

Patient Information Leaflet

Gacet -500

(Paracetamol Effervescent Granules 500 mg)

Read all of this leaflet carefully before you start taking or giving this medicine.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms do not improve after three days.
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paracetamol effervescent granules is and what it is used for.
2. Before you take Paracetamol effervescent granules.
3. How to take Paracetamol effervescent granules.
4. Possible side effects.
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1. What Paracetamol Effervescent Granules is and what it is used for

Paracetamol effervescent granules contains paracetamol. Paracetamol is a pain killing drug that also helps to reduce your temperature when you have a fever. Paracetamol effervescent granules provides relief from headaches, including migraine and tension headaches, backaches, rheumatic and muscle pain, neuralgia, toothache and period pain. Paracetamol effervescent granules also relieves the fever, aches and pains of colds and 'flu.

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

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 Granules:

- 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)
- If you have a severe infection as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- Deep, rapid, difficult breathing
- Feeling sick (nausea), being sick (vomiting)
- Loss of appetite

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 concerns you do not use with alcohol. If you are already taking other pain medication containing paracetamol do not use Paracetamol Effervescent Granules without first speaking to your doctor or a pharmacist.

Never take more Paracetamol Effervescent Granules 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 Granules than recommended in this leaflet.

Children and adolescents

Do not use Paracetamol Effervescent Granules in children younger than 12 years of age.

Other medicines and Paracetamol Effervescent Granules.

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 Granules 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)
- Paracetamol may extend the duration of action of chloramphenicol
- 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.

Effects of Paracetamol Effervescent Granules on laboratory tests

Uric acid and blood sugar tests may be affected.

Paracetamol Effervescent Granules 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 Granules 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 Granules have no influence on the ability to drive and use machines.

Paracetamol Effervescent Granules contain sodium and aspartame.

This medicine contains 463.01 mg sodium (main component of cooking/table salt) in each effervescent Granules. This is equivalent to 23.15% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 20 mg aspartame in each effervescent Granules. 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 Granules

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

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.

Paracetamol Effervescent Granules are for oral administration. Place the tablet 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 Granules to use please consult your doctor.

Use in children and adolescents:

- Adolescents of 12 to 15 years, the posology is one tablet per dose, repeated every 4-6 hours if necessary, without exceeding 4 Granules daily.
- Adolescents of 16 to 18 years and weighing more than 50kg: as adults

Adults:

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 Granules], repeated every 6 hours as needed, up to a maximum of 8 Granules (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 Granules] 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 Granules) 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 Granules more than 10 days without consulting the doctor.

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

Paracetamol Effervescent tablet could be taken with or without food and drinks.

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 Granules 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 Granules

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

Talk to your doctor before taking Levetiracetam:

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

Stop taking Paracetamol Effervescent Granules and tell 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 Rare (may affect up to 1 in 1,000 people):

- Bleeding problems or clotting disorders (platelet disorders), decreased formation of cells, severe decrease in white blood cells which may lead to severe infections (agranulocytosis), frequent infections due to poorly functioning white blood cells or decrease in white blood cells (leucopenia), reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia) abnormal breakdown of red blood cells, which may cause weakness or

pale skin (haemolytic anaemia), decrease in blood count (pancytopenia), reduced neutrophil count in blood (neutropenia).

- Allergies (excluding swelling on the face, mouth, hands).
- Depression, confusion, sensing unreal things
- Tremor, headache
- Abnormal vision.
- Abnormal accumulation of fluid under the skin (oedema).
- Stomach pain, diarrhoea, nausea (feeling sick), vomiting, bleeding (haemorrhage)
- Abnormal liver function, liver failure, death of liver cells (hepatic necrosis), jaundice
- Dizziness, feeling of general discomfort or uneasiness (malaise), fever, drowsiness, drug interaction.
- Overdose and poisoning.

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

- Damage caused to the liver (hepatotoxicity)
- Immediate severe allergic reaction (hypersensitivity reaction requiring discontinuation of treatment)
- Low levels of glucose in the blood (hypoglycaemias)
- Cloudy urine and kidney disorders.
- Life-threatening skin disease causing rash, skin peeling and sores (epidermal necrolysis)
- Allergic reaction of the skin (erythema multiforme)
- Severe life-threatening skin disease causing rash, skin peeling, sores (Stevens–Johnson syndrome)
- Accumulation of fluid in the voice box (larynx)
- Severe allergic reaction (anaphylactic shock)
- Decrease in red blood cells (anemia)
- Severe kidney impairment (renal alteration)
- Kidney disorder (nephrite interstitial)
- Blood in urine (haematuria)
- Inability to urinate (anuresis)
- Stomach ulcers and bleeding (gastrointestinal effects)

- Uneasiness
- serious skin reactions

If 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.

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

5. How to store Paracetamol Effervescent Granules

- Keep this medicine out of the sight and reach of children.
- Do not use Paracetamol Effervescent Granules 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.
- Do not store above 25⁰c and protect from light and moisture.
- Do not use the product if you notice visible signs of deterioration, like brown or black spots on the Granules, bulging of Granules or discoloration of the Granules.
- 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 Granules 500 mg contains:

Sorbitol, Sodium Bicarbonate, Sodium Saccharin, Sodium Carbonate, Povidone(K30), Dimethicone, Isopropyl Alcohol, Anhydrous citric acid, Powdarome Orange 4153.

4 x 4 Aluminium strips are packed in carton along with insert.

Marketing Authorisation Holder & Manufacturer:

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