

Package leaflet: Information for the patient

/.../ 0.5 mg/ml nasal spray, solution

/.../ 1 mg/ml nasal spray, solution

xylometazoline hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days

<[To be completed nationally]>

What is in this leaflet:

1. What /.../ is and what it is used for
2. What you need to know before you use /.../
3. How to use /.../
4. Possible side effects
5. How to store /.../
6. Contents of the pack and other information

1. What /.../ is and what it is used for

The active ingredient in this medicine is xylometazoline. It constricts blood vessels in the nasal mucosa, thereby reducing its swelling due to various causes, and makes breathing through the nose easier.

/.../ 0.5 mg/ml nasal spray is used for short-term relief of nasal congestion due to a cold or sinusitis in children between 2 and 10 years of age.

/.../ 1 mg/ml nasal spray is used for short-term relief of nasal congestion due to a cold or sinusitis in adults as well as in children 10 years of age and older.

2. What you need to know before you use /.../

Do not use /.../:

- if you or your child is allergic to xylometazoline or any of the other ingredients of this medicine (listed in section 6).
- if you or your child has had recent brain surgery through the nose or mouth.
- if you or your child has narrow angle glaucoma (increased pressure in the eye).
- if you or your child has a dry and inflamed nose (rhinitis sicca)
- if you or your child has a long-term nasal condition associated with thin nasal mucosa (atrophic rhinitis) or swelling of the blood vessels in the nose (vasomotor rhinitis)
- if you or your child are taking, or have taken in the last two weeks, medicines for depression known as Monoamine Oxidase Inhibitors (MAOIs).

Warnings and precautions

Talk to your doctor or pharmacist before using /.../

This is particularly important if you or your child have:

- previously had a strong reaction to sympathomimetic drugs, such as adrenaline. In this case, use of /.../ may cause insomnia, dizziness, shaking, irregular heartbeat or increased blood pressure. Ask your doctor or pharmacist if you are not sure.
- heart disease
- high blood pressure
- hyperthyroidism (overactive thyroid gland)
- diabetes mellitus
- an adrenal gland tumour (phaeochromocytoma)
- an enlarged prostate (prostatic hyperplasia)

Direct contact with the eyes should be avoided.

Swelling of the nasal mucosa (the inner lining of the nose and sinuses) may recur when long-term treatment with xylometazoline is stopped. In order to prevent this, the treatment period should be kept as short as possible.

If you think that you or your child have a bacterial infection, please consult your doctor as an infection must be treated appropriately.

This medicinal product should not be used by more than one person in order to prevent the risk of spreading infections.

Other medicines and /.../

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

It is not recommended to use this medicine together with certain antidepressants, such as:

- tricyclic- or tetracyclic antidepressants
- monoamine oxidase (MAO) inhibitors, or if they have been taken within the last two weeks

Also, it is not recommended to use this medicine:

- if you are taking medicines that may cause increased blood pressure
- if you are taking alpha- or beta-blockers (used to treat high blood pressure)

Pregnancy, breast-feeding and fertility

<0.5 mg/ml nasal spray only>:

<This strength of /.../ is intended for use in children. The information below applies to the active ingredient xylometazoline.>

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

Pregnancy and breastfeeding:

This product should not be used during pregnancy or breast-feeding, unless recommended by your doctor.

Driving and using machines

When used properly, this medicine does not affect the ability to drive or operate machines. However, if you feel drowsy or sleepy while using this medicine, you should not drive or operate machines.

3. How to use /.../

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before the first application it is necessary to spray a few times (4 times) in the air, to achieve a uniform dose. The bottle should be in a vertical position. If the product is not used for several days, at least one test spray in the air should be done in order to achieve a uniform dose.

/.../ 0.5 mg/ml nasal spray is intended for use **in children between 2 and 10 years of age.**

/.../ 1 mg/ml nasal spray is intended for use in adults as well as in children **10 years of age and older.**

Dosage

The recommended dose is one spray into each nostril no more than three times per day **for a maximum of 5 days.**

The recommended dose is 1 spray into each nostril no more than three times per day **for a maximum of 7 days.**

/.../ 0.5 mg/ml nasal spray is **not recommended for children younger than 2 years.** The safety and efficacy of /.../ 0.5 mg/ml in children younger than 2 years have not yet been established.

/.../ 1 mg/ml nasal spray is **not recommended** for children younger than 10 years.

Patients 10 years of age and older should use /.../ 1 mg/ml.

Children between 2 and 10 years of age should use /.../ 0.5 mg/ml.

Duration of treatment

The duration of the therapy should be as short as possible.

The recommended dose should not be exceeded.

You must talk to a doctor if you or your child do not feel better or if you or your child feel worse after 3 days.

The maximum treatment duration is 5 days

The maximum treatment duration is 7 days

Instructions for use

The spray should be administered to the child while they are in an upright position.

Therefore, it is best for small children to sit on your lap during the application.

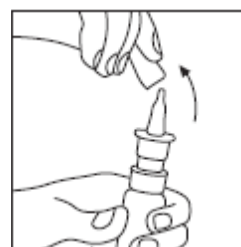
Blow your child's nose before using this medicine. Remove the cap as shown in picture 1.

Blow your nose before using this medicine.

Remove the cap as shown in picture 1.

Use this medicine whilst seated.

Picture 1



Hold the bottle between your index and middle fingers while supporting the bottom with your thumb as shown in picture 2; To spray, press the pump in a downward direction.

When using this medicine for the first time, spray into the air a few times (4 times) in order to get fine mist. It is also good to test the pump before each use by pressing it down at least once.

Picture 2



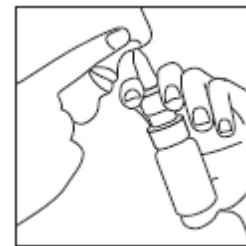
Insert the pump into the nostril, as shown in picture 3. Press the pump downwards and at the same time have the child breathe in through the nose while you gently close the other nostril with the index finger of your other hand. Release the pump and remove from the nostril. Repeat this process in the other nostril.

Wipe off the pump and replace the plastic cap after use.

Insert the pump into the nostril, as shown in picture 3. Press the pump downwards and at the same time breathe in through your nose while you gently close the other nostril with the index finger of your other hand. Release the pump and remove from the nostril. Repeat this process in the other nostril.

Wipe off the pump and replace the plastic cap after use.

Picture 3



For hygienic reasons and to avoid infections, each spray bottle should only be used by the same person.

If your child uses more /.../than he or she should

If your child (or someone else) has taken an overdose of this medicine, visit your doctor immediately. Symptoms of overdose may include sleepiness, dry mouth, sweating, fast or irregular heartbeat and increased blood pressure

If you use more /.../ than you should

If you (or someone else) have taken an overdose of this medicine, visit your doctor immediately. Symptoms of overdose may include sleepiness, dry mouth, sweating, fast or irregular heartbeat and increased blood pressure

If you forget to use /.../

If you forget to use your spray on time, use it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions are a rare side effect of /.../ that may affect up to 1 in 1,000 people.

Stop using /.../ and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

The following additional side effects have been reported:

Common side effects (may affect 1 in 10 people)

- stinging or burning in the nose and throat
- dry nasal mucosa

Rare side effects (may affect up to 1 in 1,000 people)

- nervousness
- difficulty sleeping
- headache
- dizziness
- transient visual disturbances
- feeling your own heart beat (palpitations)
- nausea (feeling sick)
- high blood pressure

Not known (frequency cannot be estimated from the available data)

- increased swelling of the nasal mucosa (the inner lining of the nose and sinuses) after treatment has stopped
- nosebleeds

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /.../

Keep out of the sight and reach of children.

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

After first opening, the nasal spray should be used within 6 months.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What /.../contains

The active substance is xylometazoline hydrochloride.

1 ml of the solution contains 0.5 mg of xylometazoline hydrochloride.

1 spray of /.../ 0.5 mg/ml (= 90 microlitres) contains 45 micrograms of xylometazoline hydrochloride.

The active substance is xylometazoline hydrochloride.

1 ml of the solution contains 1 mg of xylometazoline hydrochloride.

1 spray of /.../ 1 mg/ml (= 90 microlitres) contains 90 micrograms of xylometazoline hydrochloride.

The other ingredients are sodium chloride, potassium dihydrogen phosphate, and purified water.

What /.../ looks like and contents of the pack

Clear, colourless solution.

Multidose HDPE bottle with target delivery amount of 10 ml of solution, and with PP/PE/Steel metered dose spray pump attached to the bottle neck with a plastic cover

The number of sprays per bottle is not less than 100.

Marketing Authorisation Holder

Actavis Group PTC ehf.

Reykjavíkurvegi 76-78

220 Hafnarfjörður

Iceland

Manufacturer

Jadran-Galenski laboratorij d.d.

Pulac 4A

51000 Rijeka

Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	SENZIOLA
Bulgaria	SENZIOLA
Finland	SENZIOLA
Ireland	SENZIOLA 0.5 mg/ml: 1 mg/ml Nasal spray, solution
Iceland	SENZIOLA
Norway	SENZIOLA
Romania	PINEX NAZAL 0,5 mg/ml picături nazale, soluție PINEX NAZAL 1 mg/ml picături nazale, soluție
Sweden	SENZIOLA

This leaflet was last revised in {MM/YYYY}.

