

Package leaflet: Information for the user

Zymelin Comp 0.5 mg/ml + 0.6 mg/ml nasal spray, solution

Xylometazoline hydrochloride/ipratropium bromide

Blue box Prescription status:

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

Blue box OTC Status:

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.

What is in this leaflet

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

1. What Zymelin Comp is and what it is used for

Zymelin Comp is used for the treatment of nasal congestion with running nose (rhinorrhea).

Zymelin Comp is a combination medicinal product consisting of two different substances (Xylometazoline hydrochloride and ipratropium bromide). One reduces the nasal secretion, the other has a decongesting effect.

2. What you need to know before you use Zymelin Comp

Do not use Zymelin Comp

- If you are allergic to xylometazoline hydrochloride or ipratropium bromide or any of the other ingredients of this medicine (listed in section 6).
- If you are hypersensitive to atropine or similar substances, e.g. hyoscyamine and scopolamine.
- In children and adolescents below 18 years of age, as sufficient documentation in children is not available.
-
- If you have had the hypophysis removed by operation through the nose.
- After operations through the nose or mouth, where the membrane of the brain may have been damaged.
- If you suffer from glaucoma.
- If you suffer from inflammatory nasal dryness (rhinitis sicca).

Warnings and precautions

Talk to your doctor or pharmacist before using Zymelin Comp.

In the following circumstances you should always contact your doctor before you use Zymelin Comp:

- If you are sensitive to certain adrenergic substances (e.g. adrenaline, ephedrine), side effects may occur in form of sleeplessness, dizziness, tremor, rapid heart beat or elevated blood pressure.
- If you suffer from cardiovascular disease (e.g. long QT syndrome), elevated blood pressure, diabetes or increased release of thyroid gland hormone (hyperthyroidism).
- In case of enlargement of the prostate, narrow passage through the ureter, narrow-angle glaucoma.
- Avoid spraying Zymelin Comp in or around the eye. If Zymelin Comp gets in contact with the eyes, you may experience temporary blurred vision, irritation of the eye, pain or red eye. Worsening of narrow-angle glaucoma may also occur. Rinse the eyes with cold water and contact your doctor if your eyes are sore or your vision is blurred.
- If you get nosebleeds easily.
- If you suffer from obstruction of the intestine or cystic fibrosis.
- If you suffer from benign tumour producing high amounts of adrenaline and noradrenaline.

Other medicines and Zymelin Comp

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

Zymelin Comp may influence or be influenced by:

- Certain medicines used for treatment of depression (MAO inhibitors and tri-cyclic and tetra-cyclic antidepressants):
Zymelin Comp plus MAO inhibitors may substantially increase blood pressure during concomitant use or two weeks after suspension of the therapy with Zymelin Comp.
Zymelin Comp plus tri-cyclic and tetra-cyclic antidepressants may increase the effect of xylometazoline hydrochloride (one of the ingredients of the medicinal product) during concomitant use or two weeks after suspension of the therapy with Zymelin Comp.
- Certain medicines used for reducing the intestinal motility and transport sickness (medicines containing anticholinergic substances):
Zymelin Comp plus certain medicines used for reducing the intestinal motility and transport sickness (medicines containing anticholinergic substances) may increase the effect of these medicines used for reducing the intestinal motility and transport sickness.

If you use any above mentioned medicines, consult a doctor before using Zymelin Comp.

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.

Zymelin Comp should not be used during pregnancy unless your doctor recommends it.

Zymelin Comp should not be used during breast-feeding unless your doctor recommends it.

Driving and using machines

Zymelin Comp does not affect your ability to drive and use machines.

3. How to use Zymelin Comp

Adults: One puff in each nostril as needed, maximum 3 times daily for maximum 7 days. At least 6 hours should elapse between two doses. You should not use Zymelin Comp longer than 7 days as chronic treatment with nasal decongestants such as xylometazoline hydrochloride (one of the active substances in Zymelin Comp) may cause swelling of the nasal mucosa (so called rhinitis medicamentosa).

It is recommended to stop the treatment with Zymelin Comp, when the symptoms have diminished, even before the maximum duration of treatment of 7 days, in order to minimise the risk of side effects.

Zymelin Comp should not be given to children under the age of 18.

There is only limited experience of use in patients above 70 years of age.

If you experience a too strong or too weak effect of Zymelin Comp, consult your doctor or pharmacist.

Use Zymelin Comp in the following way:

Always blow your nose before using the nasal spray.

Remove the dust cap.

Before using the pump for the first time or when the product has not been used in 9 days: the spray should be pumped a number of times until a uniform spray is obtained.

Hold the bottle upright.

Bend your head slightly forward.

Close one nostril by placing your finger against the side of your nose and insert the spray tip into the other nostril. Press the pump quickly while inhaling through the nose.

Repeat this procedure in the other nostril.

The effect occurs within 5-15 minutes.

There will always be a residual volume left in the bottle. This is compensated for by filling, and usage volume will always be at least 10 ml.

Ask your doctor or pharmacist for advice if you are unsure.

If you use more Zymelin Comp than you should

If you have taken more medicine than you should, contact your doctor, hospital or emergency room for assessment of the risk and for advice. This is particularly important for children who are more likely to develop adverse events than adults. Symptoms of overdose are severe dizziness, sweating, severely lowered body temperature, headache, slow heart beat, rapid heart beat, impaired breathing, coma, hypertension which may be followed by hypotension.

Other symptoms may be dry mouth, difficulties focusing with the eye and hallucinations.

4. Possible side effects

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

The most common side effects are nose bleeding and nasal dryness. Many of the side effects reported are also symptoms of common cold.

Very common (may affect more than 1 in 10 people):

Nose bleeding, nasal dryness.

Common (may affect up to 1 in 10 people):

Nasal discomfort, congestion of the nose, dry and irritated throat, pain in the nose, dry mouth, altered taste sensation, headache.

Uncommon (may affect up to 1 in 100 people):

Nasal ulcer, sneezing, pain in the throat, cough, hoarseness, stomach upsets, feeling sick, altered smell sensation, dizziness, shakiness, discomfort, tiredness, sleeplessness, irritation of the eyes, dry eyes, increased pulse rate, irregular pulse.

Rare (may affect up to 1 in 1000 people):

Runny nose.

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

Discomfort around the nose, difficulties in swallowing, discomfort in the chest, thirst, severe allergic reactions, difficulties focusing with the eye, worsening of glaucoma, pain in the eye, visual disturbances, itching, difficulties emptying the bladder.

In order to minimise the risk of side effects such as nose bleeding and other effects on the nose, it is recommended to stop the treatment with Zymelin Comp when the symptoms of nasal congestion and runny nose have diminished; even before the recommended maximum duration of treatment of 7 days has passed.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 any side effects directly (see details listed below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally].

5. How to store Zymelin Comp

Keep this medicine out of the sight and reach of children.

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

Do not freeze.

Empty medicinal package is disposed of in accordance with local regulations.

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 to protect the environment.

6. Contents of the pack and other information

What Zymelin Comp contains

The active substances are xylometazoline hydrochloride and ipratropium bromide.

1 ml contains 0.5 mg xylometazoline hydrochloride and 0.6 mg ipratropium bromide.

1 puff contains 70 micrograms xylometazoline hydrochloride and 84 micrograms ipratropium bromide.

The other ingredients are disodium edetate, glycerol (85%), purified water, as well as sodium hydroxide and hydrochloric acid (to adjust pH).

What Zymelin Comp looks like and contents of the pack

Zymelin Comp is a clear solution.

The bottle contains approx. 70 puffs.

Zymelin Comp is available as a 10 ml nasal spray with pump.

Marketing Authorisation Holder

[To be completed nationally].

Manufacturer

Takeda GmbH
Robert-Bosch-Str. 8
78224 Singen
Germany

Curida AS
Solbærvegen 5
NO-2409 Elverum
Norway

This leaflet was last revised in 2026-05-18.