

Package leaflet: Information for the patient

Paracetamol/Phenylephrine Hydrochloride 500 mg/12.2 mg Powder for Oral Solution

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 or pharmacist 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 or pharmacist. 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 3 days
- The full name of this medicine is Paracetamol/Phenylephrine Hydrochloride 500 mg/12.2 mg Powder for Oral Solution but within the leaflet it will be referred to as Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg.

What is in this leaflet

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1. What Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg is and what it is used for

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg contains paracetamol, an analgesic which relieves aches and reduces fever, and phenylephrine, a decongestant to relieve a blocked up nose.

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg is used for the relief of the symptoms of colds and influenza, including the relief of aches, headache, nasal congestion and lowering of temperature at adults and adolescents over 16 years of age.

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 take Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg

Do not take Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg:

- if you are **allergic** to paracetamol and phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have a **serious heart condition**
- if you have **high blood pressure**

- if you have **glaucoma** (a disorder of the eyes often associated with increased pressure of the fluid in the eye)
- if your **thyroid gland is overactive (Hyperthyroidism)**
- if you are taking **monoamine oxidase inhibitors** (used to treat depression) or have taken them within the last 14 days
- if you are taking **tricyclic antidepressants** (for depression)
- if you suffer from **severe liver disease (severe hepatic insufficiency)**
- if you suffer from acute inflammation of the liver (acute hepatitis).
- if you suffer from **alcohol abuse**

Warnings and precautions

Talk to your doctor before taking Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg

- if you have Raynaud's Phenomenon, a condition caused by poor blood-circulation in the fingers and toes.
- if you have Diabetes mellitus, a condition associated with high levels of blood-sugar.
- if you suffer from moderate and severe renal insufficiency.
- if you suffer from mild to moderate liver disease, or are receiving treatment with medicinal products affecting liver function.
- if you suffer from haemolytic anaemia (a reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness).
- if you suffer from dehydration.
- if you suffer from chronic malnutrition.
- if you have an enlarged prostate.
- if you have a tumour of the adrenal glands (phaeochromocytoma).
- if you suffer from reduced glutathione levels.
- if you have asthma and are hypersensitive to acetylsalicylic acid (for pain relief or for blood-dilution). You may also be hypersensitive to Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg.

Important:

This product contains Paracetamol. Do not take with any other paracetamol-containing products. Never take more Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg than recommended. Higher doses than those recommended do not increase the pain-relieving effect, but may cause very serious liver damage. The symptoms of liver damage normally do not appear until after a few days. After an overdose, it is therefore very important to seek medical advice as soon as possible, even if you feel well. Do not take with any other flu, cold or decongestant products.

Do not take any other decongestant product at the same time as Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg

Please contact your doctor, if your symptoms are not relieved or even deteriorated within 3 days of therapy with Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg

Children and adolescents

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg is indicated for adults and adolescents over 16 years of age.

Other medicines and Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg

Do not use Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg if you are taking monoamine oxidase inhibitors (MAO inhibitors, such as moclobemide or tranylcypromin) or tricyclic

antidepressants (such as amitriptyline, amoxapine, clomipramine, desipramine and doxepine), used for treatment of depression, or have taken them within the last 14 days.

As both of the active substances of Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg, phenylephrine hydrochloride and paracetamol, may adversely interact with other medicines, please make sure that you tell your doctor or pharmacist about all other medicines you might be using at the same time, especially:

- Drugs, which may interfere with phenylephrine as medicines used for the treatment of high blood pressure, heart or circulatory problems as
 - ephedrine, epinephrine, dopamine
 - medicines such as hydralazine and minoxidil which lower blood pressure by widening blood vessels
 - beta-blockers or other medicines to treat high blood pressure.
- Drugs, which may increase the effect of phenylephrine on the blood vessels, such as
 - digoxin (for heart diseases)
 - tetracyclics (for depression) such as maprotiline
 - antidepressants such as phenelzine, isocarboxylic acid, nialamide
 - Parkinson's disease drugs such as selegiline
 - furazolidone (for bacterial infections)
- Drugs, which may interfere with the liver-metabolism of the active substances of Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg and may increase the toxic effects of paracetamol on the liver, as
 - alcohol
 - barbiturates (sedatives),
 - anticonvulsants (for epilepsy) such as phenytoin, phenobarbital, methylphenobarbital and primidone
 - rifampicin (for tuberculosis)
 - probenecid (for gout)
- Drugs, which have an influence of the availability of paracetamol in the body, as
 - anticholinergic drugs (e.g. glycopyrronium, propantheline)
 - metoclopramide or domperidone (for feeling sick or being sick)
 - cholestyramine (to reduce blood fat levels)
 - isoniazide (for tuberculosis)
 - propranolol (for high blood pressure)
- warfarin and other coumarins (blood thinners), as their anticoagulant effect may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses of Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg have no significant effect.
- Regular use of paracetamol may increase the toxic effects of zidovudine (AZT) (for treatment for HIV)

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

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg with food and drink and alcohol

Do not drink alcohol (e.g. wine, beer, spirits) whilst taking Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg.

The effect of alcohol will not be enhanced by the addition of paracetamol, but alcohol may increase the toxic effects of paracetamol on your liver.

Pregnancy and breast-feeding

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.

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg is not recommended during pregnancy and breastfeeding.

Driving and using machines

There have been no reports on negative influence of Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg on the ability to drive and to use machines up to date.

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg contains sucrose, aspartame, sorbitol, carbohydrates

This medicine contains aspartame (E951) which is a source of phenylalanine. May be harmful for people with phenylketonuria (a hereditary metabolic-disorder).

The medicine contains sorbitol (E420) and sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Each sachet contains approximately 1.9 g of carbohydrates. This should be taken into account in patients with diabetes mellitus.

3. How to take Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg

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

The recommended dose is:

Age	How many	How often
Adults and adolescents over 16 years of age	One sachet	The dose may be repeated in 4 to 6 hours. Do not take more than 4 sachets in 24 hours.

Please observe that higher doses than those recommended may result in a risk of very serious liver damage.

Method of administration

Oral administration after dissolution in water.

Dissolve the contents of the sachet in a half filled a mug (approximately 125 ml) of hot, but not boiling, water. Stir shortly until dissolved and drink the colourless solution.

Use in children and adolescents

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg is not recommended for use in children below 16 years of age.

Elderly

There is no indication that the dosage needs to be modified in the elderly.

Patients with impaired kidney or liver function

In patients with impaired kidney or liver function and patients with Gilbert's syndrome the dosing interval should be prolonged. In patients with severely impaired kidney function the dosing interval of Paracetamol/Phenylephrine Hydrochloride has to be at least 8 hours. Ask your doctor or pharmacist for advice.

If you take more Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg 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/Phenylephrine Hydrochloride 500mg/12.2mg

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

Most people will not have problems, but some may get some.

The following summary includes side effects of paracetamol and phenylephrine.

Paracetamol

In therapeutic doses, the undesirable effects of paracetamol occur rarely and with mild clinical course.

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

Blood and lymphatic system disorders: blood disorders which may be seen as unexplained bruising, paleness or poor resistance to infections: Blood dyscrasias including platelet disorders, reduction of specific blood-cells (agranulocytosis, leucopenia, thrombocytopenia), haemolytic anaemia, pancytopenia.

Hepatobiliary disorders: Abnormal hepatic function (increase in liver enzymes), liver failure, jaundice (yellowing of the skin or eyes).

Skin and subcutaneous tissue disorders: Hypersensitivity including skin rash and hives, itching, sweating, purpura (small bleedings underneath the skin), angioedema (sudden swelling of the skin and mucous membrane).

Immune system disorders: Allergic or hypersensitivity reactions including skin rashes, hives, anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness).

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

Respiratory, thoracic and mediastinal disorders: bronchospasm (difficulty in breathing or wheezing)

Renal and urinary disorders: After prolonged use of high doses of paracetamol sterile pyuria (urine which contains white blood cells, cloudy urine) and renal side effects may develop

Gastrointestinal disorders: Acute pancreatitis (inflammation of the pancreas which causes severe pain in the abdomen or back)

Very rare cases of serious skin reactions have been reported.

Not known (frequency cannot be estimated from the available data):

Red skin rash possibly with blisters, swelling of the throat, anaphylactic shock, anaemia, changes in liver function and hepatitis, changes in kidney function (kidney failure, blood in the urine, difficulty passing urine), gastro intestinal problems and vertigo.

Phenylephrine

Common (may affect up to 1 in 10 people):

Gastrointestinal disorders: Loss of appetite, nausea and vomiting

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

Cardiac disorders: Tachycardia (faster heart beat), palpitation (feeling your heartbeat)

Vascular disorders: blood pressure increase

Immune system disorders: Allergic or hypersensitivity reactions including skin rashes, urticaria, anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness) and bronchospasm (difficulty in breathing or wheezing)

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

Nervous system disorders: Insomnia (difficulty in sleeping), nervousness, tremor (shaking), anxiety, restlessness, confusion, irritability, dizziness and headache may occur

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

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

5. How to store Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg

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

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

Duration of storage after reconstitution:

The reconstituted solution in hot water should be consumed immediately.

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

This medicine does not require any special temperature storage conditions.

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 to protect the environment.

6. Content of the pack and other information

What Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg contains

- The active substances are: Paracetamol 500mg and Phenylephrine hydrochloride 12.2mg (equivalent to phenylephrine base 10.0mg)
- The other ingredients are: ascorbic acid, sucrose, aspartame (E951), lemon flavour (lemon flavour contains: natural lemon oils and flavouring substances, maltodextrin, mannitol (E421), gluconolactone, acacia gum, sorbitol (E420) , silica colloidal anhydrous, and α -tocopherol (E 307)), saccharin sodium, silica colloidal anhydrous, citric acid anhydrous, and sodium citrate.

What Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg looks like and contents of the pack

Paracetamol/Phenylephrine Hydrochloride 500mg/12.2mg is a white coloured powder for oral solution which is packed in laminated aluminium paper foil sachets in a carton box.
After reconstitution, the solution is colourless and slightly opalescent.

Pack-sizes:

5, 6, 8, 10, 12, 16, 20 sachets are contained in a cardboard carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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