Nasodren®
for sinusitis treatment

Hartington Pharma

2nd Edition 2014
NASODREN®, Breathe the difference

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Chapter 1

THE NOSE AND PARANASAL SINUSES
Anatomy of the nose

The nasal pyramid, or nose, is a hollow triangular pyramid that forms the anterior part of the nasal fossa. It contains the nasal fossae, two long trenches that move in an anteroposterior direction, that are depressed in the transversal direction and are higher than they are wide. The nasal pyramid is comprised of a bony-cartilaginous structure, with a cutaneous-mucosal inner covering and an external muscular, cutaneous covering.

Paranasal sinuses

The paranasal sinuses are a set of pneumatized chambers located at the front of the skull that surround the nasal fossae and which are connected to them through small apertures called ostia.

The role the sinuses play with regard to the rest of the body is not fully known. Multiple functions have been attributed to them:

• Lightening the bone structure of the skull
• Protecting the skull’s nervous structures in the event of possible trauma
• Thermal insulation of the brain
• Soundbox and cesaesthetic controller of sound during phonation
• Thermohygrometric conditioner of inspired air
• Regulator of nasal pressure in the course of breathing and abrupt changes in pressure
• Storage of odorous particles
• Contributor to the shape of the adult face.

Rhinosinusitis

Inflammation of the nasal mucosa is called rhinitis and inflammation of the sinus mucosa is called sinusitis. However, rhinitis and sinusitis usually coexist and are concurrent in most individuals and, as such, the term rhinosinusitis has been widely adopted.

Rhinosinusitis is the inflammation of the nose and paranasal sinuses. The inflammation in the sinuses gives rise to a loss of drainage through the ostia, leading to an accumulation of mucosity and a subsequent increased sensation of congestion.
The characteristic symptoms of rhinosinusitis are nasal obstruction/blockage/congestion, nasal discharge (anterior posterior nasal drip), facial pain/pressure and reduction/loss of smell.

**Types of Rhinosinusitis**

According to the duration of the symptoms, we distinguish the following types:

- **ACUTE RHINOSINUSITIS (ARS)**: if the process lasts less than 12 weeks with complete resolution of symptoms

- **CHRONIC RHINOSINUSITIS (CRS)**: if the process lasts more than 12 weeks.

CRS may also be subject to exacerbations. CRS patients have an average of 2.5 episodes a year.

**Causes of Rhinosinusitis**

Most acute rhinosinusitis is caused by viral infections associated with the common cold (viral ARS). A small percentage of patients with viral ARS will have a bacterial superinfection, which is called bacterial ARS.
Chapter 2

NASODREN®
NASODREN®, in the form of a nasal spray, is used for the relief of nasal congestion (blocked up feeling in your nose), nasal secretions, loss of smell and facial pain. By clearing and draining mucus secretions retained in the sinuses (passages leading to the nose), nasal cavities and upper respiratory tract, Nasodren® provides fast symptom relief from the very first dose.

When you spray Nasodren® into your nostrils you will experience an intense discharge of dammed up secretions from the nose and paranasal cavities, which can last up to two hours. As a result, headaches or facial pain, which often accompany nasal congestion, rapidly cease. Nasodren® is a natural extract of Cyclamen europaeum L. (a plant) that has draining and decongestant properties, cleaning sinuses and relieving rhinosinusitis symptoms. It does not contain antibiotics, corticosteroids or preservatives. Unlike other products commonly used to treat rhinosinusitis symptoms, Nasodren® not only acts at nasal mucosa level but also at sinus level.

Nasodren® is a very safe product. Its active ingredient, saponins, is not absorbed and consequently does not reach the bloodstream, thereby avoiding systemic side effects, i.e. it does not affect the liver, kidneys or other organs.

The safety, efficacy and tolerability of Nasodren® have been demonstrated in 29 clinical trials (two of them recently published in Rhinology and Laryngoscope, amongst the most relevant journals for ENT specialists). More than 3 million rhinosinusitis patients worldwide have already benefitted from Nasodren®.
Composition and properties

A Nasodren® pack contains a vial with a lyophilized powder obtained from a natural extract of fresh tubers of *Cyclamen europaeum* L. A solvent (5 ml of water) is provided for the reconstitution of the lyophilized powder. There are no other ingredients or preservatives in Nasodren®.

*Cyclamen europaeum* L is a member of the primrose family (Primulaceae) and has been used since ancient times. It is known, for example, that Theophrastus (Ancient Greece, 4th-3rd centuries BC) recommended inserting a mixture of *Cyclamen europaeum* L and honey into the nose for the treatment of nasal catarrh and headaches, “to clear the head”.

Nasodren® only contains extract of *Cyclamen europaeum* L., rich in triterpenic saponins that act as a local surfactant on the mucous membranes, promoting intranasal drainage of fluid from the sinuses by means of a physical mechanism.
Chapter 3

MECHANISM OF ACTION
The effectiveness of Nasodren® lies in its saponin content. Saponins are present in the plant world and most plants contain them in the form of triterpene and steroid glycosides. The term “saponin” comes from a Celtic word. It means soap and is found in all European languages. Saponins have some of the characteristic properties of soap, particularly detergent and surfactant properties, the ability to reduce surface tension and create a reasonably stable film and, therefore, the property to form a foam. Due to these properties, the saponins adhere to surfaces, such as those of the mucous membranes.

The extract from the fresh tubers of Cyclamen europaeum L in Nasodren® contains saponins.

The surfactant action of Nasodren® saponins on the nasal mucosa reduces surface tension, facilitating humidification of the zone in addition to the secretion of mucin by goblet cells. This decreases the viscosity of the mucus accumulated in the nasal and sinus cavities facilitating its elimination and thereby relieving congestion.

In addition, saponins physically stimulate nerve endings present in the mucosa, generating a reflex reaction observed in all the upper respiratory tract mucosa, that is to say, the nose, the sinuses, the eustachian tube and internal ear. Thus, the accumulated secretions in the sinuses are consequently drained through the nose, providing rapid symptomatic relief from nasal congestion. In other words, Nasodren® performs by activating the physiological mechanisms of the upper airways which are impaired during rhinosinusitis.

**Clinical evidence for Nasodren® Nasal Spray**

Every year a large number of people consult their physician with some form of nasal/paranasal inflammatory disorder that traditionally has been called sinusitis, but today is more commonly known as rhinosinusitis. In the majority of cases the patient presents a variety of symptoms such as nasal blockage/congestion, facial pressure/pain, nasal discharge, reduced sense of smell, toothache, earache, headache, tenderness, cough, fever, malaise, etc. In view of this symptomatology, rhinosinusitis has the potential to impact both mental and physical health, and this underlies the need for appropriate management to produce rapid symptomatic relief. As a result of the diverse symptoms attributed to rhinosinusitis, a number of treatment options are available, including analgesics, decongestants, antihistamines, anti-inflammatory agents (including corticosteroids), antibiotics, antifungals, saline douches, mucolytics, phytotherapy, and so the list goes on. It has been estimated that approximately 90% of patients who consult their General Practitioner with rhinosinusitis are prescribed an antibiotic. This is disappointing given that the vast majority of cases have a viral origin for which antibacterial therapy has largely proven to be of little value. Antibiotics are appropriate, however, for patients with confirmed bacterial disease and in those at high-risk or who are systemically very unwell. Interestingly, it is acknowledged that inflammatory processes are clinically important in the pathogenesis of rhinosinusitis and are responsible for some of the most distressing symptoms such as nasal congestion, blockage and facial pain. Products that can reduce inflammation and improve drainage from the sinuses are therefore likely to be of significant clinical benefit.
Nasodren® is a naturally derived extract from *Cyclamen europaeum* L tubers that has been used for centuries to relieve symptoms associated with rhinosinusitis. It has a number of properties that support its utility in the treatment of rhinosinusitis and related diseases such as otitis media. Perhaps most importantly:

- It reduces oedema in the nasal cavity through a local action on the mucous membranes
- It restores ciliary cleaning activity and natural drainage of the sinuses
- It causes the opening of the ostia
- It improves ventilation of the sinuses

Such actions are ideal in a product intended for the treatment of rhinosinusitis - based upon the current concept of it being an inflammatory disease of the contiguous nasal and paranasal sinuses.

Nasodren® has been investigated in clinical studies performed across Eastern and Western European countries as well as in the USA, involving more than 2,000 patients with acute or chronic sinusitis and/or related diseases such as secretory otitis media as well as postoperatively following nasal surgery. The study groups usually consisted of patients of either sex, aged between 5 and 75 years, with treatment generally administered for 3-14 days. In the rhinosinusitis studies, the methods of evaluation were comparable and involved the physician’s assessment of signs and symptoms of the disease at each clinic visit. The patient’s assessment of specific symptoms (nasal obstruction, anterior/posterior mucus secretion, facial pain and loss/reduction of smell) was also recorded using visual analogue scales (VAS). In some studies endoscopic evaluations were performed to investigate for the presence of mucopurulent secretions in the middle meatus, mucosal oedema, crusts and granulations. Interestingly, the study conducted in 25 sites of the USA is the only clinical trial in rhinosinusitis that has used CT scan to screen patients and assess efficacy. In all studies the patients were required to maintain a diary of disease symptoms and possible adverse events. Finally, in some studies both patients and physicians were required to complete a global evaluation, rating their satisfaction with treatment.

The results from these trials with Nasodren® were very favourable and have been published in the most relevant scientific journals.
In addition, the results from the trials in terms of efficacy, safety and tolerability have led *Cyclamen europaeum* to be included in the European Position Paper on Rhinosinusitis and Nasal Polyps 2012 (EPOS12) with a high level of evidence.

**Nasodren® Mechanism of action**

Click on the image to watch the video
Chapter 4

FREQUENTLY ASKED QUESTIONS
1. What is Nasodren® and what is its composition?

Nasodren® is a product indicated for the symptomatic treatment of acute and chronic rhinosinusitis, postoperative care after sinonasal surgery, and otitis media with effusion. It is composed of saponins (active substance) from Cyclamen europaeum L that give fast relief from rhinosinusitis symptoms such as nasal blockage, obstruction, congestion, nasal discharge, facial pain and loss of smell.

2. Why is Nasodren® different?

Nasodren® is different because it has a unique, physiological mechanism of action that produces reflex secretion, thereby cleaning and draining the nose and sinuses from accumulated mucus.

It is currently the only nasal spray that has shown, through controlled trials, that it clears mucus from the nose and the sinuses.

3. How does Nasodren® work?

Nasodren® has a dual mechanism of action: one direct effect and the other indirect. Saponins are well-established, surface-active agents that reduce the surface tension of the cell membrane of the nasal mucosa, thereby facilitating mucin secretion and decreasing nasal congestion through a direct osmotic effect. Once administered into each nostril, saponins do not penetrate the membrane, acting as a topical surfactant agent that is not absorbed. Nasodren® also physically stimulates the nociceptive terminals of the trigeminal nerve (indirect effect). This leads to a seromucous discharge, reducing inflammation of the mucosa and opening the ostia (the passages that communicate the sinuses to the nasal cavity), thus cleaning sinuses and nasal cavity. Hence, Nasodren® performs by activating the physiological mechanisms of the upper airways: increased mucus secretion, greater ciliary cleansing activity and increased arterial blood flow, which are impaired during rhinosinusitis.

4. Is Nasodren® a safe product?

Following instillation into the nostrils, Nasodren® does not disperse over the entire mucous surface, since it does not penetrate into the paranasal cavities. Its activity is confined to the vestibular area and the inferior nasal meatus. This means that Nasodren® is a very safe product. Saponins, its main ingredient, are not absorbed and consequently do not reach the bloodstream, are not metabolised and hence, do not produce adverse effects, i.e. do not affect the liver, kidneys or other organs.

5. What concomitant/undesirable effects may Nasodren® produce?

Nasodren® acts physiologically, stimulating the terminal endings of the trigeminal nerve in the nasal mucosa. This specific mechanism of action can produce some itching, sneezing and a brief sensation of mild to moderate burning in the nasopharynx and, more rarely, a brief lacrimation and flushing of the face. These are manifestations of the positive response to the product. All these effects usually diminish during the course of treatment.

6. How many applications of Nasodren® does a patient need to feel relief?

According to clinical data, many patients feel symptom relief from the first application. After the 2nd day of application, symptoms such as facial pain will be significantly reduced. Mucopurulent secretions will stop after the 4th day.
It is recommended that you use Nasodren® daily during 7 to 10 days. Treatment may be extended up to 14 days if necessary.

7. I have not improved after several days of treatment. Why?

There are some reasons why Nasodren® may show a lack of efficacy. Firstly, due to an idiopathic reason, i.e. any product may be efficient in a high percentage of patients but for unknown reasons inefficient in a small percentage of patients. If patients have extremely large polyps, these may block the opening of the sinuses and the nasal passage, impeding mucus drainage. Other anatomical malformations can produce similar results. Another cause that affects the efficacy of Nasodren® is when only a short time is left between the administration of nasal decongestants (vasoconstrictive nasal drops) and Nasodren®. This effect is seen when nasal drops act on the mucous membrane, which seems to be related to the blocking of unicellular glands. There is no need to use a decongestant when using Nasodren®, but in cases where you would like to use both, a gap of at least 2 hours should be left between product application.

8. Does Nasodren® work for chronic sinusitis?

Yes, Nasodren® is indicated for the symptomatic treatment of acute rhinosinusitis and exacerbations of chronic rhinosinusitis.

9. Can I use Nasodren® if I have polyps?

Yes, you can, although Nasodren® will not shrink the polyps. In cases where polyps are too large, they can obstruct the sinus conducts and impede mucus drainage.

10. Can I use Nasodren® as monotherapy?

Yes, Nasodren® used by itself cleans and drains accumulated mucus in the sinonasal area. Clinical trials have shown the efficacy of Nasodren® in monotherapy as well as in combination with other rhinosinusitis treatments (antibiotics, corticosteroids, etc.)

11. Can I be allergic to Cyclamen?

Yes. Although it is infrequent, some persons can develop an allergy to Primulaceae, the family of plants *Cyclamen europaeum* L (Nasodren® active substance) belongs to. Unfortunately, allergy cannot be foreseen. If it does occur, it is advisable to visit the allergist to confirm the diagnosis.

12. When is Nasodren® indicated?

As soon as a patient feels nasal blockage, obstruction, congestion or nasal discharge, facial pain/pressure or a reduction of smell.

13. Can Nasodren® be used in allergic rhinitis?

Nasodren® can be recommended as part of a combined treatment of allergic rhinitis, as a means of washing the allergens present in the mucous membrane. This treatment is very much in vogue at the moment and is referred to as irrigation-elimination. We can, and ought to, increase the use of Nasodren® for such purposes. However, it is essential to stress that Nasodren® must be used in combination with a basic antiallergic treatment. The use of Nasodren® as a monotherapy is not effective, given that *Cyclamen europaeum* L does not act on the main link of allergic rhinitis, the antigen-antibody immune response, responsible for the activation of the mechanism of allergic inflammation. Nasodren® can, however, act against the accumulation of mucus in the unicellular glands, thereby enhancing treatment.
14. Can Nasodren® be used in children?

Some of the clinical trials conducted with Nasodren® included children of 5 years and over with rhinosinusitis. The results of these studies show the efficacy and safety of Nasodren® in this population. However, from a practical point of view, since its mechanism of action may produce itching, sneezing or burning sensation, our advice is to recommend Nasodren® only to those children whose parents can understand that this temporary discomfort is, by far, lesser than the benefit: symptom relief.

15. Does Nasodren® work for otitis?

The administration of Nasodren® is effective in the treatment of secretory otitis media leading to rapid symptom relief, shortening treatment time and avoiding the use of aggressive therapies.

16. Do I need to inhale Nasodren®?

Nasodren® exerts its action on the nasal mucosa (osmotic effect and physical stimulation of trigeminal nerve endings). Nasodren® is a very safe product; it is not absorbed and, obviously, does not produce morphological changes on the mucosa of the nasal cavity and sinuses.

However, it is recommended not to inhale during the administration of Nasodren® as it may increase the intensity and duration of undesirable effects (sneezing, itching, burning sensation). To avoid inhalation it is recommended to stop breathing while spraying Nasodren® and then to breathe out through the mouth before breathing normally.

17. How does Nasodren® work without reaching the bloodstream?

The main component of Nasodren® is saponins. Saponins are present in the plant world and most plants contain them in the form of triterpene and steroid glycosides. The term “saponin” comes from a Celtic word. It means soap and it is found in all European languages.

Saponins from Cyclamen europaeum L have a molecular weight between 1000 and 1500, and are polar chemical compounds. Hydrophilic polar molecules of high molecular mass are not absorbed through biological membranes - nasal mucosa - and consequently do not reach the bloodstream. Moreover, the saponins are gradually washed out by the reflex secretion from the nasal mucous membrane.

Therefore, the saponins exert purely local action, a direct osmotic effect. All events occurring thereafter are caused by physical stimulation of the trigeminal nerve endings, which innervate the glands in the paranasal sinuses and the entire nasal cavity. These glands are responsible for producing most of the secretion that contributes to the physiological drainage of the inflamed sinuses, leading to the relief of rhinosinusitis symptoms.

18. Why do we use freeze-drying with Nasodren®?

Due to the efficiency of this method, we are able to ensure our product offers high levels of quality and stability. Its characteristics can be summarised as: optimum stability; easy, swift and total solubility; unlimited conservation; good protection against external toxic influences; rapid reconstitution.

19. Why is Nasodren® able to be stored for up to 16 days in a refrigerator?
Stability studies were performed on the reconstituted solution, both at room temperature and in a refrigerator, over a period of 16 days in each study, while following ICH stability guidelines. The absence of preservatives enables the solution to become contaminated at ambient temperature, mainly with fungi (species not determined). However, the analyses performed indicate that the reconstituted product can be stored at 4-8°C (refrigerator) for 16 days without contamination. This time is sufficient, given that treatment duration is between 7-10 days.
Chapter 5

HOW TO USE NASODREN®
**Instructions for preparation:**

Nasodren® is a nasal spray containing *Cyclamen europaeum* L. It is prepared by dissolving the powder in the water and screwing the spray nozzle onto the vial.

Nasodren® is for use in your nose only. Follow the instructions and **video** below.

![Click on the image to watch the video](image)

**How to prepare the solution**

- Open the vial containing the powder by turning the cap counter-clockwise and removing the stopper.
- Open the plastic bottle with the liquid by breaking off the upper part.
- Pour all of the liquid into the vial with the powder.
- Screw the spray nozzle onto the vial and shake gently until fully dissolved. Wait until no foam is visible.
- Remove the protective cap from the spray nozzle.

Prior to the first administration, press the spray nozzle 2-3 times, aiming it away from the body into the air, avoiding the eyes!
**How to use Nasodren®**

Hold your head vertically, do not lean forwards or backwards. Insert the spray nozzle into the right nostril. Stop breathing for a short time (3-5 seconds) and spray the solution into the right nostril by pressing the spray nozzle once only. Breathe out deeply through the mouth once and then breathe normally. Do not inhale while administering the spray!

Then repeat the process in the left nostril.

Clean the spray nozzle with a clean paper tissue. Replace the protective cap over the spray nozzle.

**How much Nasodren® should you use?**

The solution should be sprayed daily, only once into each nostril, preferably at the same time of day, approximately 2 hours before bedtime. Increasing the daily dose does not result in an increased effect.

**How long should you use Nasodren® for?**

The treatment normally lasts for 7-10 days but may be extended up to 14 days.

A significant improvement or total symptomatic relief is achieved after 6-8 applications. However, headaches often associated with the condition may reduce or stop completely after only 3-5 applications of Nasodren®. Nevertheless, treatment should be continued for the recommended duration of 7-10 days.

In cases complicated by purulent infection, you should contact a doctor. If a second course of treatment is necessary in severe or chronic cases, this should only be initiated 7-10 days after completion of the previous course.

**If you use more Nasodren® than you should.**

Nasodren® overdosage can cause an intense burning sensation in the nasopharyngeal space, without serious consequences. In the event of an accidental overdose, irrigation of the nasal cavity through the nostrils with warm water, as well as pharyngeal gargling with warm water, can be useful.

**If you forget to use Nasodren®.**

If you forget to take a dose, continue with treatment on the next day as recommended.

**If you stop using Nasodren®.**

Do not stop treatment sooner than stated in these instructions of use, as you may not obtain the expected results. Similarly, do not use Nasodren® longer than stated in the instructions of use.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**Possible side effects:**

Like all products, Nasodren® can cause side effects.

If prolonged shedding of tears or saliva is experienced for more than 2 hours, medical attention should be sought.
If any of the side effects become serious, or if you notice any side effects not listed in these instructions, please tell your doctor or pharmacist.

**Before using Nasodren®**

**When is Nasodren® not recommended?**

If you are allergic (hypersensitive) to Cyclamen, Primula and other Primulaceae.

Take special care with Nasodren® nasal spray:

- Avoid inhaling during application
- Apply only one spray per day into each nostril.
- Avoid eye contact. Contact of the product with the eyes may result in irritation and symptoms of acute conjunctivitis.
- Take note of the section “If you are taking medicines”.
- A brief sensation of mild and transient itchiness or burning, sneezing and shedding of tears or an increase in nasal secretions can occur a few minutes after administration. This is entirely normal and occurs when Nasodren® begins to take effect, indicating an optimum reaction to the product’s effectiveness. Treatment should therefore not be interrupted. There may be a pinkish-coloured discharge from the nose; this should also be no cause for concern.
- Accidental use by patients allergic to Cyclamen, Primula and other Primulaceae, which could lead to swelling of the nasal mucosa, eyelids and/or face.

**If you are taking medicines.**

Please tell your doctor or pharmacist if you are taking or have recently taken any medicines, including medicines obtained without a prescription. This is especially important if you are receiving treatment with anticoagulants (such as coumarin derivatives, acetylsalicylic acid) or anticholinergics (such as atropine).

- Other nasal products can be used 2 hours after using Nasodren®.
- Nasodren® is not affected by food and drink.
- Driving or using machines is not recommended for 2 hours after using the spray.

**If you are pregnant or breast-feeding.**

Ask your doctor or pharmacist for advice before using Nasodren®. There is no experience regarding the administration of Nasodren® during pregnancy and breast-feeding. Therefore, Nasodren® should not be used if you are pregnant or breast-feeding unless prescribed by your doctor.

**Using Nasodren® in children.**

Nasodren® can be used in children aged 5 years and above. Dosing instructions must be followed exactly.
Special precautions for storage

The lyophilized powder and the water, in their original containers, are stable when stored in a dark place and at a temperature less than 25°C during 3 years. The reconstituted solution must be stored in a refrigerator up to a maximum of 16 days, protected from light, at a temperature of 2-8°C. The product must be stored out of the reach and sight of children.


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Hartington Corporate company video

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