



**DO NOT
INHALE**
when spraying

because sneezing,
tearing, and a limited
burning sensation
which are a normal
reaction to the unique
mechanism of action
could intensify

**PLEASE READ THE
INSTRUCTIONS BEFORE
USING NASODREN**

NASODREN® Nasal Spray

DRAIN MUCUS AND CLEARS THE NOSE AND SINUSES

INSTRUCTIONS FOR USE

Product Description

Nasodren is an aqueous solution made of a natural extract of fresh tubers of the plant *Cyclamen europaeum* L. No other ingredients or preservatives are added to the product.

Contents - Each pack of Nasodren contains:

- 1 vial (A) with Cyclamen lyophilized extract;
- 1 ampoule (B) with Water to dissolve the lyophilisate;
- 1 spray nozzle

Qualitative and quantitative composition:

- Vial A: Lyophilized extract of *Cyclamen europaeum* L., 50 mg;
- Ampoule B: Water, 5 ml

Intended purpose and clinical benefit

Nasodren is a nasal spray used to drain mucus and clear the nose and sinuses.

Precautions prior to using the spray

If you are taking anticoagulants and/or anticholinergics, do not use Nasodren without the consent of your doctor.

The mixed solution should be sprayed only once per day into each nostril, preferably at the same time of day, approximately two hours before bed.

Using more than once a day does not result in an improved performance and should be avoided.

The spray should be used for 7-10 days but this can be extended to 14 days, if necessary. After this, if needed, the product should only be used again after waiting for another 7-10 days.

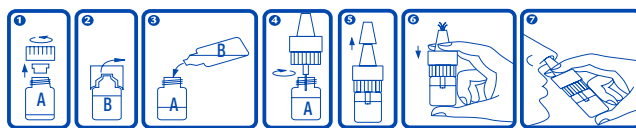
Nasodren can be used in adults and in children from 12 years of age and older. Use in children should be supervised.

Do not use Nasodren if you are allergic (hypersensitive) to Cyclamen, Primula and other Primulaceae.

Directions for use

Nasodren is for use in your nose only.

Follow the instructions and pictures below to mix the constituents of the device before spraying into the nostril.



How to prepare the solution

1. Open the vial containing the powder (A) by turning the cap anti-clockwise and removing the stopper.
2. Open the plastic bottle with the water (B) by breaking off the upper part.
3. Pour the entire liquid (B) into the vial with the powder (A).
4. Screw the spray nozzle onto the vial and shake gently until fully dissolved. Wait until no foam is visible.
5. Remove the protective cap from the spray nozzle.
6. Before first use in the nose, press the spray nozzle 2-3 times, aiming it away from the body into the air, avoiding the eyes!

Conforme	Producto: NASODREN SPRAY 50 mg - UK (LAB. HARTINGTON SLU- ESPAÑA)	CÓDIGOS
	Material: Ófset blanco 50 g	Reig Jofre Group: B11722-03
Fecha	Color: Pantone 485 Pantone 293	Hartington: L5GB
Edición: 10.12.21	Tamaño: 110x200 mm Plegado a: 110x50 mm cara	G. Maculart: 108C11722C

How to spray Nasodren

7. Hold your head vertically; do not lean forwards or backwards. Insert the spray nozzle into the right nostril. Breathe in deeply and hold your breath 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 breathe in while spraying the device.
8. Then repeat into the left nostril; as described under 7 above.
9. Clean the spray nozzle with a clean paper tissue. Replace the protective cap on the spray nozzle.

Precautions when using the product:

Contact a doctor if your symptoms do not improve after 10 days or if they worsen after 5 days.

Contact your doctor or pharmacist in case of any side effect or if something unexpected happens that is not listed on this leaflet.

Ask your pharmacist if you need more information about the product.

It is recommended that you do not drive or use machines for 2 hours after using the spray. It is better to use the spray two hours before going to bed.

IMPORTANT INFORMATION

A brief sensation of mild and transient itchiness, a burning sensation, sneezing, tearing and an increase in nasal secretions may occur a few minutes after administration. These are signs of the positive response to the product and although they may cause some discomfort for a short time, these are not unexpected responses. There may also be a pinkish coloured discharge from the nose; this should also be no cause to worry. It is recommended to remove the product from the refrigerator 2 to 3 minutes before its use to reduce intensity of the mentioned undesirable effects, which may be partly due to the cold temperature. Immediately after using, the product must be kept in the fridge again.

Do not inhale or breathe in during spraying as it can make the above mentioned effects more intense and last longer.

In case of overdose

In case of any accidental over use or repeat spraying, rinsing or irrigation of the nasal cavity through the nostrils with warm water, and throat gargling with warm water can be useful.

Other recommended precautions:

In case of any accidental over use or repeat spraying, rinsing or irrigation of the nasal cavity through the nostrils with warm water, and throat gargling with warm water can be useful.

If you forget to take Nasodren for a day or more do not worry, you can continue using this product for one or two days more. Do not spray more than once per day to try to make up for any missed days.

If you stop using Nasodren sooner than it is recommended, then the expected results might not be achieved.

Do not use Nasodren for more than 10-14 days.

Although Nasodren is not absorbed through the nose, it is recommended to ask for the advice of your doctor or pharmacist in case you are taking prescription medicines.

In case you are using any other nasal products, a gap of at least 2 hours should be left between uses of the products.

Any serious incident related to the product must be reported to the manufacturer and to the competent authority of the member state in which the user and/or patient are established.

If you are pregnant or breast-feeding:

Ask your doctor or pharmacist for advice before using Nasodren.

There is no experience regarding the use of Nasodren during pregnancy and breast-feeding. Therefore, Nasodren should not be used if you are pregnant or breast-feeding unless recommended by your doctor.

Storage:

Keep out of the reach and sight of children.

The original package must be protected from light and stored below 25°C.

Once the solution is prepared, NASODREN must be stored in a refrigerator at a temperature of 2-8°C and protected from light.

The expiry date is printed on the carton, the glass vial containing the powder and the water bottle. Do not use after the printed expiry date.

Do not use for more than 14 days after preparation of the solution.

For the disposal of the product, it must be treated as urban waste.

 Hartington Pharmaceutical, S.L.U. Avda. Ernest Lluch 32, TCM3, 6.3, 08302 Mataro, Spain

 UNIQUE DEVICE IDENTIFIER	 TEMPERATURE LIMIT	 EUROPEAN CONFORMITY MARKING	 CAUTION
 RECYCLING	 MEDICAL DEVICE	 EXPIRY DATE	 NAME AND ADDRESS OF DISTRIBUTOR
 KEEP OUT OF THE SUNLIGHT	 CATALOG NUMBER	 LOT CODE	 NAME AND ADDRESS OF MANUFACTURER

Date of Issue: 10/03/2022

L6GB



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