Package leaflet: Information for the user

Paracetamol/Phenylephrine Orifarm 1000 mg/10 mg powder for oral solution in sachets

(paracetamol/phenylephrine)

[OTC]
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.

[Rx]
Read all of this leaflet carefully before you start taking this medicine because it contains important imformation 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 [Invented name] is and what it is used for

[Invented name] contains paracetamol, an analgesic which relieves pain and reduces fever, and phenylephrine, a decongestant to relieve a blocked up nose.

[Invented name] is used for the relief of the symptoms of colds and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion and lowering of temperature.

2. What you need to know before you take [Invented name]

Do not take [Invented name]
- 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 severe coronary heart disease
- 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 or

- if you are taking tricyclic antidepressants (for depression) or have taken them within the last 14 days.

Warnings and precautions
Talk to your doctor before taking [Invented name].

During treatment with [Invented name], tell your doctor straight away
- if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Take special care with [Invented name]
- 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 liver function disorders:
  mild to moderate hepatocellular insufficiency (including Gilbert's syndrome), severe hepatic insufficiency (Child-Pugh >9), acute hepatitis and concomitant treatment with medicines affecting hepatic functions
- 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 alcohol abuse
- if you suffer from chronic malnutrition
- if you suffer from glutathione depletion due to metabolic deficiencies
- if you have asthma and are hypersensitive to acetyl salicylic acid (for pain relief or for blood-dilution). You may also be hypersensitive to [Invented name].

Important: This medicine 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. Do not take with any other flu, cold or decongestant products.

Please contact your doctor, if you do not feel better or if you feel worse after 3 days of therapy with [Invented name].

Other medicines and [Invented name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not use [Invented name] if you are taking monoamine oxidase inhibitors (MAO inhibitors, such as moclobemide or tranylcypromin) or tricyclic antidepressants (such as amitryptiline, 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 [Invented name], 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:
- Medicines, which may interfere with phenylephrine as medicines used for the treatment of high blood pressure, heart or circulatory problems as
  - sympathomimetics

    - vasodilators
    - beta-blockers and other antihypertensives
- Medicines, which may potentiate the effect of phenylephrine on the blood vessels, as
    - digoxin (for heart diseases)
    - tetracyclics (for depression) such as maprotiline
    - antidepressants such as phenelzine, isocarboxylic acid, nialamide
    - Parkinson's disease medicines such as selegiline
    - furazolidone (for bacterial infections)
- Substances, which may interfere with the liver-metabolism of the active substances of [Invented name] and may increase the toxic effects of paracetamol on the liver, as
    - alcohol
    - barbiturates (sedatives)
    - anticonvulsants (for epilepsy) such as phenytoine, phenobarbital, methylphenobarbital and primidone
    - rifampicin (for tuberculosis)
    - probenecid (for gout)
- Medicines, which have an influence on the availability of paracetamol in the body, as
    - anticholinergic medicines (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 [Invented name] have no significant effect
- regular use of paracetamol may increase the toxic effects of zidovudine (AZT) (for treatment for HIV)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2 “During treatment with [Invented name], tell your doctor straight away”).

[Invented name] with food and drink
Do not drink alcohol (e.g. wine, beer, spirits) whilst taking [Invented name]. 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 bay, ask your doctor or pharmacist for advice before taking this medicine.

[Invented name] is not recommended during pregnancy and breastfeeding.

Driving and using machines
There have been no reports on negative influence of [Invented name] on the ability to drive and to use machines up to date.

[Invented name] contains aspartame, sorbitol and sucrose
This medicine contains 35 mg aspartame (E951) in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains 1 mg sorbitol (E420) and 3.8 g sucrose in each sachet.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Each sachet contains approximately 3.9 g of carbohydrates. This should be taken into account in patients with diabetes mellitus.

3. How to take [Invented name]

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

[OTC]
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 if you are not sure.

The recommended dose is:

Age	How many	How often
Adults and adolescents over 16 years of age who weigh more than 50 kg	One sachet	The dose may be repeated in 4 to 6 hours. Do not take more than 3 sachets in 24 hours.

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

Use in children and adolescents
[Invented name] is not recommended for use in children and adolescents below 16 years of age without medical advice.

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

Method of administration:
Dissolve the contents of the sachet in a mug (250 ml of hot, but not boiling, water). Stir until dissolved and drink the lemon flavour and coulorless solution.

If you take more [Invented name] than you should
If you or someone else took too much of [Invented name], or if you think a child has swallowed any content of the sachets, contact your nearest hospital casualty department or your doctor immediately, even if you/the other person feel/feels well, because of the risk of delayed, serious liver damage. Please take this leaflet, any remaining sachets and the container with you to the hospital or doctor so that they know which medicine was consumed.

If you forget to take [Invented name]
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.

The following summary includes side effects of paracetamol and phenylephrine. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

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 disorders which may be seen as unexplained bruising, paleness or poor resistance to infections: Blood dyscrasias including platelet disorders, agranulocytosis, leucopenia, thrombocytopenia, haemolytic anaemia, pancytopenia

- abnormal hepatic function (increase in hepatic transaminases), hepatic failure, hepatic necrosis, jaundice (yellowing of the skin or eyes)

- hypersensitivity including skin rash and urticaria, pruritus, sweating, purpura, angioedema

- allergic or hypersensitivity reactions including skin rashes, urticaria, anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness)

Very rare (may affect up to 1 in 10,000 people):
- bronchospasm (difficulty in breathing or wheezing)

- after prolonged use of high doses of paracetamol sterile pyuria (urine which contains white blood cells, cloudy urine) and renal side effects may develop

- 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):
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Phenylephrine
Common (may affect up to1 in 10 people):
- loss of appetite, nausea and vomiting

Rare (may affect up to 1 in 1,000 people):
- tachycardia (faster heartbeat), palpitation (feeling your heartbeat)

- blood pressure increase

- 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):
- 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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.

This medicine does not require any special storage conditions. Store in the original package.
The reconstituted solution in hot water is stable for 60 min at room temperature.

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 protect the environment.

6. Contents of the pack and other information

What [Invented name] contains

- The active substances are paracetamol 1000 mg and phenylephrine hydrochloride 12.2 mg (equivalent to phenylephrine 10.0 mg).
- The other ingredients are ascorbic acid, sucrose, aspartame (E951), lemon flavour (lemon flavour contains: natural lemon oils and flavouring substances, maltodextrin, mannitol, gluconolactone, acacia, sorbitol (E420), α-tocopherol (E307) and silica, colloidal anhydrous), saccharin sodium, silica, colloidal anhydrous, citric acid, and sodium citrate.

See section 2 [Invented name] contains aspartame, sorbitol and sucrose.

What [Invented name] looks like and contents of the pack

[Invented name] is a white powder which is packed in laminated sachets in a carton box. The medicine is available in cartons of 5, 8, 10 or 12 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer
Hermes Pharma Ges.m.b.H.
Schwimmschulweg 1a
9400 Wolfsberg
Austria

This medicine is authorised in the Member States of the European Economic Area under the following names:

<{Name of the Member State}> <{Name of the medicine}>
<{Name of the Member State}> <{Name of the medicine}>

This leaflet was last revised in 10 February 2026