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## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Paracetamol 500mg Suppositories

## Paracetamol

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor or pharmacist if you do not feel better or if you feel worse after 3 days.
- Your product is called Paracetamol 500mg Suppositories but will be referred to as Paracetamol Suppositories throughout this leaflet.

### What is in this leaflet

1. What Paracetamol Suppositories are and what they are used for
2. What you need to know before you use Paracetamol Suppositories
3. How to use Paracetamol Suppositories
4. Possible side effects
5. How to store Paracetamol Suppositories
6. Contents of the pack and other information

### 1. WHAT PARACETAMOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

Paracetamol Suppositories contain a medicine called paracetamol. This belongs to a group of medicines called pain-killers (analgesics). A suppository is a small, torpedo-shaped medicine which is inserted into the back passage (rectum). Paracetamol Suppositories are used to treat pain and high temperature (fever) in adults and children over 10 years of age. They are used when it is difficult to take paracetamol as tablets or syrup. You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE PARACETAMOL SUPPOSITORIES

#### Do not use Paracetamol Suppositories:

- if you are allergic to paracetamol, soya, peanuts or any of the other ingredients of this medicine (listed in Section 6).

#### Warnings and precautions

Talk to a doctor or pharmacist before using Paracetamol Suppositories.

During treatment with Paracetamol Suppositories, tell your doctor straight away if:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

#### Take special care with the use of Paracetamol Suppositories and talk to your pharmacist or doctor if:

- you have problems with your liver or kidneys.

#### Other medicines and Paracetamol Suppositories

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Paracetamol Suppositories can have an effect on the way some medicines work and some medicines can have an effect on how Paracetamol Suppositories work.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Other medicines containing paracetamol – **do not use your Paracetamol Suppositories at the same time.**
- Medicines to treat nausea (feeling sick) and vomiting (being sick), such as metoclopramide and domperidone.
- Colestyramine, used to reduce the level of cholesterol (fat) in the blood.
- Medicines called anticoagulants, such as warfarin, used for treating blood clots or “thinning the blood”.
- Medicines called anticonvulsants used for treating epilepsy or fits (e.g. phenytoin, carbamazepine).
- The antibiotic rifampicin.
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

#### Pregnancy and breast-feeding

If necessary, Paracetamol Suppositories 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.

### 3. HOW TO USE PARACETAMOL SUPPOSITORIES

This medicine is for rectal use only. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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#### The recommended dose is:

Age	Number of suppositories	Minimum length of time between doses	Maximum number of suppositories in 24 hours
10 years to 12 years (body weight 30-40kg)	1	4 – 6 hours	4
Adults + children over 12 years	1 or 2	4 – 6 hours	8

**Do not use more suppositories than stated above.**

**This product is not suitable for use in children under 10 years of age.**

#### How to use the suppositories:

- Your bowels need to be empty when you use this medicine. If you need to go to the toilet, make sure that you do it before you use the suppository.
- It may be easier to use the suppository if you are lying on your front or side on a bed.
- Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.
- Gently push the suppository into your back passage with the pointed end first. To make it easier to use the suppository you may warm it slightly between your hands beforehand.
- Try to keep still for a minute or two and then wash your hands.
- If you need to use another suppository, then follow the above procedure again.

#### If you take more Paracetamol Suppositories than you should

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 Suppositories

Do not take a double dose to make up for the forgotten dose.

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

### 4. POSSIBLE SIDE EFFECTS

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

**Stop using Paracetamol Suppositories immediately and call your doctor if you notice you have any signs of allergic reaction.**

Signs of an allergic reaction include a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue. The following side effects can happen with this medicine.

#### Common side effects (affects more than 1 in 100 people taking this medicine):

- Redness or soreness in and around the back passage.

#### Rare side effects (affects less than 1 in 1000 people taking this medicine):

- Blood problems. If these happen, you may bruise or bleed more easily than usual, be more susceptible to infections, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems. Symptoms may include jaundice (yellowing of the skin or whites of the eyes).

#### Frequency “Not known” (frequency cannot be estimated from the available data):

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

#### 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. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

### 5. HOW TO STORE PARACETAMOL SUPPOSITORIES

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip. The expiry date refers to the last day of that month.

Do not store over 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Paracetamol Suppositories contain

The active substance is paracetamol. Each suppository contains 500mg of paracetamol.

The other ingredients are hydrogenated fat and soybean lecithin.

#### What Paracetamol Suppositories look like and contents of the pack

Cream coloured, torpedo shaped suppository, available in packs of 10 suppositories.

#### Marketing Authorisation Holder and Manufacturer

**Marketing authorisation holder:** Amdeepcha Limited, 85 Yarmouth Road, Blofield, Norwich, Norfolk, NR13 4LQ, UK.

**Manufacturer:** Dr. Pflieger Arzneimittel GmbH, Dr. Robert Pflieger Strasse 12, Bamberg, D-96052, Germany.

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