Package leaflet: Information for the user

Allergospasmin® N
1 mg/0.5 mg per spray
Pressurized inhalation, suspension

Active substances: Sodium cromoglicate (Ph. Eur.)/
Reproterol hydrochloride

For use in children and adults

Read the entire package leaflet carefully before you start using this medicine because it contains important information.
- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. See section 4.

What is in this package leaflet

1. What is Allergospasmin N and what is it used for?
2. What should you consider before using Allergospasmin N?
3. How to use Allergospasmin N?
4. What side effects are possible?
5. How to store Allergospasmin N?
6. Contents of the pack and other information

1. What is Allergospasmin N and what is it used for?

Allergospasmin N is an anti-inflammatory and bronchodilator agent. Indications
– For the symptomatic acute treatment of sudden onset of shortness of breath (especially allergic forms as well as those triggered by exertion, stress, or infections). Note: Long-term treatment should be symptom-oriented and only in conjunction with an anti-inflammatory maintenance therapy.
– Targeted prevention of exercise-induced asthma or in the case of foreseeable allergen contact.

2. What should you consider before using Allergospasmin N?

Allergospasmin N must not be used,
- if you are allergic to sodium cromoglicate, reproterol hydrochloride, and menthol/peppermint oil or any of the other ingredients of this medicine listed in section 6.1.
- if a specific form of pneumonia (eosinophilic pneumonia) occurs during treatment. In this case, treatment with Allergospasmin N should be discontinued.
- in infants and young children under 2 years (risk of laryngospasm).

Warnings and precautions
Inform your doctor before starting the application if you have any of the following conditions:

- Heart diseases in your medical history, especially a recent heart attack,
- pathological changes in the coronary arteries with angina pectoris,
- heart rhythm disorders
- pathological enlargement of the heart (hypertrophic obstructive cardiomyopathy)
- adrenal gland tumor (pheochromocytoma)
- severe hyperthyroidism

If you suffer from palpitations (tachycardic arrhythmias), the use of Allergospasmin N should only be carried out under special precautions, e.g., monitoring (ECG control). Since high doses can increase blood sugar levels and free fatty acids, regular blood sugar monitoring is required for diabetics. In the case of higher dosed use, monitoring of the potassium level in the blood serum is also necessary, especially with simultaneous treatment with diuretic drugs and those for the treatment of heart failure (e.g., cardiac glycosides).

An increasing need for Allergospasmin N is a sign of a worsening of the disease. In this situation, the treatment plan must be reconsidered by the doctor and, if necessary, redefined by the administration of additional anti-inflammatory or other medications.

If there is no satisfactory improvement or even a worsening of the condition despite the prescribed treatment, medical advice is required to possibly supplement the treatment with a combination of other medications (additional anti-inflammatory such as corticosteroids and/or bronchodilators like theophylline) or to determine a change in dosage.

A sudden and increasing worsening of asthma symptoms can be life-threatening. In these cases, medical help must be sought immediately. A significant overdose can be dangerous.
There have been repeated reports of a significant risk of severe complications of the underlying disease, including fatalities, when asthma was treated with β-sympathomimetic-containing inhalation monopreparations over a long period with high or excessive doses and the anti-inflammatory treatment was inadequate. The causal relationships have not yet been sufficiently clarified. However, inadequate anti-inflammatory treatment seems to play a decisive role.

Children
Infants and toddlers under 2 years of age must not use Allergospasmin N (risk of laryngospasm).

Children should be informed by their doctor about the dosage to be followed and possible side effects according to their age.

Effects of misuse for doping purposes
The use of Allergospasmin N can lead to positive results in doping tests.

Use of Allergospasmin N with other medicines Inform your doctor or pharmacist if you are taking/using, have recently taken/used, or intend to take/use other medicines.

When used simultaneously with

- other bronchodilating agents (bronchodilators) such as adrenergics or methylxanthines (e.g., theophylline), attention should be paid to a possible enhancement of the side effects described for reproterol hydrochloride.

- antihypertensive agents (primarily β-receptor blockers), the effect of reproterol hydrochloride is nullified. This can lead to an asthma attack.
- monoamine oxidase inhibitors (MAO-A inhibitors) and tricyclic antidepressants can trigger an enhanced effect of reproterol hydrochloride on the cardiovascular system.

Use of Allergospasmin N with alcohol
In general, alcohol consumption should be avoided during medication treatment. Otherwise, no special precautions are necessary.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine. During pregnancy, Allergospasmin N should only be used in
severe cases of illness under strict consideration of the benefit-risk ratio, as there is insufficient experience with Allergospasmin N during pregnancy. Sodium cromoglicate passes into breast milk in extremely small amounts.
After inhalative use of reproterol hydrochloride, the dose that reaches the mother's bloodstream is not measurable. Therefore, a risk to the breastfed infant is unlikely.

Driving and using machines
Allergospasmin N has a minor influence on the ability to drive and use machines. Due to individually occurring different reactions, in individual cases, especially at the beginning of treatment and with higher or excessive dosage, the ability to actively participate in road traffic or operate machines may be impaired. This is particularly true when alcohol, sedatives, and sleeping pills are taken simultaneously.

Allergospasmin N contains ethanol (alcohol)
This medicine contains 0.7mg of alcohol (ethanol) per spray corresponding to 0.7mg/70.0mg. The amount in 1 spray of this medicine is equivalent to less than 1ml of beer or 1ml of wine. The small amount of alcohol in this medicine has no noticeable effects.

Allergospasmin N contains sodium.
This medicine contains less than 1mmol (23mg) of sodium per 10ml, i.e., it is almost "sodium-free".

3. How to use Allergospasmin N?
Always use this medicine exactly as instructed by your doctor. Ask your doctor or pharmacist if you are not sure. The dosage depends on the type and severity of the condition.

For adults and children who are old enough to handle a metered-dose inhaler correctly, the following recommendations apply:
The dosage depends on the extent of respiratory complaints (such as cough, sputum, shortness of breath). The initial dosage is 2 sprays 4 times daily.
Allergospasmin N, i.e., 2 inhalations each after getting up, at noon, in the early evening, and before going to bed, with a minimum interval of 3 hours. Once the therapeutic effect is achieved, the daily dose can be gradually reduced under medical supervision as long as the symptoms are under control.

For targeted prevention in exercise-induced asthma or foreseeable allergen contact, 2 sprays of Allergospasmin N can be inhaled about 10 - 15 minutes beforehand. This is usually only necessary if the previous inhalation was more than 3 hours ago.

For acute treatment of sudden bronchial spasms and episodic shortness of breath, an additional spray of Allergospasmin N can be inhaled. This usually leads to rapid relief of breathing. If shortness of breath has not noticeably improved five minutes after inhaling the first spray, another spray can be inhaled. If even a second spray does not relieve the severe attack of breathlessness, further sprays may be necessary. In these cases, medical help must be sought immediately.

The total daily dose should not exceed 16 sprays, as a higher dosage generally does not provide additional therapeutic benefit but increases the likelihood of also serious side effects.

Instructions for use:
The aerosol should always be held upright, with the bottom facing up, regardless of the body position in which it is inhaled. If possible, the application should be done sitting or standing.
Before first use, release 4 sprays into the air to make the metered-dose inhaler ready for use! If Allergospasmin N has not been used for more than 2 days,
at least 2 sprays must be released into the air to make the metered-dose inhaler ready for use again.
1. Remove the orange protective cap.
2. Shake the upright metered-dose inhaler vigorously before each spray.
3. Exhale deeply. Do not breathe into the mouthpiece.
4. Enclose the mouthpiece fully with your lips. Inhale slowly and deeply while simultaneously pressing the metal canister down to release a spray.
5. Remove the mouthpiece from the mouth. Hold your breath for a few seconds, then exhale slowly through the nose.
6. Usually, after about one minute, repeat the inhalation following points 3 - 5. Then replace the orange protective cap on the plastic housing.

Important notes on care and cleaning
Allergospasmin N is a pharmaceutical preparation in which both active ingredients are present in a finely distributed, solid form. A certain residue of these solids in the plastic housing is unavoidable. To ensure your metered-dose inhaler functions correctly, the plastic housing must be cleaned every two to three days, preferably daily. This prevents the spray opening from becoming clogged through use.

If the spray opening becomes clogged or such a malfunction is indicated, do not attempt to take further sprays, but use the plastic housing only after cleaning it again. The metered-dose inhaler will then function properly again.

To clean, remove the orange protective cap and take the metal container out of the plastic housing. Hold the plastic housing with the mouthpiece down vertically under warm running water to dissolve any possible blockages in the spray opening (see illustration). Then shake off the water and let the plastic housing dry thoroughly (preferably overnight) before reinserting the

metal container and replacing the orange protective cap. The rubber protective cap on the valve of the metal container itself must fit precisely and firmly and must not be removed. This cap is important for the proper functioning of the spray device.

Duration of use:
The duration of use is determined by your treating physician. The treatment of asthma is usually a long-term treatment and should be carried out in stages according to the severity. The success of the treatment should be checked by regular medical examinations. It may be dangerous for you to increase the use of Allergospasmin N on your own without medical instruction. An increasing need for Allergospasmin N is a sign of a worsening condition. In this situation, the treatment plan must be reconsidered by the doctor and, if necessary, redefined by the administration of additional anti-inflammatory or other medications. For the medical assessment of the disease progression and the success of the bronchodilator and anti-inflammatory treatment, daily self-monitoring according to medical instructions is important. This is done
e.g., by recording the breathing rate measured with the peak flow meter. Please talk to your doctor or pharmacist if you feel that the effect of Allergospasmin N is too strong or too weak.

If you have used more Allergospasmin N than you should
Overdose symptoms are mainly due to the active ingredient reproterol hydrochloride contained in Allergospasmin N. In case of severe overdose of reproterol hydrochloride, it can lead to heart palpitations (tachycardia), heart rhythm disturbances (arrhythmias), low blood pressure (hypotension) up to shock, restlessness, chest pain, headaches, and severe trembling of the hands
(tremor), but also of the whole body. Furthermore, the potassium concentration in the serum may decrease, the blood sugar level may rise, or a condition with a low pH value in tissue and blood due to increased lactic acid content (lactic acidosis) may occur.

In case of suspected overdose with Allergospasmin N, no further inhalations should be performed. Immediately notify your doctor, who can initiate symptomatic treatment.

If large amounts of the metered-dose inhaler have been accidentally swallowed, gastric lavage should be considered; activated charcoal and laxatives can reduce the unwanted effect of the β2-sympathomimetic. As an antidote, β1-receptor blockers (e.g., atenolol, metoprolol) are suitable, but these should also be used cautiously to avoid exacerbating shortness of breath in patients with asthma. In patients with heart failure, it is better to administer sedatives (e.g., benzodiazepines). At the same time, heart function should be monitored by ECG.

If you forget to use Allergospasmin N
Do not use a double dose if you have forgotten the previous application, but continue the treatment as normal.

If you stop using Allergospasmin N
If you want to interrupt or prematurely end the treatment, please inform your doctor so that he can discuss further treatment measures with you.
If you have further questions about the use of this medicine, please contact your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following frequency categories are used to evaluate side effects:
Very common: more than 1 in 10 treated
Common: 1 to 10 in 100 treated
Occasional: 1 to 10 in 1,000 treated
Rare: 1 to 10 in 10,000 treated
Very rare: less than 1 in 10,000 treated
Not known: frequency cannot be estimated from the available data

Reproterol hydrochloride
Occasionally, especially in cases of particular sensitivity and/or higher dosage, fine tremor of the fingers (tremor) as well as palpitations, a feeling of restlessness, or headaches may occur, which usually subside after 1 - 2 weeks of continued therapy.
An increased occurrence of such symptoms and tachycardia are signs of an overdose. The medicine should be dosed lower in such cases, and the treating physician should be informed immediately.

During treatment with reproterol hydrochloride, serum potassium levels may decrease and blood sugar levels may increase. However, these effects generally only become apparent at higher dosages (please also refer to the information in the section "If you have used more Allergospasmin N than you should").

Sodium cromoglicate
After inhalation of sodium cromoglicate, irritation of the throat and trachea accompanied by coughing may occur, which in individual cases can lead to bronchial spasms (reflex bronchoconstriction).
In very rare cases, the bronchospasm can be so pronounced that the therapy must be interrupted.

Bronchoconstriction is counteracted in this combination by the simultaneously inhaled bronchodilating (bronchospasmolytic) reproterol hydrochloride. In asthmatics, skin or muscle inflammation (dermatitis, myositis) as well as inflammation of the stomach and intestinal mucosa (gastroenteritis) have been observed under sodium cromoglicate therapy. These side effects were not severe and resolved completely after discontinuation of sodium cromoglicate. In rare cases, the occurrence of
skin rash (exanthema) has been reported. Very rarely, a specific form of pneumonia (eosinophilic pneumonia) has been observed.

In individual cases, severe hypersensitivity reactions (generalized anaphylactic reactions) with bronchial spasms (bronchospasms) have been reported in connection with sodium cromoglicate therapy.

Furthermore, the following adverse effects have been described in individual cases, some of which are part of the known side effect spectrum of sodium cromo-

glicat falling out:
Laryngeal swelling (laryngeal edema), hoarseness, tissue swelling (angioedema) involving lips, face and/or limbs, dizziness, nausea, swelling of the parotid gland (parotid swelling), joint pain, hemoptysis, muscle pain, peripheral neuritis, arteritis, pericarditis, dysuria, and nephrotoxicity.

The following table provides an overview of the side effects that may occur with the use of reproterol or sodium cromoglicate, organized by system organ classes and frequency.

Diseases of the immune system	Very rare ly	Hypersensitivity reac- tions with bronchial spasms (Anaphylactic reaction with bronchospas- ms)
	Not known	Hypersensitivity reac- tions (including itching, ur- ticaria (urticaria), skin rash (exanthema), low blood pressure (hypo- tonie), tissue swelling- s (angioedema) involving- lips, face and/or limbs) metabolic and nutritional disorders
Very rare Lowering of potassium con- centration in serum, in-	crease in blood sugar level- in serum	Psychiatric dis- orders Occasion- ally
Not- known	Occasional light Not be- known	Feeling of restlessness Hyperactivity, sleep dis- orders, hallucinations (especially in children up to 12 years)
Nervous system disorders	Occasion- ally Very rare- ly	Fine tremor of the fingers (fine tremor), headaches Dizziness, peripheral nerve inflammation (peripheral neuritis) Heart diseases
Occasion-	ally light Very rare- ly Not de- termined	Palpitations, tachycardia (Tachycardia) Pericarditis (Pericarditis) Arrhythmias, Influence on blood pressure (decrease or increase)
Vascular diseases	Very rare- ly	Arteritis Respiratory
tract diseases, thoracic and me- Thoracic cavity and me- diastinums	Very rare- ly	Cough, irritation of the tra- chea and bronchi, Bronchospasm, special- form of lung in- flammation (Eosinophilic Pneumonia), laryngeal swelling (laryngeal edema), hoarseness, coughing up blood (he- moptysis)
Diseases of the	Very rare-	Inflammation of the

gastrointestinal tract	ly	stomach and intestines (Gastroenteritis), vomit- irritation, swelling of the parotid gland (parotid swelling)
Diseases of the skin and sub- cutaneous tissue	Very rare- ly	skin inflammation (dermati- tis)
Skeletal muscle, connective tissue and bone diseases Very rare-	ly muscle inflammation (myosi-	tis), joint pain, muscle pain Diseases of the
Diseases of the Kidneys and urinary tract	Very rare ly	Difficulty urinating (Dysuria), Kidney damage (Neph rotoxicity)

Significant side effects or signs to watch for, and actions to take if affected:
If mild side effects occur, Allergo- spasmin N should be dosed lower.

If severe side effects occur, Allergo- spasmin N should no longer be inhaled and the doctor should be informed immediately about the symptoms you have experienced!
Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects not listed in this leaflet.

Other possible side effects
In sensitized patients, menthol can trigger hypersensitivity reactions (including shortness of breath).

Reporting side effects
If you notice side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: https://www.bfarm.de. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Allergospasmin N?
Keep this medicine out of the reach of children.
You must not use the medicine after the date on the outer packaging and the container after "Use by" date do not use. The expiration date refers to the last day of the specified month.
Storage conditions:
Container is under pressure. Protect from sunlight and excessive heat (over +50°C) as well as from moist environments. Do not force open. Even after use, do not force open or burn.

6. Contents of the package and further information
What Allergospasmin N contains:
– The active substances are:

1 spray puff of 70.00mg contains:
1mg sodium cromoglicate (Ph. Eur.) and 0.5mg reproterol hydrochloride, which corresponds to an amount released from the mouthpiece of 0.82mg sodium cromoglicate and 0.41mg reproterol hydrochloride.
– The other ingredients are:
Apafluran, poly (oxyethylene)-25-glycerol trioleate, ethanol, saccharin sodium, Dentomint PH 799959 (flavoring agent)

This medicinal product contains fluorinated greenhouse gases.
Each inhaler contains 17.234g HFA-227ea equivalent to 0.055 tons CO2 equivalent (global warming potential GWP =3220).

What Allergospasmin N looks like and contents of the package:
The two active substances are present as a white powder. Aller-
gospasmin® N is available in the following packages:
1 x 10ml pressurized inhalation, suspension with at least 200 puffs
2 x 10ml (N 2) pressurized inhalation, suspension with at least 2 x 200 puffs
3 x 10ml (N 3) pressurized inhalation, suspension with at least 3 x 200 puffs

Pharmaceutical entrepreneur

Viatris Healthcare GmbH
Lütticher Straße 5
53842 Troisdorf
Manufacturer:
SANOFI WINTHROP INDUSTRIE
30-36 Avenue Gustave Eiffel
37100 Tours
FRANCE
or
Mylan Germany GmbH
Branch office Bad Homburg
Benzstraße 1
D-61352 Bad Homburg v. d. Höhe

This package leaflet was last revised in
November 2024.
Allergospasmin® N is prescription-only

Dear patient,
Allergospasmin N contains a bronchodilator (Reproterol hydrochloride) and an anti-inflammatory (Sodium cromoglicate) active ingredient. The success of treatment with Allergospasmin N depends on using the medication according to the dosage recommendations of your doctor.
Please remember: Only if you use Allergospasmin N regularly according to your doctor's instructions
can the medication fully develop its effectiveness. Take advantage of the opportunity for self-monitoring by

daily measuring your peak flow with a peak flow meter. Regularly recording the results allows your treating doctor a better
assessment of your illness - an important prerequisite for your treatment.