

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour

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 or nurse has 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet:

1. What Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour is and what it is used for
2. What you need to know before you take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour
3. How to take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour
4. Possible side effects
5. How to store Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour
6. Contents of the pack and other information

1. What Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour is and what it is used for

Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour is for relief of symptoms of colds and flu, such as headaches, aches and pains, sore throat, nasal congestion and lowering of temperature. It contains two active ingredients;

- Paracetamol is a well known pain killer (analgesic) and can also reduce fever (antipyretic).
- Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose and so relieves a blocked nose.

You should only use this medicine if you have a combination of cold and flu symptoms such as pain/fever and nasal congestion.

You must talk to your 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 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour

Do not take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour if you:

- are allergic to paracetamol, phenylephrine, or to any of the ingredients (see section 6)
- have serious heart disease
- have high blood pressure (hypertension)
- have severe liver disease
- have kidney disease or kidney problems
- have severe over-activity of the thyroid (hyperthyroidism)
- have glaucoma (increased pressure in the eye) of the narrow-angle type
- are currently taking monoamine oxidase inhibitors (MAOIs) or have taken them within the last two weeks
- are taking other decongestants for colds and flu

Children and adolescents

Do not give Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour to children under 16 years of age.

Important: Contains Paracetamol. Do not take with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour if you:

- have a problem with your liver function
- have an over-active thyroid (hyperthyroidism)
- are male and have an enlarged prostate gland, as you may have more difficulty passing water
- are diabetic or have a blood circulation problem (including Raynaud's syndrome)
- are suffering from malnutrition (if you are severely underweight)
- suffer from glucose-6-phosphate dehydrogenase deficiency (a genetic disorder)
- are pregnant or breast-feeding

Other medicines and Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor or pharmacist before you take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour if you are taking:

- medicine containing paracetamol or other decongestants for colds and flu.
If you are taking these, do not take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used

- monoamine oxidase inhibitors (MAOIs) used in the treatment of depression or Parkinson's disease. Do not take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour if you have taken MAOIs in the last 14 days.
- tricyclic antidepressants for depression, such as amitriptyline or imipramine.
- medicine for high blood pressure (antihypertensives), including beta-blockers, or for improving heart function or correcting abnormal heart rhythms (digoxin, lanoxin, digitoxin).
- medicine for nausea and vomiting (such as metoclopramide or domperidone)
- medicine for thinning the blood (anticoagulants), such as warfarin or other coumarins
- medicine for high cholesterol (such as cholestyramine)
- sedatives (barbiturates)
- aspirin-containing products
- chloramphenicol (an antibiotic)
- probenecid or AZT (zidovudine)

Taking Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour with food and drink

Do not take this product with alcoholic drinks.

Pregnancy and breast- feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If necessary and only if advised by a doctor or pharmacist, Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour can be used during pregnancy and breastfeeding.

Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour contains Aspartame (E951): a source of phenylalanine. May be harmful for people with phenylketonuria.

Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour contains 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.

Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour contains Sodium: This medicine contains 117.5 mg sodium (the main component of cooking/table salt) in each sachet. This is equivalent to 5.875% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour

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

Dosage

This medicine is a powder to be dissolved in water and taken as a hot drink.

Pour one sachet of powder into a mug of standard size. Fill with hot, not boiling water (approx. 250ml). Allow to cool to a drinkable temperature.

Adults: 1 sachet every 4-6 hours as required

Adolescents (aged 16 years of age and over): 1 sachet every 6 hours as required.

Do not take more than 4 sachets in any 24 hour period.

Use in children and adolescents

Do not give to children under 16 years of age.

Do not exceed the recommended dose

If symptoms persist for more than 3 days or worsen, consult your doctor.

If you take more Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour than you should:

Seek medical advice immediately if you accidentally take more than you should, even if you feel well because of the risk of delayed, serious liver damage.

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

4. Possible side effects

Like all medicines, Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour can cause side effects, although not everybody gets them. If you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately.

Phenylephrine may rarely cause a rapid heart beat (palpitations).

High blood pressure with headache, vomiting and palpitations may also occur rarely.

Phenylephrine may also cause trouble sleeping (insomnia), nervousness, shaking (tremor), anxiety, restlessness, confusion, irritability or headache.

These side effects are rare (affect less than 1 in 1000 people but more than 1 in 10,000).

Loss of appetite, nausea or vomiting are common with phenylephrine (affects more than 1 in 100 people but less than 1 in 10).

Certain blood cell disorders have been reported with paracetamol, but this is very rare (affects less than 1 in 10,000 people). If this happens, symptoms may include unusual bruising, or infections such as sore throats.

Allergic reactions (such as skin rashes or hives); severe allergic reaction (anaphylaxis); wheezing or breathing difficulties may occur rarely (affect less than 1 in 1000 people but more than 1 in 10,000). Very rare cases of serious skin reactions have been reported.

Abnormal liver blood tests (less than 1 in 10,000 people).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effect directly via HPRAs Pharmacovigilance website www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine

5. How to store Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour

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

Do not take Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour after the expiry date printed on the sachet or carton. The expiry date refers to the last day of the month stated.

Do not store above 25°C.

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

6. Contents of the pack and other information

What Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour contains

- The active substances are paracetamol and phenylephrine hydrochloride. One sachet contains 1000mg paracetamol and 12.2 mg phenylephrine hydrochloride (equivalent to 10mg phenylephrine).
- The other ingredients are sucrose, sodium citrate, citric acid, ascorbic acid, acesulfame potassium (E950), aspartame (E951), quinoline yellow (E104), lemon flavours.

What Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour looks like and contents of the pack

Paracetamol 1000mg, Phenylephrine hydrochloride 12.2mg, Powder for oral solution, Lemon flavour is a yellow powder for oral solution which is packed in laminated sachets in a carton box. The product is available in cartons of 5 and 10 sachets.

If you would like any further information about this product, please ask your pharmacist or doctor, or contact the marketing authorisation holder.

Marketing Authorisation Holder

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This leaflet was last revised in September 2022