PRITAMOL SUPPOSITORIES

Paracetamol (125mg, 250mg)

What is in this leaflet

- 1. What *Pritamol* is used for
- 2. How Pritamol works
- 3. Before you use *Pritamol*
- 4. How to use *Pritamol*
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Pritamol
- 8. Product description
- 9. Manufacturer and Product Registration Holder

10.Date of revision

What Pritamol is used for

For symptomatic relief of fever associated with common childhood infections. For the relief of minor pains like headache, toothache and earache.

How Pritamol works

Pritamol contains paracetamol, a medicine which works by relieving pain and reducing high temperature and fever.

Before you use Pritamol

- When you must not use it

Do not take *Pritamol* if allergic to paracetamol or to other ingredients in it. 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.

- <u>Before you start to use it</u>

Inform the doctor or pharmacist if there are liver or kidney problems, or regularly taking other medicines that affect the liver.

- 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.

How to use Pritamol

- How much to use

1-6 years: 125 to 250mg, to be inserted well up into the rectum or back passage 3–4 times a day.

Follow all directions given 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.

- When to use it

3–4 times a day.

- How long to use it

Continue taking *Pritamol* 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.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take 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 taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Signs of overdose are diarrhea, increased sweating, loss of appetite, nausea, vomiting and stomach cramps. Less frequent complications of paracetamol overdosage include heart damage, generalized bleeding, kidney damage and low blood sugar.

While you are using Pritamol

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Pritamol*.

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

- Things you must not do

This preparation contains

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

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

Do not take any new medicines without consulting your doctor or pharmacist. Do not give *Pritamol* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Special care is recommended during pregnancy. The benefits must be assessed against possible effects on the child.

Side effects

Like all medicines, *Pritamol* can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. In recommended therapeutic dosage, paracetamol is usually well-tolerated. Side effects of paracetamol are usually mild, though, blood disorder reactions have been reported. Skin rashes and other allergic reactions occur occasionally. Skin hypersensitivity reactions including skin rashes, swelling beneath the skin, serious skin reactions such as Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Pritamol

- Storage

Store in cool, dry place. Protect from light. Keep out of reach and sight of children.

- Disposal

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

- What it looks like

White colour suppositories.

- <u>Ingredients</u>
- Active ingredient: paracetamol
- Inactive ingredient: subanal EF-37

- MAL numbers:

<u>Pritamol 125</u>: MAL19962541XZ Pritamol 250: MAL19971383XZ

Manufacturer and Product Registration Holder

Prime Pharmaceutical Sdn. Bhd. 1505, Lorong Perusahaan Utama 1 Taman Perindustrian Bukit Tengah 14000 Bukit Mertajam, Penang, Malaysia.

Date of revision

10/04/2017

Serial number BPFK(R4/1)060417/00060