

Package leaflet: Information for the patient

Rowasip Cold and Flu with Decongestant 500 mg/12.2 mg powder for oral solution paracetamol/phenylephrine 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 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.

What is in this leaflet

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

1. What Rowasip is and what it is used for

Rowasip contains paracetamol, an analgesic which relieves aches and reduces fever, and phenylephrine, a decongestant to relieve a blocked up nose.

Rowasip is used for the relief of the symptoms of colds and influenza, including the relief of pain, headache, nasal congestion and lowering of temperature of adults and adolescents over 16 years of age.

Use Rowasip only if you have a cold or influenza accompanied by a stuffy nose. If you do not have a stuffy nose, monocomponent products containing only paracetamol should be preferred.

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 Rowasip

Do not take Rowasip:

- 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** (a condition associated with impaired function of the heart)
- 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
- 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 or pharmacist before taking Rowasip

- 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 medicinal products 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
- 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 acetylsalicylic acid (for pain relief or for blood-dilution). You may also be hypersensitive to Rowasip.
- if you have an enlarged prostate
- if you have a tumour on the adrenal gland (called phaeochromocytoma).

Important:

This product contains Paracetamol. Do not take with any other paracetamol-containing products. Never take more Rowasip 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.

Children and adolescents

Rowasip is indicated for adults and children over 16 years of age.

Other medicines and Rowasip

Do not use Rowasip if you are taking monoamine oxidase inhibitors (MAO inhibitors, such as moclobemide or tranylecypromine) 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 Rowasip, 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 such as medicines used for the treatment of high blood pressure, heart or circulatory problems such as
 - sympathomimetics, including nasal or eye decongestant products
 - vasodilators
 - alpha- and beta-blockers (e.g. propranolol) and other antihypertensives (e.g. guanethidine).
- drugs, which may potentiate 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 Rowasip and may increase the toxic effects of paracetamol on the liver, such 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, such 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).
- 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 Rowasip have no significant effect
- regular use of paracetamol may increase the toxic effects of zidovudine (AZT) (for treatment for HIV)
- the duration of action of chloramphenicol may be prolonged by paracetamol.

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

Rowasip with food, drink and alcohol

Do not drink alcohol (e.g. wine, beer, spirits) whilst taking Rowasip.

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.

Rowasip is not recommended during pregnancy and breast-feeding.

Driving and using machines

There have been no reports on negative influence of Rowasip on the ability to drive and to use machines up to date.

Rowasip contains sucrose, sorbitol, aspartame and sodium

This medicine contains 17.5 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) in each sachet.

This medicine 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.

Each sachet contains 1.8 g of sucrose per dose. This should be taken into account in patients with diabetes mellitus.

This medicinal product contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

3. How to take Rowasip

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

The recommended dose is:

Age	How many	How often
Adults and children 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 small cup (125 ml) of hot, but not boiling, water. Stir shortly until dissolved and drink the lemon-flavoured and colourless solution.

Use in children and adolescents

Rowasip is not recommended for use in children and adolescents below 16 years of age.

Elderly

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

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

If you take more Rowasip than you should

If you or someone else took too much of Rowasip, or if you think a child has swallowed any of the 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 medicinal product was consumed.

If you forget to take Rowasip

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 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.
- abnormal hepatic function (increase in hepatic transaminases)
- hepatic failure
- hepatic necrosis
- jaundice (yellowing of the skin or eyes)
- bronchospasm (difficulty in breathing or wheezing)
- allergic or hypersensitivity reactions including skin rashes, urticaria, pruritus, sweating, purpura (small bleedings underneath the skin), angioedema (sudden swelling of the skin and mucous membrane), anaphylaxis (serious allergic reaction which causes difficulty in breathing or dizziness).

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

- 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.

Phenylephrine

Common (may affect up to 1 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
- headache.

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rowasip

Keep this medicine out of the sight and reach of children

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

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

This medicinal product does not require any special temperature storage conditions.

Shelf-life after reconstitution in hot water: 1 hour.

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 Rowasip contains

- The active substances are paracetamol and phenylephrine hydrochloride. Each sachet contains 500 mg of paracetamol and 12.2 mg of phenylephrine hydrochloride (equivalent to 10.0 mg phenylephrine base).
- The other ingredients are: ascorbic acid, sucrose, aspartame (E951), lemon flavour (containing: natural lemon oils and nature identical flavouring substances, maltodextrin, mannitol (E421), gluconolactone, acacia gum, sorbitol (E420), silica colloidal anhydrous, α -tocopherol (E307)), saccharin sodium, silica colloidal anhydrous, citric acid and sodium citrate.

What Rowasip looks like and contents of the pack

Rowasip is a free flowing, white powder with lemon odour which is packed in laminated aluminium paper foil sachets and inserted in a carton.

Pack sizes:

6, 10, 20 sachets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Hermes Pharma Ges.m.b.H., Allgäu 36, 9400 Wolfsberg, Austria.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

BG	PARACETAMOL/PHENYLEPHRINE SANDOZ 500 MG/12,2 MG POWDER FOR ORAL SOLUTION
EE	Swispara
EL	LEKADOL (500+12,2)mg κόινις για πόσιμο διάλυμα
HU	Flunathan Sandoz 500 mg/12,2 mg por belsőleges oldathoz
IE	Rowasip Cold and Flu with Decongestant 500 mg/12.2 mg powder for oral solution
IT	PARACETAMOLO E FENILEFRINA SANDOZ
RO	LEKADOL 500 mg/12,2 mg pulbere pentru solutie orală
SI	LEKADOL COMBO 500 mg/12,2 mg prašek za peroralno raztopino
UK	Paracetamol/Phenylephrine Hydrochloride 500 mg/12.2 mg Powder for Oral Solution

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