GACET (PARACETAMOL SUPPOSITORIES)

Paracetamol (125mg, 250mg)

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What Gacet is used for

Gacet is used for the treatment of mild to moderate pain and fever in children. Gacet suppositories may be especially useful in patients unable to take oral forms of paracetamol e.g post operatively or with nausea and vomiting.

How Gacet works

Paracetamol had been thought to work by inhibiting the production of a compound in the central nervous system. Recently, is was found that paracetamol may have been acting via interaction in spinal cord pathways and inhibition of spinal substance.

Before you use Gacet

- When you must not use it

Do not use Gacet if you are hypersensitive to Paracetamol or any other ingredients in the product.

Do not use Gacet if you have any of the following conditions:

- Serious liver disorder
- Bleeding or swelling of the rectal (contraindication related directly to the administration route of the medicine).

Pregnancy and lactation

Ask your doctor or pharmacist for advice before using Gacet if you are pregnant, trying to get pregnant or think you may be pregnant or if you are breast-feeding.

- Before you start to use it

Paracetamol should be taken with care to if you have impaired liver or kidney function. In the event of uric acid or sugar content tests, you may be advised to disclose your intake of paracetamol. If the pain persists for more than 5 days or the fever for more than 3 days, or in the event of worsening, stop taking paracetamol without seeking advice from the doctor.

Gacet contains paracetamol. Do not take any other paracetamol containing medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blister or rash. These could be sign of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Tell your doctor if you are particularly taking:

- Alcohol
- Rifampicin- used to treat infections
- Barbiturates or other antiepleptic or antiseizure medicines
- Any other medicines containing paracetamol

How to use Gacet

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Recommended dose: GACET-125(Paracetamol Suppositories BP 125 mg) 1-5years (10-20kg): 1-2 suppositories. GACET-250(Paracetamol Suppositories BP 250 mg) 6-12years(20-40kg): 1-2 suppositories.

These doses may be repeated up to a maximum of 4 times in 24 hours. The dose should not be repeated more frequently than every 4 hours. The recommended dose should not be exceeded. Higher doses do not produce any increase in pain relief effect. Only whole suppositories should be administered – do not break suppository before administration.

Gacet suppositories is for rectal administration only.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Gacet for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Used the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- <u>Things you must do</u>

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Gacet.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Gacet to anyone else, even if they have the same symptoms or condition as you.

<u>Things to be careful of</u>

Driving and using machines

This medicine may affect your ability to drive or use machines. If the suppositories make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

If used as directed, paracetamol rarely causes severe toxicity or side effects. In some rare cases, a skin or allergic reaction may occur. Redness of the rectum and local blood vessel changes may be reported. Liver toxicity may occur after overdosage. You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website <u>npra.moh.gov.my</u> (Consumers \rightarrow Reporting \rightarrow Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Gacet

- <u>Storage</u>

Keep out of the reach and sight of children.

Store in a dry place, below 30°C. Protect from light.

- <u>Disposal</u>

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.

Product Description

 <u>What it looks like</u> GACET-125 (Paracetamol Suppositories BP 125 mg) are white opaque bullet shaped suppositories.

GACET-250 (Paracetamol Suppositories BP 250 mg) are white opaque bullet shaped suppositories.

<u>Ingredients</u>
Active ingredient(s)
Paracetamol

- Inactive ingredients Hard fat (Witespol H 15)

 <u>MAL number(s):</u> GACET-125(Paracetamol Suppositories BP 125 mg) MAL20106015XZ

GACET-250(Paracetamol Suppositories BP 250 mg) MAL20106016XZ

Manufacturer

BLISS GVS PHARMA LTD. Plot No. 11, Dewan Udyog Nagar, Aliyali, Palghar 401 404, Maharashtra State, INDIA.

Product Registration Holder

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