

Package leaflet: information for the user

Rowa Cold & Flu 500 mg/30 mg Granules for Oral Suspension

Acetylsalicylic acid / pseudoephedrine 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 Rowa Cold & Flu is and what it is used for
2. What you need to know before you take Rowa Cold & Flu
3. How to take Rowa Cold & Flu
4. Possible side effects
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1 What Rowa Cold & Flu is and what it is used for

Rowa Cold & Flu is used to treat nasal congestion in **colds** associated with pain and fever

Rowa Cold & Flu should only be used when nasal congestion appears together with pain and/or fever.

Take a medicine that contains only one of the active substances if you have only one of the symptoms above.

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 Rowa Cold & Flu

Do not take Rowa Cold & Flu if you are/have

- **allergic** to acetylsalicylic acid, salicylates (a medicine group used to treat pain or inflammation, and to which acetylsalicylic acid belongs), pseudoephedrine or any of the other ingredients of this medicine (listed in section 6)
- had **asthma** or **stomach and bowel ulcer** due to use of salicylates or similar medicines used to treat pain, fever or inflammation
- stomach ulcers
- active bleeding
- an increased tendency to **bleed**
- **pregnant** or **breast-feeding**
- severe reduced **liver** or **kidney function**
- severe **heart failure**

- taking 15 mg or more of **methotrexate** per week (a medicine for e.g. joint inflammation and tumors)
- very high **blood pressure**
- severe disease of the **heart arteries**
- a child or an adolescents younger than 16 years
- taking certain medicines to treat depression or Parkinson's disease, known as monoamine oxidase (MAO) inhibitor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rowa Cold & Flu if you have/are:

- allergic (hypersensitive) to medicines used to treat pain, rheumatism or inflammation other than those listed above under "Do not take Rowa Cold & Flu if you are/have"
- hypersensitivity to certain ingredients of cough and cold medicines, such as phenylephrine or ephedrine, known as sympathomimetics
- allergies
- long-standing swelling of the mucous membrane of the nose
- asthma or other long-standing lung diseases
- had stomach ulcers
- had stomach or bowel bleeding
- reduced kidney or liver function

Do not take this medicine if your liver or kidney function is severely reduced. See above under "Do not take Rowa Cold & Flu if you are/have".

- impaired cardiovascular function (for example when the heart inadequately pumps blood through the body, volume depletion, major surgery, blood infection or major haemorrhagic event)
- planning any surgery including minor operations such as a tooth extraction
- overactive thyroid
- mild to moderately high blood pressure
- diabetes mellitus
- heart disease

Do not take this medicine if you have any of the heart diseases listed above under "Do not take Rowa Cold & Flu if you are/have".

- increased pressure in the eye
- enlarged prostate gland
- are prone to having gout

At low doses acetylsalicylic acid reduces the excretion of uric acid in urine, which may cause a gout attack.

- long lasting profuse vomiting, headache and clouding of consciousness after first improvement of signs of feverish disease (in this case, contact immediately your doctor or the nearest hospital).
- a G6PD (Glucose-6-phosphate dehydrogenase) deficiency (a hereditary disease affecting red-blood cells), since elevated doses of acetylsalicylic acid could lead to haemolysis (destruction of red-blood cells)
- a history of a form of a severe skin reaction called acute generalized exanthematous pustulosis (AGEP) (with symptoms and signs such as fever, redness and small generalized pustules) with pseudoephedrine-containing products.

If you develop a feverish generalised erythema associated with pustules, stop taking Rowa Cold & Flu and contact your doctor or seek medical attention immediately. See section 4.

Patients over 65 years

Elderly patients may be particularly sensitive to pseudoephedrine and may experience sleeplessness or sense things that are not real.

Children under 16 years

Rowa Cold & Flu must **not** be given to this age group. There is a possible association between acetylsalicylic acid and a very rare type of organ damage when given to children with fever. This damage can be fatal.

Other medicines and Rowa Cold & Flu

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription.

Your doctor will decide if an adjustment of the medicines is required.

The following medicines can affect or be affected by Rowa Cold & Flu:

- **medicines to inhibit blood coagulation**, such as ticlopidine
- medicines used to treat inflammation, such as **cortisone** or **prednisolone**, when taken by mouth or by injection
- **digoxin**: a medicine to treat heart weakness
- group of **medicines to treat pain**, inflammation and rheumatism, such as ibuprofen or diclofenac
Taking a number of painkillers together increases the risk of permanent kidney disease.
- **medicines to lower blood sugar**
- **methotrexate**: a medicine to treat severe joint inflammation, tumours and the skin disease psoriasis
Please consider the advice above under “Do not take Rowa Cold & Flu if you are/have”.
- **valproic acid**: a medicine to treat epilepsy, euphoric and depressive disorders
- **medicines to treat depression**
Please consider the advice in the last bullet point under “Do not take Rowa Cold & Flu if you are/have”.
- medicines used to **expand the airways** (such as **salbutamol**):
Simultaneous use may cause an irregular or faster heartbeat. This should not stop you from using an inhaler at the prescribed dose.
- medicines containing **phenylephrine** and **ephedrine** or similar substances, for example those included in nasal decongestants, such as nose drops
Do not combine decongestant nose drops with Rowa Cold & Flu.
- **medicines to increase water output**
 - spironolactone or similar substances
 - medicines with active substance names mostly ending with “semide” or “tanide”
- **medicines that lower blood pressure**, such as
 - guanethidine
 - methyl dopa
 - medicines with active substance names ending with “olol”
- **medicines to treat heart failure** with active substance names ending with “pril”
- **medicines to treat gout** that promote excretion of uric acid, such as probenecid, sulphinpyrazone
- **chickenpox vaccination**
Avoid using Rowa Cold & Flu in the first six weeks after a chickenpox vaccination.

Rowa Cold & Flu with food, drink and alcohol

Avoid alcohol while taking this medicine as it can increase the risk of stomach/bowel bleeding and impair your ability to react.

Pregnancy, breast-feeding and fertility

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.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Do not take Rowa Cold & Flu if you are pregnant, trying to become pregnant or breast-feeding.

Driving and using machines

Do not drive or use machines if your capabilities are impaired as Rowa Cold & Flu can impair your ability to react.

Rowa Cold & Flu contains sucrose

This medicine contains 1.9 g of sucrose per sachet. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Rowa Cold & Flu

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

The recommended dose for adults is

Single dose: 1 to 2 sachets

If necessary, the single doses can be repeated at intervals of 4 to 8 hours. However, do not exceed the **maximum dose of 6 sachets daily**. Do not use Rowa Cold & Flu longer than needed.

Use in children and adolescents

Rowa Cold & Flu must not be given to children and adolescents under 16 years. Due to the limited experience with Rowa Cold & Flu there are no special dose recommendations for **paediatric patients** (persons up to 18 years).

Method of administration

Pour the contents of one or two sachets of granules in a glass of water and stir well. Note: The granules do not dissolve completely.

Drink the entire content of the glass immediately, which can be with or without food.

Duration of treatment

Do not take this medicine longer than 3 days. Please talk to your doctor if you still have nasal congestion, pain or fever after 3 days of treatment.

If you take more Rowa Cold & Flu than you should

Contact your doctor immediately.

Overdose signs are headache, dizziness, fits, vomiting, noises in the ears, fast heartbeat, chest pain, restlessness or shortness of breath.

If you forget to take Rowa Cold & Flu

Do not take a double dose to make up for a forgotten dose. Just use your next dose as recommended.

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.

Stop taking this medicine and inform your doctor immediately or go to your nearest hospital if you are affected by:

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

- stomach or bowel discomfort such as stomach ache, indigestion and inflammation of the lining of the stomach
- nausea, vomiting, diarrhoea.

Uncommon (may affect up to 1 in 100 people):

- sleeplessness and other effects caused by brain stimulation
- skin reactions such as rash, nettle rash, itching
- difficulty in passing urine, especially in patients with enlarged prostate.

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

- allergic reactions
Symptoms of allergic reactions are breathing difficulties, skin reactions or fall in blood pressure. People suffering from asthma can be particularly affected.
- stomach ulcers
This may lead to perforation in isolated cases.
- stomach or bowel bleeding which may result in iron-deficiency anaemia in single cases
Signs are black stool or vomiting blood.
- seeing things that are not there
- effects on the heart, such as fast heartbeat, irregular heartbeat or abnormal contraction of the heart arteries.

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

- increased levels of liver enzymes
- severe allergic reactions.

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

- increased risk of bleeding (e.g. haematoma, nosebleed, gum bleeding)
- bleeding may result in anaemia
Signs are pallor or weakness.
- haemolysis (destruction of red-blood cells) in case of severe forms of G6PD (Glucose-6-phosphate dehydrogenase) deficiency
- flushing
- abnormal contraction of the heart arteries resulting in myocardial infarction
- increase in blood pressure, although not in controlled hypertension
- dizziness, ringing in the ears (tinnitus)
- kidney impairment, kidney failure

- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with Rowa Cold & Flu. See section 2.

Stop using Rowa Cold & Flu if you develop these symptoms and contact your doctor or seek medical attention immediately.

Patients taking this medicine have an increased risk of bleeding.

Dizziness and ringing in the ears may be symptoms of overdose.

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 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 Rowa Cold & Flu

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 sachets. The expiry date refers to the last day of that month.

Do not store above 25°C

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Rowa Cold & Flu contains

The active substances are acetylsalicylic acid and pseudoephedrine hydrochloride

Each sachet contains 500 mg acetylsalicylic acid and 30 mg pseudoephedrine hydrochloride.

The other ingredients are:

- citric acid anhydrous
- grapefruit flavour including acacia gum (E414), antioxidants and maltodextrine
- hypromellose
- sucrose.

What Rowa Cold & Flu looks like and contents of the pack

Rowa Cold & Flu consists of white to off-white granules, with occasional yellowish agglomeration for oral suspension used to prepare an oral suspension.

This product is available in the packs containing: 10, 16, 20, 28 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

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

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

Allphamed PHARBIL Arzneimittel GmbH, Hildebrandstr. 10-12, 37081 Göttingen, Germany.

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

Austria ASS+Pseudoephedrin Hexal 500 mg/30 mg – Granulat zur Herstellung einer Suspension

Ireland Rowa Cold & Flu 500 mg/30 mg Granules for Oral Suspension

This leaflet was last approved in 05/2018.

The following information is intended for health care professionals only:

Overdose

Acetylsalicylic acid:

There is difference between chronic overdose with disturbances mainly of the central nervous system ("salicylism") and acute intoxication, in which the main manifestation is severe disturbance of the acid-base equilibrium. In addition to the disturbances of the acid-base equilibrium and the electrolyte equilibrium (e.g. potassium loss), hypoglycaemia, skin rashes, gastrointestinal bleeding, the symptoms may include hyperventilation, tinnitus, nausea, vomiting, hearing and vision impairment, headache, vertigo and confusion.

Delirium, tremor, dyspnoea, sweating, dehydration, hyperthermia and coma may develop in case of severe intoxication. In intoxication with lethal outcome, death usually occurs due to respiratory failure.

Pseudoephedrine:

Very strong sympathomimetic reactions may develop following intoxication, e.g. tachycardia, chest pain, agitation, hypertension, whistling breathing, dyspnoea, convulsions, hallucinations.

The measures to be taken for treatment of intoxication with Rowa Cold & Flu depend on the degree, stage and clinical symptoms of intoxication. They correspond to the usual measures for reducing active substance absorption: acceleration of excretion, monitoring of water and electrolyte balance, impaired thermal regulation, breathing, cardiovascular and cerebral function. Immediate medical treatment is absolutely necessary, even if there are no observable manifestations and symptoms.