Package leaflet: Information for the user

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.

For medicine available without a prescription:

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 contact a doctor if you do not feel better or if you feel worse after 3 days.

For medicine available only on prescription:
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is this leaflet:

1. What Paracetamol Effervescent Tablets is and what it is 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 is and what it is used for

This medicine contain paracetamol, which belongs to a group of medicines called analgesics and antipyretics that relieve mild to moderate pain and/or fever.

It can be used to relieve headache, migraine, neuralgia, toothache, period pain, rheumatic aches and pains, sore throat and the symptoms of colds and flu.

You must talk to a doctor if you do not feel better or if you do not improve after 3 days

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 ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Paracetamol Effervescent Tablets:

- If you are suffering from kidney problems

- If you are suffering from liver problems including liver problems due to excessive alcohol consumption.
- If you have Gilbert's syndrome (mild jaundice)
- If you have hemolytic anemia (abnormal breakdown of red blood cells)
- If you are an asthmatic and sensitive to aspirin (acetylsalicylic acid).
- If you are suffering from dehydration or chronic malnutrition.
- If you are on paracetamol containing medicines
- If you have fever after paracetamol therapy
- If you suffer from glucose-6-phosphate dehydrogenase deficiency(enzyme deficiency)

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

Do not use paracetamol unless prescribed by your doctor if you have an addiction to alcohol or liver damage. If this applies to you, you must not take these tablets with alcohol. If you are already taking other pain medication containing paracetamol these tablets without first speaking to your doctor or a pharmacist.

Never take more Paracetamol Effervescent Tablets than recommended. A higher dose does not increase pain relief; instead it can cause severe liver damage. The symptoms of liver damage occur first after a few days. It is important therefore that you contact your doctor as soon as possible if you have taken more Paracetamol Effervescent Tablets than recommended in this leaflet.

Children and adolescents
Do not use Paracetamol Effervescent Tablets in children younger than 12 years of age.

Other medicines and Paracetamol Effervescent Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 i.e.gout)
- Medicine to treat fever or mild pain (Aspirin (acetylsalicylic acid), Salicylamide)
- Drugs such as rifampicin (drug that helps to fight infection) and some antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone (drugs used to treat or cure convulsions)
- Medicines used to treat epilepsy (Lamotrigine)
- Medicines to treat tuberculosis (Isoniazid)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Paracetamol may extend the duration of action of chloramphenicol

Effects of Paracetamol Effervescent Tablets on laboratory tests
Uric acid and blood sugar tests may be affected.

Paracetamol Effervescent Tablets with food
There is no significant effect on absorption of Paracetamol when taken with meal.

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 any 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.

Paracetamol passes into breast milk. Therapeutic doses of Paracetamol can be administered during breast-feeding.

Driving and using machines
Paracetamol Effervescent Tablets have no influence on the ability to drive and use machines.

Paracetamol Effervescent Tablets contain sodium and aspartame
This medicine contains 439.46 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 21.97% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 20 mg aspartame in each effervescent 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 Effervescent Tablets

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

For medicine available without a prescription

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.

For medicine available only on prescription

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

Paracetamol Effervescent Tablets are for oral administration and may be taken with or without food. Place the tablets in a full glass of water. Allow it to completely dissolve. Then drink the solution straight away.

If you have doubts on the correct dose of Paracetamol Effervescent Tablets to use please consult your doctor.

<u>Use in children and adolescents:</u>
- Adolescents of 12 to 15 years and weighing 41 to 50 kg, the posology is one tablet per dose, repeated every 4-6 hours if necessary, without exceeding 4 tablets daily.
- Adolescents of 16 to 18 years and weighing more than 50kg: as adults.

<u>Adults:</u>
In adults and adolescents (aged 16 years and older) weighing more than 50 kg, the usual dose is one to two [Paracetamol 500 mg Effervescent Tablets], repeated every 6 hours as needed, up to a maximum of 8 tablets (4000 mg) in 24 hours.

In adults and adolescents (aged 16 years and older) weighing less than 50 kg, the usual dose is one [Paracetamol 500 mg effervescent tablet] repeated every 6 hours as needed. The maximum dose in 24 hours should not exceed 60 mg per kg of bodyweight. i.e. this would be up to a maximum of 2000 mg (4 tablets) in 24 hours.

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 Paracetamol Effervescent Tablets more than 10 days without consulting the doctor.

If complaints persist or worsen, you should seek medical advice. Do not exceed the stated dose.

Kidney problems:
In moderate kidney problems: The usual dose is 500 mg repeated every 6 hours.

In severe kidney problems: The usual dose is 500 mg repeated every 8 hours

Liver problems:
In case of problems with your liver please consult your doctor. Your doctor may decide to reduce the dose.

In chronic alcoholics, a dose of 2000 mg per day should not be exceeded.

Do not exceed the stated dose. Do not give to adolescents below 12 years of age.

If you take more Paracetamol Effervescent Tablets than you should:
Symptoms of paracetamol overdose in the first 24 hours may include paleness, nausea (feeling sick), vomiting, lack of desire to eat and stomach pain. 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. Never double-up on a dose to make up for the one you have missed.

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:

- Swelling in the face, tongue or throat, difficulty swallowing, red and itchy swellings on the skin and difficulty in breathing.
- Serious skin reactions causing rash or skin peeling or sores or blisters

Other side effects includes:

Rare (may affect up to 1 in 1,000 people):
- Bleeding problems or clotting disorders, decreased formation of cells, severe decrease in white blood cells which may lead to severe infections, frequent infections due to poorly functioning white blood cells or decrease in white blood cells, reduction in blood platelets, which increases the risk of bleeding or bruising abnormal breakdown of red blood cells, which may cause weakness or pale skin, decrease in blood count, reduced neutrophil count in blood.
- Allergies (excluding swelling on the face, mouth, hands).
- Depression, confusion, sensing unreal things
- Tremor, headache

- Abnormal vision.
- Abnormal accumulation of fluid under the skin.
- Stomach pain, diarrhoea, nausea, vomiting, bleeding
- Abnormal liver function, liver failure, death of liver cells, jaundice
- Dizziness, feeling of general discomfort or uneasiness, fever, drowsiness, drug interaction.
- Overdose and poisoning.

Very rare (may affect up to 1 in 10,000 people):
- Damage caused to the liver
- Immediate severe allergic reaction (hypersensitivity reaction requiring discontinuation of treatment)
- Low levels of glucose in the blood
- Cloudy urine and kidney disorders.
- Allergic reaction of the skin
- Accumulation of fluid in the voice box
- Decrease in red blood cells
- Severe kidney impairment
- Kidney disorder
- Blood in urine
- Inability to urinate
- Uneasiness

Reporting of side effects
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. You can also report side effects directly via the national reporting system(See details below). By reporting side effects you can help provide more information on the safety of this medicine.
Yellow card scheme at Website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Paracetamol Effervescent Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use Paracetamol Effervescent Tablets after expiry date which is stated on the label after EXP. The expiry date refers to last day of that month.
- This medicinal product does not require any special temperature conditions.
- Store in the original package to protect from light and moisture.
- The solution is stable up to 8 hours below 25^0C after dissolving the tablet, hence solution should be consumed within 8 hours.
- Do not use the product 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 dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Paracetamol Effervescent Tablet contains:
The active substance is paracetamol. Each effervescent tablet contains 500 mg of paracetamol.

The other ingredients are;
Citric acid (anhydrous) (E330), povidone, sodium bicarbonate (E500), sodium saccharin (E954), sodium carbonate (anhydrous) (E500), simeticone (E900), polysorbate 80 (E443), aspartame (E951)

What Paracetamol Effervescent Tablets looks like and content of the pack:
White to off-white, circular, flat-faced, bevelled edge tablets debossed with a ring on one side and plain

on the other. Diameter 25.2 mm.

Laminate blister strips packed into cardboard cartons.

Pack size(s) for strip pack: -8, 10, 12, 16, 20, 24, 32, 50, 60, 100 units.

Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer:

Cipla (EU) Limited
Dixcart House, Addlestone Road,
Bourne Business Park,
Addlestone, KT15 2LE,
Surrey, United Kingdom.

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