Denk Pharma

ParaCo-Denk 1000/60 Suppos

Suppositories – rectal use

Analgesic

For adults, adolescents and children over 12 years of age

Active substances: paracetamol + codeine

Package leaflet:
Information for the patient

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What ParaCo-Denk is and what it is used for

ParaCo-Denk is a pain reducing drug (analgesic). It is used for the relief of moderate to severe pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics, which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

2. What you need to know before you use ParaCo-Denk

Do not use ParaCo-Denk

- if you or your child are allergic to paracetamol, codeine phosphate, soya or any of the other ingredients of this medicine (listed in section 6)
- if you or your child have impaired lung function (respiratory insufficiency) or depressed breathing (respiratory depression)
- in the event of deep unconsciousness (coma)
- in the event of an inflammation of the lungs (pneumonia)
- if you or your child suffer an acute attack of asthma
- if you or your child have a chronic cough, which may for example be a warning sign of the onset of bronchial asthma (particular attention to this is required in children)
- if you are due to give birth shortly
- if you have been found to be at imminent risk of giving birth prematurely
- in children under 12 years of age
- for pain relief in children and adolescents (0 – 18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- if you know that you or your child metabolise very rapidly codeine into morphine
- if you are breastfeeding

Warnings and precautions

Talk to your doctor or pharmacist before using ParaCo-Denk, in case of:
- opioid dependence (including strong analgesics and sedatives)
- impaired consciousness
- conditions associated with increased intra-cranial pressure
- disorders of the respiratory centre and the respiratory function
- simultaneous use of monoamine oxidase (MAO) inhibitors (group of medicines for the treatment of depression)
- ventilation disorder of the lung due to chronic bronchitis or (bronchial) asthma
- previously removed gallbladder (status post-cholecystectomy)
- higher doses if you or your child have low blood pressure due to a lack of fluid

You or your child may only use ParaCo-Denk in smaller doses or less often than stated in the dosage instructions (dose reduction or prolongation of the dosage interval) if you have:
- liver function disorders (for example due to long-term alcohol abuse or inflammation of the liver)
- impairment of liver function (inflammation of the liver, Gilbert-Meulengracht disease)
- kidney function disorders (including if dialysis is required)
- diseases that may be associated with reduced glutathione levels (dose adjustment where necessary, e.g. in diabetes mellitus, HIV, Down's syndrome, tumours)

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. In these people, symptoms of overdosage are possible, even when treated with doses of ParaCo-Denk prescribed by a doctor. If you notice any of the following side effects, you or your child must stop using this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, vision disorders, circulatory problems, nausea or vomiting, constipation, lack of appetite.

In order to avoid the risk of an overdose, it is necessary to ensure that concurrent medication does not contain paracetamol or codeine phosphate.

If large amounts of analgesics are used for extended periods of time and not as directed by the doctor or pharmacist, they may cause headache, which should not be treated with increased doses.

In general, the habitual use of analgesics, especially the combination of different analgesic drugs, may lead to permanent kidney damage, which might result in renal failure (analgesic nephropathy).

Headache, fatigue, muscular pain, nervousness and vegetative symptoms may occur after abrupt discontinuation of analgesics not used as directed or used in large doses over long periods of time. No analgesic should be used before subsidence of such symptoms, which usually disappear within a few days. A physician should be consulted before resuming treatment.

At the beginning of treatment, your doctor will monitor your individual response to ParaCo-Denk. This applies in particular to elderly patients and patients with impaired kidney function or disorders of respiratory function. Severe acute hypersensitivity reactions (for example anaphylactic shock) are very rarely observed.

Treatment must be discontinued on the first signs of a hypersensitivity reaction after using ParaCo-Denk. Any medically necessary measures commensurate with the symptoms must be instigated by professional staff.

Children and adolescents

Use in children and adolescents after surgery

ParaCo-Denk should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems

ParaCo-Denk is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and ParaCo-Denk

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Concomitant use of ParaCo-Denk and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe ParaCo-Denk together with sedative medicines, the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The sedative effect of the product and its depressive action on respiration may be increased by the concomitant use of the following other drugs: tranquilizers and hypnotics, psychotropics (phenothiazine, for example chlorpromazin, thioridazine, perphenazine), other drugs depressing the central nervous system, drugs for the treatment of allergies (antihistaminics as for example promethazin, meclozin), antihypertensive drugs, certain analgesics as well as by alcohol.

When medicines are used simultaneously that result in an accelerated breakdown of medicines in the liver (enzyme induction), such as certain sleeping tablets and antiepileptic drugs (including phenobarbital, phenytoin, carbamazepine) as well as rifampicin (an antituberculosis agent), otherwise harmless doses of paracetamol (an ingredient of ParaCo-Denk 1000/60 Suppos) can cause liver damage. The same applies in the case of alcohol abuse.

Concomitant use of paracetamol and zidovudine (AZT or Retrovir) may cause a reduction in the number of white blood cells (neutropenia). ParaCo-Denk 1000/60 Suppos should therefore only be used with zidovudine upon the advice of your doctor.

When medicines for the treatment of increased uric acid levels such as probenecid and ParaCo-Denk are used at the same time, the dose of paracetamol should be reduced.

Cholestyramine (a preparation for lowering raised cholesterol levels) reduces the absorption of paracetamol.

Alcohol should be avoided during treatment with ParaCo-Denk, as co-ordination and thought processes can be substantially affected.

Certain medicines for depression (tricyclic antidepressants) such as imipramine, amitriptyline and opipramole can cause a codeine-related breathing disorder.

When other medicines for depression (MAO inhibitors), such as tranylcypromine, are given at the same time, an increase in central nervous effects and other side effects may be observed to an unforeseeable extent. ParaCo-Denk must therefore not be used until two weeks after the end of treatment with MAO inhibitors.

When analgesics such as buprenorphine or pentazocine are taken at the same time, unlike other analgesics a reduction in effect is possible.

Cimetidine and other medicines that affect liver metabolism can increase the effect of ParaCo-Denk.

The use of paracetamol can affect laboratory tests, such as uric acid or blood sugar determination.

ParaCo-Denk with food, drink and alcohol

Alcohol should be refrained from during treatment with ParaCo-Denk.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

If you are pregnant, you may only use ParaCo-Denk on the express instructions of your doctor, since unwanted effects on the development of the unborn child cannot be excluded.

You must not use ParaCo-Denk if you are about to give birth or if there is an imminent risk of giving birth prematurely, since the active substance codeine contained in ParaCo-Denk 1000/60 Suppos crosses the placental barrier and can cause breathing disorders in newborns.

If ParaCo-Denk is used for a prolonged period, codeine dependence can develop in the foetus. There are reports of withdrawal symptoms in newborns after repeated use of codeine in the last third of pregnancy. Therefore, please contact your doctor immediately if you are planning a pregnancy or are already pregnant in order to decide jointly on whether to continue with or stop the treatment.

Breastfeeding

Do not use ParaCo-Denk while you are breastfeeding. Paracetamol and codeine as well as

its degradation product morphine pass into breast milk.

Driving and using machines

Even if used as directed, ParaCo-Denk can modify your reactions impairing your ability to drive a car or operate machinery, as well as to carry out dangerous activities.

ParaCo-Denk 1000/60 Suppos contain lecithin.

If you are allergic to peanuts or soya, do not use this medicinal product.

3. How to use ParaCo-Denk

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If not instructed otherwise by your doctor, the usual dose is:

The dosage is based on the information in the following table. Adults, adolescents and children aged 12 years or above should use 1 suppository ParaCo-Denk 1000/60. Do not use more than 4 suppositories in 24 hours.

Do not exceed the maximum daily dose. This is based, among other things, on the patient's body weight and must not exceed 60 mg per kg body weight in relation to the paracetamol fraction of ParaCo-Denk 1000/60.

In relation to the codeine fraction of ParaCo-Denk 1000/60, this results in a maximum daily dose of 240 mg codeine phosphate hemihydrate (equivalent to 4 suppositories).

Your doctor will determine the individually appropriate maximum total daily dose for you or your child.

The corresponding dosage interval is based on the symptoms and the maximum total daily dose. It should be not less than 6 hours.

Body weight (Age)	**Single dose**	**Max. daily dose** (24 hrs)
43 kg and over (children ≥ 12 years, adolescents and adults)	**1 ParaCo-Denk 1000/60 Suppos** (1,000 mg paracetamol + 60 mg codeine phosphate hemihydrate)	up to **4 ParaCo-Denk 1000/60 Suppos** (4,000 mg paracetamol + up to 240 mg codeine phosphate hemihydrate)

The maximal daily intake indicated in the table (24 hours) must not be exceeded.

Method of administration

Suppositories for rectal use.

The suppositories should be inserted deeply into the anus after bowel movement. They may be warmed in the hand or dipped into hot water to improve sliding properties.

Length of the administration

Your doctor will determine the length of the administration.

Special patient groups

Impaired liver function and slight renal impairment

The dose should be reduced or the interval between doses should be increased in the presence of impaired liver or kidney function or of a congenital increase in blood bilirubin concentrations (Gilbert's syndrome).

Severe renal insufficiency

In case of severe renal insufficiency (creatinine clearance < 10 ml/min), a dose interval of at least 8 hours must be observed.

Elderly patients

No particular dosage adjustment is required.

Children and adolescents

ParaCo-Denk should not be used by children below the age of 12 years or below 43 kg body weight, due to the risk of severe breathing problems.

Please speak to your doctor if you feel that the effect of ParaCo-Denk is too strong or too weak.

If you use more ParaCo-Denk than you should

In order to avoid the risk of an overdose, it is necessary to ensure that concurrent medication does not contain paracetamol or codeine phosphate.

Overdosage of paracetamol may lead to severe liver damage. Symptoms of an overdose are vomiting, nausea, pallor and lower abdominal pain.

The characteristic feature of an overdose with codeine is the extreme reduction in respiratory drive. The symptoms to a large extent match those of acute morphine intoxication with extreme sleepiness that may progress to unconsciousness. At the same time, constricted pupils, vomiting, headache and urinary and faecal retention usually occur. An undersupply of oxygen (cyanosis, hypoxia), cold skin, increased tension of the smooth muscles (with individual doses of more than 60 mg codeine) and an absence of reflexes occur, as well as slow heart rate and a fall in blood pressure; seizures occasionally occur, particularly in children.

If you use more ParaCo-Denk than you should, consult a doctor immediately and he will take appropriate measures.

If you forget to use ParaCo-Denk

Do not take a double dose to make up for a forgotten dose. If you or your child forget a dose, you or your child must wait for an interval of at least 6 hours before using the next dose.

If you stop using ParaCo-Denk

If ParaCo-Denk is used as instructed, no particular precautions need to be observed.

If you suddenly stop using (discontinue) analgesics after prolonged and inappropriate use of high doses, headache as well as tiredness, muscle pain, nervousness and autonomic symptoms can occur. The consequences of this discontinuation disappear within a few days. Until then, no analgesics should be used. Even after that time you should not start using them again without medical advice.

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.

Note:

Hypersensitivity reactions such as facial puffiness, difficulty in breathing, sweating, nausea, sharp fall in blood pressure including shock have been reported very rare.

Treatment should be discontinued and a physician should be consulted immediately at the earliest signs of hypersensitivity reactions.

Other side effects have been reported:

Very common (may affect more than 1 in 10 people)

- nausea, vomiting, constipation
- fatigue, mild headache

Common (may affect up to 1 in 10 people)

- mild drowsiness
- after taking large doses, fall in blood pressure, temporary suspension of consciousness

Uncommon (may affect up to 1 in 100 people)

- dry mouth
- sleep disturbances
- itching, redness of the skin, urticaria
- shortness of breath
- buzzing in the ears (tinnitus)

Rare (may affect up to 1 in 1,000 people)

- rise in certain liver enzymes (serum transaminase)
- serious hypersensitive reactions (including Stevens-Johnson syndrome)
- reduction in the number of blood platelets or of white blood cells

Very rare (may affect up to 1 in 10,000 people)

- spasmodic contraction of the muscles of the airways associated with difficulty in breathing (analgesic asthma)
- Abnormally large amounts of fluid in the lungs (pulmonary oedema) have been observed, especially in patients with pre-existing disorders of lung function.
- lack of or marked decrease in the number of granulocytes, deficiency of the cellular elements of all systems effecting the formation of blood
- lecithin from soya beans may cause allergic reactions

Reporting of side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

5. How to store ParaCo-Denk

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 blister strip after "Exp". The expiry date refers to the last day of that month.

Shelf life: 5 years.

Store in a dry place below 30°C.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater. 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 ParaCo-Denk 1000/60 Suppos contains

The active substances are paracetamol and codeine phosphate hemihydrate.

Each suppository contains 1000 mg of paracetamol and 60 mg of codeine phosphate hemihydrate (equivalent to 44.2 mg codeine).

The other ingredients are: hard fat and soya lecithin.

General classification for supply

Medicinal product subject to medical prescription

What ParaCo-Denk 1000/60 Suppos looks like and contents of the pack

ParaCo-Denk 1000/60 Suppos are white to ivory coloured, torpedo shaped suppositories.

ParaCo-Denk 1000/60 Suppos is available in aluminium/PE blisters.

Pack size: 10 suppositories

Marketing Authorisation Holder

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This leaflet was last revised in 04/2019.

Vers.-Nr. 4868/003
10-000227-116