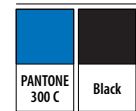


Project Name / Design IE Sudafed Decongestant Nasal Spray 15 ml PIL

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Product / Eurocode / Mat. ID Code 6263608 Job / Version No. 401995916_r1 Date 20-08-2020



REPRESENTATION: Colours represented with a diagonal line have been modified to aid PDF approval.

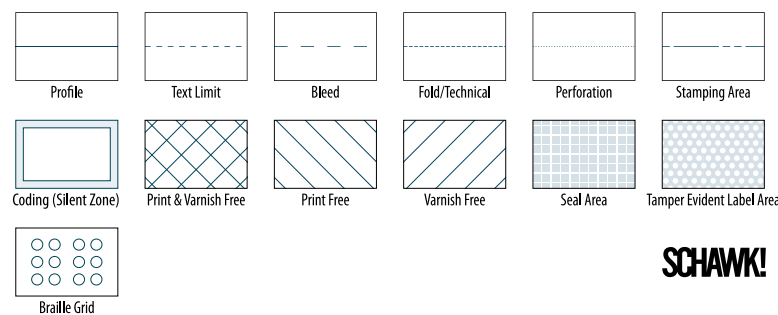
MANUFACTURING SITE

Reference NOTP002 Security Code / ICFP Leatus Pharma 100

TECHNICAL DETAILS

Component Leaflet Plant Delpharm Orléans

Dimensions 148 x 210 mm Master Dieline JJDEL_00035_V1 Date 14-03-2020



SCHAWKI

Fonts used	Arial-Regular	Smallest Text Size
	Bliss-Bold	5.0 pt
	Bliss-ExtraBold	Ave. Text Size
	Bliss-Regular	7.0 pt
	MetaPlusBook--Roman	Largest Text Size
	OCR B Std-Medium	13.0 pt
Zapf Dingbats-Regular		

SUDAFED®

0.1% w/v NASAL SPRAY SOLUTION

Xylometazoline hydrochloride

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Sudafed Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side-effects get serious, or if you notice any side-effect not listed in this leaflet, please tell your doctor or pharmacist.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet:

- What Sudafed Nasal Spray is and what it is used for
- What you need to know before you use Sudafed Nasal Spray
- How to use Sudafed Nasal Spray
- Possible side-effects
- How to store Sudafed Nasal Spray
- Contents of the pack and other information

1 What Sudafed Nasal Spray is and what it is used for

Sudafed Nasal Spray is a medicine which is used to help clear the stuffy, blocked up feeling in your nose and sinuses caused by colds and allergies such as hay fever.

The spray contains xylometazoline hydrochloride, which is a topical decongestant that relieves nasal and sinus congestion.

This product is non-drowsy.

This medicine is for use in adults and children aged 6 years and over.

2 What you need to know before you use Sudafed Nasal Spray

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not use Sudafed Nasal Spray...

- If you have ever had a hypersensitive reaction (e.g. rash, swelling of the face and throat, difficulty breathing) to xylometazoline or to any of the ingredients listed in Section 6.
- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- If you have recently had brain surgery.
- If you have had your pituitary gland removed.
- For a child under 6 years old.

If any of these apply to you, get advice from a doctor or pharmacist without taking Sudafed Nasal Spray.

Talk to your doctor or pharmacist

- If you have high blood pressure.
- If you suffer from a heart disease (e.g long QT syndrome).
- If you have diabetes.
- If you have an overactive thyroid gland.
- Before use in children aged 6 - 12 years.

If any of these bullet points apply to you now or in the past, talk to a doctor or pharmacist.

Special Warning: If this medicine is used continuously for long periods, congestion symptoms may return.

Pregnancy and Breast-feeding

- If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Other Medicines and Sudafed Nasal Spray

- Please tell your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Driving and Using Machines

- Sudafed Nasal Spray has no or negligible influence on the ability to drive and use machines.

Some of the ingredients can cause problems

- This medicine contains 0.04% w/v benzalkonium chloride. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as the product may be swallowed.

3 How to use Sudafed Nasal Spray

Follow the instructions and study the pictures below to ensure that you use Sudafed Nasal Spray correctly:

- **Step 1.** Remove the plastic cap from the nozzle.



- **Step 2.** When using the spray for the first time, press the plunger downwards while supporting the base with your thumb as shown in the diagram and release until a single spray is delivered.

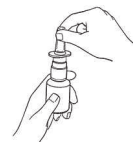


turn over ►

- **Step 3.** Hold the bottle upright and place the nozzle into one nostril. Press the plunger downwards and at the same time breathe in through your nose. Release the plunger and remove the nozzle from the nostril. Repeat this process for the other nostril.



- **Step 4.** Wipe the nozzle and replace the plastic cap after use.



Check the tables that follow to see how much medicine to use

- Do not use more than the stated dose shown in the table.

i Children under 6 years
Do not give to children under 6 years old.

i Children 6 - 12 years of age

Age	Dose
Children 6 - 12 years of age	One spray into each nostril 2 to 3 times a day

- Do not take more than 3 doses in 24 hours.
- Use only when simple measures have failed to provide adequate relief. Do not exceed the maximum daily dose: 3 doses in each nostril. Do not use with other cough and cold medicines. Do not use continuously for more than 5 days.

i Adults and Children 12 years and over

Age	Dose
Adults and children 12 years and over	One spray into each nostril 2 to 3 times a day

- Do not take more than 3 doses in 24 hours.
- Do not use continuously for more than 7 days.
- If symptoms persist talk to your doctor.

! If you use more Sudafed Nasal Spray than you should

If anyone has too much contact a doctor or your nearest Accident & Emergency Department taking this leaflet and pack with you.

! If you forget to take the medicine

If you forget to take Sudafed Nasal Spray, take the next dose when needed provided that you do not take more than 3 doses in 24 hours. Do not take a double dose.

4 Possible side-effects

Like all medicines, Sudafed Nasal Spray can cause side-effects, although not everybody gets them.

- Occasionally people may experience local irritation such as burning, soreness, dryness, stinging, itching or sneezing.
- If this medicine is used continuously for long periods, congestion symptoms may return.

Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse.

This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +35316764971; Fax: +35316762517; www.hpra.ie; medsafety@hpra.ie.

By reporting side-effects you can help provide more information on the safety of the medicine.

5 Storing this medicine

Do not store above 25°C.

Keep the container in the outer carton.

Keep the product out of the sight and reach of children.

Do not use your medicine after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6 Contents of the pack and other information

What's in this medicine

The active ingredient in Sudafed Nasal Spray is:

Xylometazoline hydrochloride 0.1% w/v.

Each metered spray (0.14 ml) delivers 140 micrograms of xylometazoline hydrochloride.

Other ingredients are: Benzalkonium chloride solution, Disodium edetate, Sodium dihydrogen phosphate dihydrate, Disodium phosphate dihydrate, Sodium chloride, Sorbitol, Liquid (Non-crystallising), Purified water.

What Sudafed Nasal Spray looks like

Sudafed Nasal Spray is a clear colourless solution in a 15 ml bottle.

Each bottle contains an average of 53 doses.

Product Authorisation holder: Johnson & Johnson (Ireland) Ltd. Airton Road, Tallaght, Dublin 24, Ireland.

Manufacturer: Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France.

This leaflet was revised in August 2020.

Sudafed is a registered trade mark.

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