

Package leaflet: Information for the user

Paracetamol/Diphenhydramine Hydrochloride 500mg/25mg Film-coated Tablets

Paracetamol/Diphenhydramine hydrochloride

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

The name of this medicine is Paracetamol/Diphenhydramine Hydrochloride 500mg/25mg Film-coated Tablets.

In the rest of this leaflet Paracetamol/Diphenhydramine Hydrochloride 500mg/25mg Film-coated Tablets is called Paracetamol/Diphenhydramine Hydrochloride.

What is in this leaflet:

1. What Paracetamol/Diphenhydramine Hydrochloride is and what it is used for
2. What you need to know before you take Paracetamol/Diphenhydramine Hydrochloride
3. How to take Paracetamol/Diphenhydramine Hydrochloride
4. Possible side effects
5. How to store Paracetamol/Diphenhydramine Hydrochloride
6. Contents of the pack and other information

1. What Paracetamol/Diphenhydramine Hydrochloride is and what it is used for

Paracetamol/Diphenhydramine Hydrochloride contains paracetamol which is an analgesic (a pain killer which relieves aches and shivers) and antipyretic (it reduces body temperature when you have a fever) and diphenhydramine hydrochloride, an antihistamine that causes sleepiness or drowsiness making it useful when pain is keeping you awake.

Paracetamol/Diphenhydramine Hydrochloride is used for fast and effective relief of, aches and pains associated with colds and flu, headaches, backache, rheumatic and muscle pains, period pains and toothache which is causing difficulty in getting to sleep.

2. What you need to know before you take Paracetamol/Diphenhydramine Hydrochloride

Do not take Paracetamol/Diphenhydramine Hydrochloride:

- If you are allergic to paracetamol or diphenhydramine hydrochloride or to any of the other ingredients of this medicine (listed in Section 6).
- If you have taken another medicine containing paracetamol in the last 4 hours.
- If you have a condition known as porphyria (too much of a pigment called porphyrin which may discolour the urine).
- If you have glaucoma (increased pressure in your eye).
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- With other medicines called antihistamines including those used on your skin or in cough and cold medicines.
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Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol/Diphenhydramine Hydrochloride if you have:

- Liver or kidney problems, epilepsy, asthma, bronchitis or other breathing problems, bowel obstruction, difficulty passing urine or have prostate problems, heart or circulation problems, or myasthenia gravis (a disease with symptoms of muscle weakness and fatigue).
- Elderly people are more likely to experience possible side effects. Carers should be aware that this medicine should not be given to elderly patients with confusion
- Glutathione deficiency
- Dehydration
- Chronic malnutrition
- Chronic alcoholism
- weight of less than 50kg

Children

Not recommended for children under 12 years except under medical advice.

Other medicines and Paracetamol/Diphenhydramine Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

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

- You are taking metoclopramide or domperidone (used to treat nausea and vomiting) or cholestyramine (used to treat high cholesterol) or warfarin (used to thin the blood).
- You are taking any other medicines particularly tablets to help you sleep or pain killers or medicines for depression or anxiety, including venlafaxine, or tricyclic antidepressants, or are taking or have taken in the last two weeks monoamine oxidase inhibitors (MAOIs).
- You are taking metoprolol or atropine or medicines for stomach cramps or travel sickness which may give you dry mouth or blurred vision.

- You are taking a medicine which can slow your heart beat (e.g. medicines used to treat arrhythmias, some antibiotics, antimalarials or medicines used to treat psychological conditions).
- You are taking a medicine which can decrease the level of potassium in your blood. You should not take Paracetamol/Diphenhydramine Hydrochloride at the same time as other medicines containing antihistamines.

Paracetamol/Diphenhydramine Hydrochloride with alcohol:

Alcohol should not be taken with Paracetamol/Diphenhydramine Hydrochloride.

Pregnancy, breastfeeding and fertility:

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 taking this medicine.

Driving and using machines:

Paracetamol/Diphenhydramine Hydrochloride may cause drowsiness, dizziness, difficulty concentrating or blurred vision which means that you should not drive or operate machinery after taking the tablets.

3. How to take Paracetamol/Diphenhydramine Hydrochloride

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

For bedtime use only.

Swallow Paracetamol/Diphenhydramine Hydrochloride with water.

Adults (including the elderly) and adolescents 16 years and over:

Take 2 tablets about 20 minutes before bedtime.

Do not take more than 2 tablets per night.

When taking Paracetamol/Diphenhydramine Hydrochloride at bedtime, you may take other tablets containing paracetamol during the day but do not take more than 4,000 mg paracetamol (including this product) in any 24 hours with at least 4 hours between doses.

Adolescents 12 years to 15 years:

Take 1 tablet about 20 minutes before bedtime.

Do not take more than 1 tablet per night.

For Adolescents 12 years to 15 years: when taking Paracetamol/Diphenhydramine Hydrochloride at bedtime, you may take other tablets containing paracetamol during the day but do not take more than 3,000mg (including this product) in any 24 hours with at least 4 to 6 hours between doses.

Do not take Paracetamol/Diphenhydramine Hydrochloride for more than 7 consecutive nights without consulting your doctor.

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Not recommended for children under 12 years except under medical advice.

- **Do not exceed stated dose.**
- **If symptoms persist contact your doctor.**
- **Prolonged use except under medical supervision may be harmful.**

If you take more Paracetamol/Diphenhydramine Hydrochloride than you should
Immediate medical advice should be sought in the event of overdosage because of the risk of irreversible liver damage.

If you forget to take Paracetamol/Diphenhydramine Hydrochloride

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

4. Possible side effects

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

Stop using this product and tell your doctor immediately if you experience any of the following:

Common (may affect up to 1 in 10 people)

- fatigue.
- sedation, drowsiness, difficulty concentrating, unsteadiness, dizziness.
- dry mouth.

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

- unexplained bruising or bleeding.
- allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- skin rash or peeling, swelling or mouth ulcers.
- previous breathing problems with aspirin or non-steroidal anti-inflammatories, and you experience a similar reaction with this product.
- changes in blood tests that measure the function of your liver.
- cases of serious skin reactions.

Other side effects may include: confusion, restlessness, headache, seizure (fits), tingling sensation in the skin, difficulty in making small movements, blurred vision, raised or abnormal heart beat, thickening of phlegm, indigestion or upset stomach, nausea, vomiting, muscle twitching, difficulty passing water.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2,
Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie,
email: medsafety@hpra.ie.

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

5. How to store Paracetamol/Diphenhydramine Hydrochloride

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

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

Store below 30°C.

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

6. Contents of the pack and other information

What Paracetamol/Diphenhydramine Hydrochloride contains

Each tablet contains the active substance : Paracetamol 500mg, Diphenhydramine hydrochloride 25mg. The tablets also contain the excipients: maize starch, pregelatinised maize starch, povidone K30, talc, stearic acid. The film coat contains: hypromellose, talc, titanium dioxide (E171), macrogol 400, indigo carmine (E132).

What Paracetamol/Diphenhydramine Hydrochloride looks like and contents of the pack

Paracetamol/Diphenhydramine Hydrochloride are blue/light blue, capsule shaped, film-coated tablets.

Paracetamol/Diphenhydramine Hydrochloride 4, 10, 12, 20, 24 and 50 tablets in blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Chanelle Medical,
Loughrea,
Co. Galway,
Ireland.

Manufacturer

Chanelle Medical,
Loughrea,
Co. Galway,
Ireland.

JSC Grindeks,
53 Krustpils street,
Riga,
LV-1057,
Latvia.

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