

# Para-Denk 125 Suppos

Suppositories – For rectal use  
Analgesic and antipyretic medicine  
Active ingredient: paracetamol  
For use in children aged between 6 months  
and 2 years

## Package leaflet: Information for the user

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to use Para-Denk Suppos carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- 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.

## In this leaflet:

1. What Para-Denk Suppos is and what it is used for
2. Before you use Para-Denk Suppos
3. How to use Para-Denk Suppos
4. Possible side effects
5. How to store Para-Denk Suppos
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## 1. What Para-Denk Suppos is and what it is used for

Para-Denk Suppos is an analgesic and antipyretic medicine. Para-Denk Suppos is used in the symptomatic treatment of mild to moderate pain and/or fever.

## 2. Before you use Para-Denk Suppos Do not use Para-Denk Suppos

- if you are allergic (hypersensitive) to paracetamol or any of the other ingredients of Para-Denk Suppos,
- if you suffer from severe impaired liver function.

## Take special care with Para-Denk Suppos

Ask for your doctor's advice before using Para-Denk Suppos under the following circumstances:

- if you suffer from chronic alcoholism,
- if you suffer from impaired liver function (such as inflammation of the liver, Gilbert's syndrome),
- if you have pre-existing kidney damage.

If your symptoms get worse or if you do not notice an improvement after 3 days or if you develop a high temperature, then you must consult your doctor.

In order to avoid the risk of an overdose, one should make sure that other medication being taken concurrently does not contain paracetamol.

Prolonged, incorrect use of high doses of painkillers may cause headache which must not be treated with increased doses.

In general, the habitual intake of painkillers, particularly in combination with other painkillers, may lead to permanent kidney damage associated with the risk of renal failure (analgesic nephropathy).

If high doses of painkillers, that have been incorrectly used for prolonged periods of time, are discontinued abruptly, headache, fatigue, muscle pain, nervousness or vegetative symptoms may occur. These withdrawal symptoms abate within a few days. Until then, painkillers should not be used and should not be tak-

en again without consulting your doctor beforehand.

Para-Denk Suppos should not be used over long periods or in high doses without consulting your doctor or dentist.

## Taking/using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Interactions are possible with:

- Drugs to treat gout, such as probenecide: The dose of Para-Denk Suppos should be reduced when co-administered with probenecide, as concomitant use may slow down the disintegration of Para-Denk Suppos.
- Sleeping pills, such as phenobarbital; drugs to treat epilepsy, such as phenytoin, carbamazepine; drugs to treat tuberculosis (rifampicin) and other drugs that may cause damage to the liver: Concomitant use with Para-Denk Suppos may cause liver damage.
- Drugs to reduce elevated serum lipids (cholesterol) may reduce the absorption and thus the effect of Para-Denk Suppos.
- Drugs given for HIV infections (zidovudine): There is an increased risk of reduction in the number of white blood cells (neutropenia). Para-Denk Suppos should therefore only be taken concomitantly with zidovudine upon medical advice.

How taking Para-Denk Suppos affects laboratory tests: Uric acid and blood sugar determination may be affected.

## Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

### Pregnancy

Para-Denk Suppos should only be used during pregnancy after careful consideration of the potential benefits and risks.

Para-Denk Suppos should not be taken over a long period of time during pregnancy, in high doses or in combination with other drugs, as its safety has not been proven in such cases.

### Breast-feeding

Paracetamol passes into human milk. As it is not known to be harmful for the infant, dis-

continuation of breastfeeding is generally not necessary.

## Driving and using machines

Para-Denk Suppos does not affect the ability to drive and operate machinery. However, caution should always be exercised after taking painkillers.

## Using Para-Denk Suppos with food and drink

Para-Denk Suppos should not be taken or administered with alcohol.

## 3. How to use Para-Denk Suppos

Always use Para-Denk Suppos strictly according to the instructions in this package leaflet. Please check with your doctor or pharmacist if you are not quite sure.

The dosage complies with the specifications in the following table. The dosage of paracetamol administered depends upon body weight and age. The usual dose is 10 – 15 mg per kg body weight as a single dose and up to a maximum of 60 mg/kg body weight as total daily dose.

The respective interval between doses depends on the symptoms and the maximum total daily dose and should be at least 6 hours.

A doctor should be consulted if symptoms persist for longer than 3 days.

### Para-Denk 125 Suppos:

Body weight kg (Age)	Single dose in number of suppositories (equivalent dose of paracetamol)	Maximum daily dose (24 hours) in number of suppositories (equivalent dose of paracetamol)
7 – 8 kg (6 – 9 months)	1 (125 mg paracetamol)	3 (375 mg paracetamol)
9 – 12 kg (9 months – 2 years)	1 (125 mg paracetamol)	4 (500 mg paracetamol)

## Mode of administration

Para-Denk Suppos are inserted deep into the anus, if possible, after a bowel movement. The suppository may be warmed in your hand or briefly immersed in hot water to improve lubrication.

## Duration of treatment

Do not use Para-Denk Suppos for longer than 3 days without consulting your doctor or dentist.

## Special patient groups

### Impaired liver function and slight renal impairment

The dosage must be reduced and/or the dosage interval prolonged in patients suffering from impaired liver or kidney function or Gilbert's syndrome.

### Severe renal failure

In cases of severe renal failure (creatinine clearance < 10 ml/min), there must be a dosage interval of at least 8 hours.

### Elderly patients

No particular dosage adjustment is required.

### Children with low body weight

Use of Para-Denk 125 Suppos is not recommended in children under the age of 6 months and/or in those with a body weight of less than 7 kg, as the dosage strength is not suitable for this age group. However, there are suitable dosage strengths and/or pharmaceutical forms available for this age group.

## If you use more Para-Denk Suppos than you should

The total daily dose of paracetamol should not exceed 4000 mg in adults and adolescents over 12 years of age (body weight of at least 43 kg) and 60 mg/kg/day in children.

In the case of an overdose, complaints such as nausea, vomiting, loss of appetite, pallor and tummy-ache usually occur within 24 hours.

If you have taken a lot more Para-Denk Suppos than recommended ask the doctor nearest to you to come to your assistance.

## If you forget to use Para-Denk Suppos

Do not use a double dose to make up for a forgotten dose.

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

## 4. Possible side effects

Like all medicines, Para-Denk Suppos can cause side effects, although not everybody gets them.

The frequency of side effects is classified as follows:

Very common:	More than 1 in 10 patients treated
Common:	Less than 1 in 10, but more than 1 in 100 patients treated
Uncommon:	Less than 1 in 100, but more than 1 in 1000 patients treated
Rare:	Less than 1 in 1000, but more than 1 in 10,000 patients treated
Very rare:	Less than 1 in 10,000 patients treated, including individual cases
Not known:	Cannot be estimated from the available data

### Hepatobiliary disorders

Reports of a slight rise in certain liver enzymes (serum transaminase) were rare.

### Immune system disorders

In very rare cases, there may be allergic reactions that are manifested by a simple rash or urticaria, and eventually shock.

In the case of an allergic shock reaction, ask the doctor nearest to you to come to your assistance.

Another very rare occurrence is the triggering of a constriction of the respiratory tract (analgic-induced asthma) in predisposed people.

### Blood and lymphatic system disorders

Changes in blood count have been reported on very rare occasions as have a reduced number of blood platelets (thrombocytopenia) or a significant reduction in the number of certain white blood cells (agranulocytosis).

## Skin and subcutaneous tissue disorders

Very rare cases of serious skin reactions have been reported.

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 Para-Denk Suppos

Store below 30 °C.

Do not use after the expiry date which is stated on the carton.

Keep out of the sight and reach of children.

## 6. Further information

### What Para-Denk 125 Suppos contains

The active substance is paracetamol.

One suppository contains 125 mg paracetamol.

The other ingredients are hard fat and lecithin.

### What Para-Denk 125 Suppos looks like and contents of the pack

Ivory colored suppositories.

Pack size: 10 suppositories.

### Marketing authorisation holder

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### Manufacturer

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