

Paracetamol 500 mg Effervescent Tablets

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

What is in this leaflet:

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

1. What Paracetamol is and what it is used for

The name of your medicine is Paracetamol 500 mg Effervescent Tablets (called Paracetamol throughout this leaflet). It belongs to a group of medicines called painkillers (analgesics).

Paracetamol works by relieving pain and reducing high temperature and fever.

It is used for:

- Mild to moderate pain including headache, migraine, neuralgia (sharp nerve pain), toothache, period pain and pain caused by rheumatism
- Relief of symptoms from colds, flu and sore throats.

2. What you need to know before you take Paracetamol

Do not take Paracetamol

- if you are allergic (hypersensitive) to Paracetamol or any of the other ingredients in your medicine (listed in Section 6: Further information)
- if you are taking anything else with Paracetamol in it. If you are not sure, talk to your doctor or pharmacist before taking Paracetamol.

Take special care and talk to a pharmacist or your doctor before taking this medicine if you are:

- suffering from liver or kidney diseases (including alcoholic liver disease) or G-6-PD deficiency (an hereditary condition leading to low red blood cell counts).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Paracetamol

- if you have severe kidney or liver problems
- if you have liver disease due to a dependence on alcohol.
- 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).

If you are not sure if this applies to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Paracetamol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because paracetamol and some medicines can affect the way each other work.

In particular, tell your doctor if you are taking any of the following:

- Metoclopramide or domperidone - used for nausea (feeling sick), vomiting (being sick) and other stomach problems
- some treatments for diarrhoea caused by gall bladder disease.
- Colestyramine - used for high cholesterol and other fats in the blood
- Anti-coagulants - used to thin the blood (such as warfarin). Do not use this medicine if you are taking medicines that reduce the clotting of the blood. However, if you need to take pain-killers every day, talk to your doctor
- Chloramphenicol (an antibiotic)
- Other medicines containing paracetamol. You should not take other medicines containing Paracetamol at the same time as taking this medicine.
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

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.

You may take Paracetamol if you are breast-feeding.

Paracetamol contains Sodium (salt), Sucrose and Lactose

- Sodium: There is 315mg of sodium in each effervescent tablet. This may be harmful to people on a low sodium or low salt diet
- Sucrose and lactose: If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

3. How to take Paracetamol

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

For oral administration and short-term use only

Taking this medicine

- Dissolve the tablets in a glass of water. Then drink the whole contents of the glass.

How much to take

Adults, the elderly and children 15 years and over:

One or two tablets to be taken every 4 hours when necessary to a maximum of 4 doses in 24 hours up to four times a day. Maximum dose 8 tablets in 24 hours.

Children aged 12 to 15 years

The recommended dose is 1 tablet every 4-6 hours as required

- Do not give more than 4 tablets in 24 hours.
- Do not give for more than 3 days at a time unless your doctor tells you to.

Children under 12 years of age

These tablets are not recommended for children under 12 years of age.

Do not exceed the stated dose.

If symptoms persist, consult your doctor.

If you take more Paracetamol 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. Take the medicine pack with you so the doctor knows what you have taken.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them and they are usually mild.

Very rare cases of serious skin reactions have been reported.

Frequency "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)"

You can reduce the chances of experiencing side effects by using the minimum dose required. Side effects may be more serious in elderly patients.

Stop taking Paracetamol and tell your doctor as soon as possible if you notice any of the following:

- Skin rash or other signs of allergy: difficulty breathing, swollen facial features or a runny nose.
- Very rare cases of serious skin reactions have been reported. Symptoms could include skin reddening, blisters or rash.
- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual. These are very rare effects in people taking Paracetamol.

If you show any of these signs stop taking Paracetamol immediately and talk to a doctor.

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist:

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.
- Other rare side effects like shortness of breath.

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.

By reporting side effects you can help provide information on the safety of this medicine.

5. How to store Paracetamol

- Keep out of the sight and reach of children, preferably in a locked cupboard or medicine cabinet
- Do not use paracetamol after the expiry date (month, year) on the label and carton. The expiry date refers to the last day of that month
- Do not store above 25°C
- Keep the container tightly closed

6. Contents of the pack and other information

What Paracetamol contains

- The active substance of Paracetamol 500 mg Effervescent Tablets is paracetamol. Each tablet contains 500 mg of paracetamol
- The other ingredients are: citric acid, lactose, sodium hydrogen carbonate, povidone, simethicone emulsion, lemon flavour (containing citral, citric acid, ethyl alcohol, lemon oil, lime oil, alpha-tocopherol, triacetate, maltodextrin, gum arabic and sucrose), saccharin.

What Paracetamol looks like and contents of the pack

Paracetamol 500 mg Effervescent Tablets are round, biplane, white or off-white tablets with facets on both sides.

They are available in packs of 32 tablets.

Marketing Authorisation Holder:

Steranco Healthcare UK Limited, Unit 2A, Olympic Way, Sefton Business Park, Bootle, Merseyside, L30 1RD, United Kingdom.

Manufacturer(s)

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Formats suitable for the blind and partially sighted are available on request from the Marketing Authorisation Holder.