Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed without a physician's prescription

RESYL SYRUP

Guaifenesin 100 mg / 5 ml

Inactive and allergenic ingredients in the preparation – see section 6. Please see also section "Important information about some ingredients of the medicine" also.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

The medicine is not intended for children and adolescents. Swallow it in a proper manner. For more information consult a pharmacist. Refer to the physician if the signs of the illness (symptoms) get worse or do not improve after 7 davs.

The effect of Resyl Syrup is increased by the abundant consumption of fluids. Smoking contributes to the secretion of mucus in the respiratory tracts and to coughing ("smoker's cough"). Resyl Syrup contains saccharin and sorbitol and therefore is also suitable for diabetics.

1. What is the medicine intended for?

Expectorant, relieves cough

Therapeutic group: Expectorants ATC Code: R05CA03

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medićine.
- You have a (rare) hereditary disease of the metabolism of sugars, called fructose intolerance. Resyl Syrup contains sorbitol as a sweetener. This sugar gives rise to the formation of fructose during digestion.
- You are breast-feeding.

Resyl Syrup contains 6% alcohol by volume. Resyl Syrup is not suitable for children or adolescents.

Special warnings regarding the use of the medicine

Before the treatment with Resyl Syrup, you must consult a doctor if

- You have respiratory failure
- The cough is associated with bloody expectorate or excessive mucus secretion
- The cough is persistent or chronic, i.e., in smokers, asthmatics, in case of chronic bronchitis or emphysema (overinflation of the pulmonary alveoli)
- If the cough lasts for more than seven days, relapses, or is accompanied by fever, a skin rash, or persistent headaches, you must stop using Resyl Syrup and consult the doctor. A persistent cough may be a sign of a serious disease.

Tell the physician or pharmacist if

- You have other diseases,
- You are allergic or
- You are already taking medicines for internal or external use (even if they are non-prescription medicines!)

Caution should be used in case of gastrointestinal disorders altered kidney function, or if you are experiencing specific muscular weakness (called myasthenia gravis).

In case of hypersensitivity reactions (see chapter 4: "Side effects"), you must stop treatment immediately and talk to a physician as soon as possible.

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.

Stop taking other medicines that relieve or soothe the cough (called expectorants) since they may cause undesirable congestion of mucus in the bronchi that is thickened by Resyl Syrup, as well as a risk of bronchospasms and pneumonia.

The effect of certain tranquillizers or preparations that may cause muscle relaxation can be increased by the concomitant use of guaifenesin.

A risk for health exists, among other risks, for individuals with liver disease, individuals who suffer from: alcohol addiction, epilepsy, cerebral damage, pregnant or breast-feeding women and children. The effect of other medicines can be strengthened or disturbed.

Pregnancy and breast-feeding

If you are pregnant, consult the physician before using medicines. Breast-feeding women must not take this medicine.

Driving and using machines

Even if used correctly, Resyl Syrup may affect reactions, the ability to drive, and the ability to use tools or machines!

Important information about some ingredients of the medicine

- Resyl Syrup contains alcohol. Adults take up to 470 mg of alcohol (10 ml) per dose.
- Resyl Syrup contains saccharin and sorbitol and is therefore also suitable for diabetics.

3. How should you use the medicine?

Check with the physician or the pharmacist if you are unsure about the dosage and treatment regimen of the medicine.

The usual dosage is:

Adults: 5 to 10 ml 4 times per day.

Resyl Syrup contains 6% alcohol by volume. Resyl Syrup is not intended for children or adolescents.

Use the measuring cup included in the package. Wash and dry the measuring cup after each use and each user.

Do not use a domestic teaspoon for measuring the amount of medicine. Domestic teaspoons differ in size, and you may not get the correct amount of medicine. Child-proof guarantee caps significantly decrease the

number of poisoning incidents caused by medicines each year. However, if you find it hard to open the pack, you can refer to the pharmacist and ask to remove the safety system of the cap and make it into a regular easy-to-open cap. In parallel with treatment, it is recommended to drink plenty

(e.g., herbal teas, fruit juices, etc.).

Take the dosage shown on the package or as prescribed by the doctor. If you feel that the effect of the medicine is too weak or too strong, tell your doctor or pharmacist. Do not exceed the recommended dose.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

How can you contribute to the success of the treatment?

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the

medicine, consult the physician or pharmacist.

4. Side effects

As with any medicine, use of Resyl Syrup may cause side effects in some of the users, but they do not occur systematically in everyone. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Gastrointestinal disorders may appear, for example, nausea, vomiting, diarrhoea, as well as a sensation of heat, dizziness, or a change in blood values (the exact frequency of these side effects is unknown).

Additional side effects

Occur rarely (frequency is between 1:1000 and 1:10000) Hypersensitivity reactions (allergies) appear, among others, in the form of a skin rash, increased heart rate and respiratory disorders. Asthmatics and patients with urticaria are particularly affected by these.

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, consult with the physician. Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.ii) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/label. The expiry date refers to the last day of that month.

 Store below 30°C.

6. Additional information

- In addition to the active ingredient the medicine also contains
 - Purified water, Sorbitol liquid (non crystallising), Ethanol 96% v/v, Glycerol, Aroma IFF 12 H 310, Saccharin Sodium
- What the medicine looks like and the content of the package:
- Syrup (transparent liquid): 100 ml packaged in an amber glass bottle with a white child-proof guarantee cap and a plastic measuring device.
- License Holder and address:
- Devries & Co. Ltd., 32 Habarzel st., Tel-Aviv
- Manufacturer and address STADA Arzneimittel AG, Stadastrasse 2-18,
- 61118 Bad-Vilbel, Germany Revised in May 2021 according to MoH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health 039-07-25775-00

