

PACKAGE LEAFLET: INFORMATION FOR THE USER

GACET - 500

(Paracetamol Effervescent Tablets BP 500 mg)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT GACET - 500 TABLETS ARE AND WHAT THEY ARE USED FOR

GACET - 500 Tablets contain Paracetamol, which relieves pain (analgesic) and reduces the body temperature in fever (antipyretic).

The tablets are recommended for use in treatment of mild to moderate pain and/or fever.

2. BEFORE YOU TAKE GACET - 500 TABLETS Do not take

GACET - 500 Tablets:

- If you are allergic (hypersensitive) to Paracetamol or any of the ingredients of Paracetamol 500 mg Effervescent Tablets.

Take special care with GACET - 500 Tablets

Tell your doctor:

- 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.
- If you are suffering from dehydration or chronic malnutrition.
- If you are on paracetamol containing drugs.
- If you have fever after paracetamol therapy.
- If you suffer from glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency).

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 GACET - 500 Tablets without first speaking to your doctor or a pharmacist.

Never take more GACET - 500 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 GACET - 500 Tablets than recommended in this leaflet.

Do not use GACET - 500 Tablets in children and adolescents below 16 years of age.

3. HOW TO TAKE GACET - 500 TABLETS

You should take GACET - 500 Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This presentation is reserved for adults and children weighing over 27 kg (from 8 years).

For children with a weight of less than 27 kg, there are other presentations of paracetamol which dosage is more suitable. Don't hesitate to ask your doctor or pharmacist.

Dosage in adults and children from 27 kg (or from 8 years)

The usual dosage is: For children weighing 27 to 40 kg (approximately 8 to 13 years), the dosage

is 1 tablet of 500 mg per dose, to be repeated if necessary after 6 hours, not exceeding 4 tablets per day.

For children weighing 41 to 50 kg (approximately 12 to 15 years), the dosage is 1 tablet of 500 mg per dose, to be repeated if necessary after 4 hours, not exceeding 6 tablets per day.

For adults and children weighing more than 50 kg (from about 15 years old):

The usual dosage is 1 or 2 tablets of 500 mg per dose (depending on the intensity of the pain), to be repeated if necessary after at least 4 hours.

It is generally not recommended to exceed 3 g of paracetamol per day, or 6 tablets per day.

However, in case of more severe pain, and on the advice of your doctor or pharmacist, the total dose can be increased up to 4 g per day, or 8 tablets per day.

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 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.

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 divide the 500 mg tablet into two equal halves for the lower doses.

Paracetamol tablets of lower strengths are available in the market.

If you take more GACET - 500 Tablets than you should:

Immediately consult your doctor or pharmacist or medical emergencies.

Overdose can lead to liver disease (hepatic insufficiency), gastrointestinal bleeding, brain disease (encephalopathy), coma, or even especially in populations at higher risk, such as young children, the elderly and in certain situations (liver disease, alcoholism, chronic malnutrition). In the first 24 hours, the main symptoms of

poisoning are: nausea, vomiting, loss of appetite, abdominal pain, fetus.

Overdosage may also result in: pancreas (pancreatitis), hyperamylaseemia (increased amylase in the blood), kidney disease (acute renal failure), and a blood problem in which red blood cells, white blood cells and platelets are all reduced in number which results in:

- fatigue, shortness of breath, and a fever;
- frequent infections accompanied by severe fever and chills, sore throat or ulcers of the mouth;
- a tendency to bleed or present spontaneous bruising, nosebleeds.

If you forget to take GACET - 500® Effervescent:

Do not double dose to make up for the dose that you missed.

If you stop taking GACET - 500® Effervescent:

Without effect.

If you forget to take GACET - 500 Tablets:

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. The minimum time interval between two doses should be 6 hours.

Never take a double dose to make up for the one you have missed.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines GACET - 500 Tablets can cause side effects, although not everybody gets them.

You should stop taking GACET - 500 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.

Rare (affects less than 1 in 1.000 patients):

- 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 (affects less than 1 in 10.000 patients):

- Damage caused to the liver (hepatotoxicity)
- Immediate severe allergic reaction (hypersensitivity reaction requiring discontinuation of treatment)
- Low levels of glucose in the blood (hypoglycemia)
- 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.

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.

5. HOW TO STORE GACET - 500 TABLETS

- Keep out of the reach and sight of children and adolescents.
- Do not use Paracetamol 500 mg Effervescent Tablets after expiry date which is stated on the label after EXP. The expiry date refers to last day of that month.
- Store below 25°C. Store in the original package in order to protect from moisture and light.
- Do not use the product if you notice visible signs of deterioration, like brown or black spots, bulging of tablets or discoloration.
- Medicines should not be disposed of 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. FURTHER INFORMATION

What GACET - 500 Tablets contain

The active ingredient is Paracetamol. Each tablet contains 500 mg.

The other ingredients are Anhydrous Citric acid, Sodium Bicarbonate, Sodium Saccharin, Sodium Benzoate, Povidone (PVP K30), Simethicone, Tween 80, Iso Propyl alcohol, Sodium Carbonate, Aspartame, Flavour Orange, Purified water.

What GACET - 500 Tablets look like and contents of the pack

GACET - 500 Tablets are white to off white colour, round flat faced beveled edged tablets with orange odour.

The tablets are supplied in boxes containing 4 Strips (Aluminium foil) of 4 tablets along with product insert.