Package leaflet: Information for the patient

Rowasip Max Strength Cold and Flu with Decongestant 1000 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

ROWEX®

1 What Rowasip Max is and what it is used for

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

Rowasip Max 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 who weigh more than 50 kg.

Use Rowasip Max only if you have a cold and 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 Max

Do not take Rowasip Max:
- 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 Max
- 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 Max.
- If you have an enlarged prostate
- If you have a tumour on the adrenal gland (called phaechromocytoma)

Important:
This product contains Paracetamol. Do not take with any other paracetamol-containing products. Never take more Rowasip Max 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 Max is indicated for adults and children over 16 years of age who weigh more than 50 kg.

Other medicines and Rowasip Max
Do not use Rowasip Max 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 Rowasip Max, 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
  - sympathomimetics, including nasal or eye decongestant products
  - vasodilators
  - alpha- and beta-blockers and other antihypertensives (e.g. guanethidine)
- drugs, 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 drugs such as selegiline
  - furazolidone (for bacterial infections)
- drugs, which may interfere with the liver-metabolism of the active substances of Rowasip Max 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 on 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 Rowasip Max 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 Max with food, drink and alcohol
Do not drink alcohol (e.g. wine, beer, spirits) whilst taking Rowasip Max. 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 Max is not recommended during pregnancy and breast-feeding.

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

Rowasip Max contains sucrose, aspartame, sorbitol, carbohydrates
This medicine contains aspartame (E951) which is a source of phenylalanine. May be harmful for people with

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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 3.9 g of sucrose. This should be taken into account in patients with diabetes mellitus.

3 How to take Rowasip Max

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 who weigh more than 50 kg	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 mug (250 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 Max is not recommended for use in children and adolescents below 16 years of age.

Older people
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 Max than you should
If you or someone else took too much of Rowasip Max, 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 Max
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)
- hypersensitivity including skin rash and urticaria, pruritus, sweating, purpura (small bleedings underneath the skin), angioedema (sudden swelling of the skin and mucous membrane)
- 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):
- 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 heart beat)
- 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, pharmacist or nurse. 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; 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 Max

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. 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:
Reconstituted solution 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 Max contains

- The active substances are Paracetamol 1000 mg and Phenylephrine hydrochloride 12.2 mg (equivalent to phenylephrine base 10.0 mg)
- 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, and α – tocopherol (E307)), saccharin sodium, silica colloidal anhydrous, citric acid, and sodium citrate.

What Rowasip Max looks like and contents of the pack
Rowasip Max is a free flowing, white powder with lemon odour which is packed in laminated aluminium paper foil sachets in a carton box.

10 sachets

Not all pack sizes may be marketed.

Marketing Authrisation Holder and Manufacturer
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

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

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

UK	Paracetamol/Phenylephrine Hydrochloride 1000 mg/12.2 mg Powder for Oral Solution
BG	LEKADOL PLUS
CZ	Paracetamol Fenylefrin hydrochlorid Sandoz 1000 mg/12,2 mg
EE	Swispara
EL	LEKADOL
ES	Paracetamol /Fenilefrina Sandoz 1.000 mg/12,2 mg polvo para solución oral EFG
HU	Paracetamol Fenilefrin Sandoz 1000 mg/12.2 mg por belsőleges oldathoz
IE	Rowasip Max Strength Cold and Flu with Decongestant 1000 mg/12.2 mg Powder for oral solution
IT	PARACETAMOLO E FENILEFRINA SANDOZ
LT	Swispara 1000 mg/12,2 mg milteliai geriamajam tirpalui
LV	Swispara 1000 mg/12,2 mg pulveris iekšķigi lietojama šķīduma pagatavošanai
RO	LEKADOL 1000 mg/12,2 mg pulbere pentru solutie orală

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