before swallowing.

The recommended dose is

Adults and children 16 years and older:

- one or two tablets every 4 – 6 hours as required, up to four times daily
- Maximum dose of 8 tablets in 24 hours
- Maximum single dose is 1g (2 tablets)

Adolescents 12 to 15 years:

- one tablet every 4-6 hours as required, up to four times daily
- Maximum dose of 4 tablets in 24 hours
- Maximum single dose is 500mg (1 tablet)
- **Do not give to children younger than 12 years.**

This medicine should not be taken for more than 3 days. If the pain or fever does not improve after 3 days, or gets worse or other symptoms appear, stop the treatment and talk to your doctor for advice. Do not take more medicine than the label or leaflet tells you to.

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, pharmacist or nurse.

4. Possible side effects

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

You should stop taking Paracetamol Effervescent Tablets and see your doctor immediately if you experience symptoms like:

- accumulation of fluid in the larynx including an itchy rash, throat swelling (severe allergic reaction)
- swelling on the face, mouth, hands (angioedema)
- serious skin disease causing rash, skin peeling and sores
- severe blistering and peeling of the skin.

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), hemolytic anemia (abnormal breakdown of red blood cells, which may cause weakness or pale skin), hypoglycemia (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 and 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.

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, 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 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 discolouration 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 contains:

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

The other ingredients are:

Citric acid (E330), Sodium hydrogen carbonate, Sorbitol (E420), Sodium carbonate, Povidone K25 (E1201), Simethicone, Saccharin sodium, Lemon flavour (containing maize maltodextrin, acacia gum (E414), alpha-tocopherol (E307) and Macrogol 6000.

What Paracetamol Effervescent Tablets look like and contents of the pack:

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

Polypropylene tube pack:

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

Pack size(s): 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 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 a Paper/PE/Aluminium/Suriyn Strip in the following pack sizes. Pack Size: 10, 16, 20, 24 and 30 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

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