

# PARAKOL TABLET

Paracetamol 500mg, Pseudoephedrine Hydrochloride 60mg and Dexchlorpheniramine Maleate 2mg

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## What PARAKOL is used for

This medicine is used for temporary relief of nasal blockage and associated aches, pains and general discomfort due to colds, flu or allergy.

## How PARAKOL works

The tablets contain combination of 3 active ingredients, which are Paracetamol, Pseudoephedrine Hydrochloride and Dexchlorpheniramine Maleate.

Paracetamol works by relieving the pain. Pseudoephedrine hydrochloride is a decongestant that relieves nasal and sinus blockage. Dexchlorpheniramine is an antihistamine that helps stop sneezing, runny nose, watery eyes and allergy.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

## Before you use PARAKOL

### - When you must not use it

Do not take this medicine if you have an allergy to:

- paracetamol
- pseudoephedrine hydrochloride
- dexchlorpheniramine maleate
- any of the other ingredients listed at the end of this leaflet
- any other similar medicines

Do not take PARAKOL if you:

- are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- are taking any other paracetamol-containing products
- are taking other medicines containing other antihistamine

If any of these apply to you, get advice from a doctor or pharmacist.

Antihistamines should be discontinued approximately 48 hours prior to skin testing procedures since these drugs may interfere with the results

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Use in pregnancy and breastfeeding:

Pregnancy: Parakol should be used during the first two trimesters of pregnancy only if clearly needed. Dexchlorpheniramine maleate should not be used in the third trimester of pregnancy because newborn and premature infants may have severe reactions to antihistamines.

Lactation: Paracetamol is excreted in breast milk. Maternal ingestion of paracetamol in usual analgesic doses does not appear to present a risk to the breastfed infant. Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast fed infants is not known. Caution should be exercised when administering Dexchlorpheniramine as it is not known if Dexchlorpheniramine products are excreted in human milk

### - Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma
- high blood pressure
- heart disease
- diabetes
- overactive thyroid gland
- increased intraocular (in the eye) pressure
- prostate enlargement
- hyperexcitability
- bladder dysfunction
- severe kidney or liver impairment

- stenosing peptic ulcer (scarring and swelling due to ulcers causes narrowing in the duodenum and gastric outlet obstruction)
- pyloroduodenal obstruction (gastric outlet obstruction)
- analgesic nephropathy (injury to the kidney caused by analgesic medications)

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breastfeeding.

Dexchlorpheniramine maleate may cause severe reactions such as convulsions in newborn or premature infants.

If you have not told your doctor about any of the above, tell him/her before you start taking PARAKOL.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PARAKOL may interfere with each other.

These include:

- decongestant
- propantheline (to treat ulcer)
- antidepressants
- narcotic analgesic (to relieve pain)
- chloramphenicol (an antibiotic)
- aluminium hydroxide
- alcohol
- monoamine oxidase inhibitor
- anti-hypertensive medicines
- other antihistamine

- Central nervous system (CNS) depressants such as hypnotic and sedatives
- metoclopramide
- medicine used to prevent blood clots
- medicine used to control epilepsy

These medicines may be affected by PARAKOL or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

**How to use PARAKOL**

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

- How much to use

The recommended dose of PARAKOL for adult is 1 or 2 tablets every six hours.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

- When to use it

Take PARAKOL as your doctor has prescribed.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Paracetamol: vomiting, abdominal pain, low blood pressure, sweating, central stimulation with exhilaration and convulsions in children, drowsiness, breathing difficulties, cyanosis (abnormal blue discoloration of the skin), liver failure.

Pseudoephedrine: high blood pressure, palpitations (irregular heartbeats), irritability, restlessness, convulsions, difficulty with urination, urinary retention, hallucinations or shortness of breath.

Immediately telephone your doctor for advice, or go to Accident and Emergency department at the nearest hospital, if you think that you or anyone else may have taken too much PARAKOL.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

### While you are using it

#### - Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PARAKOL.

Tell your doctor if you become pregnant while taking this medicine.

#### - Things you must not do

Do not take PARAKOL to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

#### - Things to be careful of

Be careful when driving or operating machinery until you know how PARAKOL affects you. This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or light-headedness may be worse.

### Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Some of the side effects include:

- skin rashes
- tachycardia (abnormally rapid heart rate)
- anxiety
- restlessness
- insomnia
- hallucination
- excessive perspiration
- chills
- dryness of mouth, nose and throat.
- headache
- palpitation (irregular heartbeat due to agitation or illness)
- hypotension (low blood pressure)
- hypertension (high blood pressure)
- dizziness
- vertigo (a sensation of whirling and loss of balance)
- tinnitus (ringing or buzzing in the ears)
- fatigue
- depression
- blurred vision
- diarrhoea
- constipation

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

### Storage and Disposal of PARAKOL

#### - Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a dry place where the temperature stays below 25°C. Protect from light.

Do not store PARAKOL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines. Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

#### - Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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

A pink, oblong tablet with marking 'dp500' on one side.

#### - Ingredients

Active ingredients  
Each tablet contains  
Paracetamol 500mg,

Pseudoephedrine  
Hydrochloride 60mg and  
Dexchlorpheniramine  
Maleate 2mg.

Inactive ingredients

- Aerosil
- Promigel
- Tween 80
- Polyvinylpyrrolidone
- Carmoisine
- Cornstarch
- Magnesium stearate

- MAL number  
MAL19900423A

**Manufacturer**

DUOPHARMA (M) SDN.  
BHD. (42491-M)  
Lot. 2599, Jalan Seruling 59,  
Kawasan 3, Taman Klang Jaya,  
41200 Klang, Selangor Darul  
Ehsan, Malaysia.

**Product Registration Holder**

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