

Size: (L X H)109mm x 188mm

GACET-125/250
Paracetamol Suppositories BP

Composition :

Each suppository contains:		Each suppository contains:	
Paracetamol BP	125 mg	Paracetamol BP	250 mg
Hard fat (Witepsol H 15)	q.s.	Hard fat (Witepsol H 15)	q.s.

Description :

A white opaque bullet shaped suppositories.

Pharmacology :

The mechanism of action : Until recently, Paracetamol was supposed to have predominantly a strong inhibitory action on prostaglandin production in the central nervous system. The rank of this mechanism has been questioned recently, and several other findings have been published: an interaction with bulbospinal pathways, inhibition of spinal substance P-mediated analgesia, and a reduction of nitric oxide generation involved in spinal hyperalgesia. Furthermore, an inhibition of DNA repair by Paracetamol was reported which may contribute to its clastogenic effects.

Pharmacokinetics :

Paracetamol is well absorbed by both oral and rectal routes.

Peak plasma concentrations occur about 2 to 3 hours after rectal administration. The plasma half life is about 2 hours.

Paracetamol is primarily metabolized in the liver by conjugation to glucuronide and sulphate. A small amount (about 3-10% of a therapeutic dose) is metabolized by oxidation and the reactive intermediate metabolite thus formed is bound preferentially to the liver glutathione and excreted as cystein and mercapturic acid conjugates. Excretion occurs via the kidneys. 2-3% of a therapeutic dose is excreted unchanged: 80-90% as glucuronide and sulphate and a smaller amount as cystein and mercapturic acid derivatives.

Indications:

For the treatment of mild to moderate pain and pyrexia 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.

Contraindications:

- Known allergy to Paracetamol
- Serious liver disorder
- Rectal bleeding or inflammation (contraindication related directly to the administration route of the medicine)

Precautions and Warning :

Paracetamol should be given with care to patients with impaired liver or kidney function. In the event of uric acid or sugar content tests, the patient should be advised to disclose the 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 aggravation, treatment should not be continued without seeking advice from the doctor. Severe or recurrent pain or high or continued fever may be indicative of serious illness.

"This preparation 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, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Adverse Effect / Undesirable Effect :

If used as directed, Paracetamol rarely causes severe toxicity or side effects. In some rare cases a cutaneous eruption or an allergic reaction may occur. Redness of the mucous membrane of the rectum and minor local vascular changes may be reported. Hepatic necrosis may occur after overdosage.

Reasons for immediate discontinuation of the drug

- Exceptional biological changes requiring a blood analysis.
- Abnormally low count of certain blood constituents (platelets)
- Local effects related to administration route. These are all the more frequent and severe if the duration of treatment is prolonged and the frequency of intake and the dosage are high.
- Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Drug Interactions :

Drugs which include hepatic microsomal enzymes such as alcohol, Rifampicin, barbiturates and other anti-convulsants may increase the hepatotoxicity of Paracetamol particularly after overdosage. The therapeutic effects of Paracetamol may also be decreased.

Dosage: GACET-125 Suppository:

1-5 years (10-20kg): 1-2 Suppositories

GACET-250 Suppository:

6-12 years (20-40kg): 1-2 Suppositories

Method of Administration:

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 analgesic effect. Only whole suppositories should be administered – do not break suppository before administration.

Overdosage:

In the event of overdosage or accidental ingestion of a very high dose (150mg/kg), the doctor should be immediately consulted. Specific antidote is N Acetyl Cysteine.

Pregnancy and Lactation : Epidemiological studies in human pregnancy have shown no ill effects due to Paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in clinically significant amounts. Available published data does not contraindicate breast feeding.

For Rectal administration only.

Not to be taken orally.

Storage:

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

Keep medicine out of reach of children.

Jauhkan daripada capaian kanak-kanak.

Presentation:

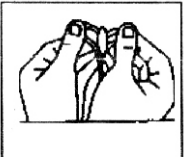
Pack of 2 x 5 & 20 x 5 Suppositories packed in a carton along with leaflet.

Date of Revision: 08/2020.

How to use Suppository

The suppositories should be inserted deeply in to the anus, if possible after having the bowels open.

1. When practical, clean the area around the rectum with mild soap and warm water, and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth.
2. Detach one suppository from the strip.
3. Remove wrapper before inserting suppository by holding suppository upright and carefully peeling wrapper evenly down both sides of the suppository. Avoid excessive handling as the is designed to melt at body temperature.
4. Store at temperature below 30°C. Throw away any unused medicine after the expiration date.
5. Position the patient flat on back or on one side, with anal opening exposed.
6. Gently insert the suppository well in to the rectum. Use fingertip to complete insertion.
7. If necessary, hold buttocks together for 30-60 second to keep suppository in place.
8. If the suppository seems soft, hold the foil wrapper under cold water for solidification and then use the suppository.



Bliss
GVS

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