RESYL® SYRUP

Composition

Active substance: guaifenesin.

Excipients: Purified Water, Sorbitol liquid (non crystallising), Ethanol 96%, Glycerol, Aroma, Saccharin Sodium.

Pharmaceutical form and quantity of the active substance per unit

Syrup: 5 mL contains 100 mg of guaifenesin.

Indications/Possible uses

Expectorant, relieves cough.

Posology/Use

Adults: 5 to 10 mL 4 times per day.

Resyl Syrup contains 6% alcohol by volume (corresponding to 5% weight/vol.). Resyl Syrup is not suitable for children or adolescents.

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

In addition to treatment, drinking plenty of liquid is recommended (e.g. infusions, fruit juices).

Contraindications

Hypersensitivity to the active substance or to one of the excipients in the composition.

Intolerance to fructose, for example, in case of hereditary fructose-1.6-diphosphatase intolerance (fructose is the result of the degradation of the sweetener sorbitol).

Warnings and precautions

Caution should be used in case of gastrointestinal disorders, myasthenia gravis, or with limited kidney function.

In case of bronchospasms or hypersensitivity reactions, treatment should be discontinued immediately, and the doctor informed.

In the following cases, patients must also contact their doctor:

- respiratory failure,
- cough with bloody expectorate or production of excessive bronchial mucus,

- persistent or chronic cough, e.g., in smokers, asthmatics, in case of chronic bronchitis or emphysema,
- if the cough lasts more than 7 days, relapses, or is accompanied by fever, a skin rash, or persistent headaches.

Resyl Syrup contains 5% weight/volume of alcohol. Adults take up to 470 mg of alcohol (10 mL) per dose.

A risk for health exists, among others, for individuals with liver disease, alcoholics, epileptics, individuals with brain damage, pregnant or breast-feeding women, and children. The effect of other medicinal products can be strengthened or disturbed.

The concomitant administration of an antitussive is not medically indicated. It can cause undesirable swelling of the secretions with a risk of bronchospasm and an infection of the respiratory tract due to the inhibition of the cough reflex and the physiological self-cleaning of the respiratory tracts.

Interactions

Resyl Syrup can emphasize the effect of sedatives and myorelaxants.

Concomitant use of antitussives: see "Warnings and precautions".

Pregnancy/Lactation

No evidence suggests a risk during pregnancy. However, controlled studies in animals or pregnant women are not available. Under these conditions, Resyl Syrup will be administered only in case of absolute necessity.

It is not known whether guaifenesin is excreted in breast milk. For safety reasons, women who are breastfeeding must not take Resyl Syrup.

Effects on ability to drive and use machines

Resyl Syrup contains alcohol. This is why, even when the product is used according to the recommendations, reaction capacity may be affected while driving or using machines.

Undesirable effects

Adverse effects are listed based on system organ class and frequency as follows. The frequencies are defined as follows: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000) or unknown (cannot be estimated based on the data available).

Blood and lymph circulation

Unknown: granulopaenia.

Immune system disorders

Very rare: hypersensitivity reactions with bradycardia, bronchospasms, dyspnoea.

Nervous system

Unknown: sensation of heat, vertigo, confused state.

Gastrointestinal disorders

Unknown: nausea, diarrhoea, and vomiting.

Uncommon: gastrointestinal disorders, for example, in the form of the need to vomit and gastric heaviness.

Skin

Rare: allergic skin reactions, in particular in patients with asthma or chronic urticaria.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il

Overdose

Taking a greater quantity than the recommended posology may cause serious health problems. In case of overdose, medical help should be sought immediately, even if there is no symptom.

Gastrointestinal disorders, nausea, and vomiting were reported after taking guaifenesin, in particular after high doses. Somnolence can also occur.

The creation of kidney stones was also observed after taking high doses of guaifenesin. Guaifenesin once absorbed is however quickly metabolised and excreted through the urine. Treatment is symptomatic.

Properties/Effects

ATC Code: R05CA03

Guaifenesin is an expectorant. It liquefies viscous mucus in the bronchi and encourages its expectoration, which calms the irritation at the source of the cough. The duration of action of a therapeutic dose is reached in 3 to 6 hours.

The syrup contains sorbitol as a sweetener which is slowly transformed into glucose and therefore is also suitable for diabetics.

Pharmacokinetics

Absorption

After oral administration in the form of an aqueous solution, guaifenesin is quickly and completely absorbed by the gastrointestinal tract.

Distribution

The maximum plasma concentrations of the unchanged active substance of 0.46 µg/mL are measured 15–30 minutes after the administration of an oral dose of 100 mg of guaifenesin.

Protein binding: 37% on average.

It is not known whether guaifenesin crosses the placenta or is excreted in breast milk.

Metabolism

Guaifenesin is mainly metabolised in the liver, essentially into beta-(2-Methoxyphenoxy)-lactic acid.

Elimination

Plasma half-life: approximately 1 hour on average.

Excretion: Guaifenesin is excreted rapidly and almost completely through the kidneys. 81% of the dose is detectable in the urine after 4 hours, and 95% after 24 hours.

Preclinical data

No data from animal experiments are available on reproductive toxicity and development, teratogenicity, or the carcinogenicity of guaifenesin.

Shelf life

The expiry date of the product is indicated on the label and packaging.

Specific remarks

Effect on diagnostic methods

Guaifenesin can interfere in the determination of urinary levels of 5-hydroxyindoleacetic acid and vanillylmandelic acid.

Stability

The medicinal product should not be used after the date following "EXP" on the container.

Remarks on storage

Keep medicinal products out of the sight and reach of children.

Store below 30°C.

License number

039-07-25775-00

Presentation

Syrup (transparent liquid):100 mL packaged in an amber glass bottle with a white child proof cap and a plastic measuring device.

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18,
61118 Bad-Vilbel, Germany

License Holder and Importer

Devries & Co. Ltd., 32 Habarzel st., Tel-Aviv

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