PACKAGE LEAFLET: INFORMATION FOR THE USER

Otrivin

Dual Relief

Nasal spray solution Each 1ml contains:
0.5 mg Xylometazoline hydrochloride and 0.6 mg Ipratropium bromide
For Nasal Administration ONLY.

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.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

In this leaflet

WHAT IS OTRIVIN DUAL RELIEF AND WHAT IS IT USED FOR?

Otrivin Dual Relief is a combination medicinal product consisting of two different substances. One of the active ingredients reduces the nasal secretion; the other has a decongestant effect. Otrivin Dual Relief is used for the treatment of nasal congestion with runny nose (rhinorrhea) in connection with common colds.

WHAT YOU NEED TO KNOW BEFORE YOU USE OTRIVIN DUAL RELIEF?

a. Do not use Otrivin Dual Relief
- In children below 18 years of age, as sufficient documentation in children is not available.
- If you are allergic (hypersensitive) to xylometazoline hydrochloride and ipratropium bromide or any of the other excipients of Otrivin Dual Relief.
- If you are hypersensitive to atropine or similar substances, e.g. hyoscyamine and scopolamine.
- After surgical operations where dura mater have been penetrated e.g (transphenoidal hypophysectomy or other transnasal operations).
- If you suffer from Glaucoma.
- If you have a very dry nose (inflammatory nasal dryness, rhinitis sicca).

b. Warnings and precautions:
Talk to your doctor or pharmacist before using Otrivin Dual Relief.
Otrivin Dual Relief must be administered with caution to patients with:
- Hypertension, cardiovascular diseases
- Hyperthyroidism, diabetes mellitus
- Hypertrophy of the prostate, stenosis of the bladder bar
- Pheochromocytoma

Caution is recommended in patients predisposed to:
- Angle closure glaucoma
- Epistaxis (e.g. elderly)
- Paralytic ileus
- Cystic fibrosis

Immediate hypersensitivity including urticaria, angioedema, rash, bronchospasm, pharyngeal oedema and anaphylaxis may occur. These symptoms may appear individually or all combined as a severe allergic reaction. If this occurs, immediately STOP using Otrivin Dual Relief.
The medicinal product must be used with caution in patients who are sensitive to adrenergic substances, which may give symptoms such as sleeping disturbances, dizziness, tremor, cardiac arrythmias or elevated blood pressure.
The treatment duration should not exceed 7 days, as chronic treatment with xylometazoline hydrochloride may cause swelling of the nasal mucosa and hypersecretion because of increased sensibility in the cells, "rebound effect" (rhinitis medicamentosa).
Patients should be instructed to avoid spraying Otrivin Dual Relief in or around the eye. If Otrivin Dual Relief gets in contact with the eyes, the following may occur: temporary blurred vision, irritation, pain, red eyes. Aggravation of angle closure glaucoma may also develop.
The patient should be instructed to rinse their eyes with cold water if Otrivin Dual Relief gets in direct contact with the eyes and to contact a doctor if they experience pain in the eyes or blurred vision.

USING OTHER MEDICINES AND OTRIVIN DUAL RELIEF

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
It is particularly important you mention the following:
- Monoamine Oxidase Inhibitors (MAO inhibitors, used for treatment of depression):

Concomitant use or use within the last 2 weeks of sympathomimetic preparations may induce severely elevated blood pressure and is therefore not recommended. Sympathomimetic preparations release catecholamine, which results in a major release of noradrenaline which in turn has a vasoconstrictive effect resulting in elevated blood pressure. In critical cases of elevated blood pressure, treatment with Otrivin Dual Relief should be discontinued and elevated blood pressure treated.
- Tri and Tetra-cyclic antidepressants: Concomitant use or use within the last 2 weeks of tri-cyclic anti depressants and sympathomimetic preparations may result in an increased sympathomimetic effect of xylometazoline and is therefore not recommended.
- Concomitant administration of antichlolinergic drugs may enhance the anticholinergic effect (medicines used for travel sickness and gut disorders particularly those for abnormal motility.

If you use any above-mentioned medicines, consult a doctor before using Otrivin Dual Relief.
The above interactions have been studied individually for both of the active substances of Otrivin Dual Relief, not in combination.
No formal interaction studies with other substances have been performed.

c. Pregnancy, breast-feeding and fertility
Pregnancy:
There are no adequate data from the use of Otrivin Dual Relief in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonal fetal development, parturition and postnatal development. The potential risk for humans is unknown. Otrivin Dual Relief should not be used in pregnancy unless clearly necessary.
Breast-feeding
It is not known whether ipratropium bromide and xylometazoline hydrochloride are excreted in the mother's milk. The systemic exposure to ipratropium bromide and xylometazoline hydrochloride is low. Effects on the breast-fed infant are therefore unlikely. The mother's need for treatment with Otrivin Dual Relief and the advantages of breast-feeding must be weighed against the potential risks to the infant.
** If you are pregnant or breast feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.*
Fertility
There are no adequate data for the effects of Otrivin Dual Relief on fertility. Animal studies with ipratropium bromide did not show adverse effects on fertility. No animal studies are available for the effect of xylometazoline hydrochloride on fertility. The systemic exposure to ipratropium bromide and xylometazoline hydrochloride is low. Effects on fertility are therefore unlikely.

d. Driving and using machines
Visual disturbances (including blurred vision and mydriasis), dizziness and fatigue have been reported with Otrivin Dual Relief. Patients should be advised that if affected they should not drive, operate machinery or take part in activities where these symptoms may put themselves or others at risk.

HOW TO USE OTRIVIN DUAL RELIEF?

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.
The recommended dose is:
Adults
One puff in each nostril as needed, up to 3 times daily for maximum 7 days. Leave at least 6 hours between two doses. Do not exceed 3 applications daily into each nostril.
You should not use Otrivin Dual Relief longer than 7 days as chronic treatment with nasal decongestants such as Xylometazoline (one of the active substances in Otrivin Dual Relief) may cause swelling of the nasal mucosa (so called rhinitis medicamentosa).
It is recommended to stop the treatment with Otrivin Dual Relief, when the symptoms have diminished, even before the maximum duration of treatment of 7 days, in order to minimize the risk of adverse reactions.
Paediatric Population
Otrivin Dual Relief is not recommended for use in children and adolescents below 18 years of age due to lack of sufficient documentation.
Elderly
There is only limited experience of use in patients above 70 years of age.
If you think the effect of Otrivin Dual Relief is too strong or too weak, consult your doctor or pharmacist.
Instructions for Use

- Always blow your nose before using the nasal spray.
- Remove the dust cap.
- Do not cut the nozzle. The metered dose spray is ready to prime before use.
- Before the first application, prime the pump by actuating 4 times.
- Once primed, the pump will normally remain charged throughout regular daily treatment periods. Should the spray not be ejected during the full actuation stroke, or if the product has not been used for longer than 6 days, the pump will need to be reprimed with 4 actuations as initially performed.
- 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 lip 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.
Avoid spraying Otrivin Dual Relief in or around the eyes. Ask your doctor or pharmacist for advice if you are unsure.

OVERDOSE

Overdose of oral or excessive administration of topical xylometazoline hydrochloride may cause severe dizziness, perspiration, severely lowered body temperature, headache, bradycardia, hypertension, respiratory depression, coma and convulsions. Hypertension may be followed by hypotension. Small children are more sensitive to toxicity than adults.
The absorption being very small after nasal or oral administration, an acute overdose after intranasal ipratropium bromide is unlikely, but if an overdose occurs the symptoms are dry mouth, accommodation difficulties and tachycardia. The treatment is symptomatic.
A considerable overdose may cause anticholinergic central nervous system (CNS) symptoms such as hallucinations, which must be treated with cholinesterase inhibitors.
Appropriate supportive measures should be initiated in all individuals suspected of an overdose, and urgent symptomatic treatment under medical supervision is indicated when warranted. This would include observation of the individual for at least 6 hours. In the event of a severe overdose with cardiac arrest, resuscitation should be continued for at least 1 hour.

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
STOP using Otrivin Dual Relief and seek medical help immediately if you have any of the following:
- Palpitations and increased heart rate (affects less than 1 in 100 people)
- Sign of an allergic reaction as difficulty breathing, speaking or swallowing; swelling of the face, lips, tongue or throat; severe itching of the skin, with a red rash or raised bumps (frequency not known cannot be estimated from available data).
- Disturbances of vision (including blurred vision, worsening of glaucoma or increased pressure in the eye), rainbow-colored circles/haloes around bright lights and/or severe eye pain (frequency not known cannot be estimated from available data).

The most commonly reported adverse reactions are nose bleeding occuring in 14.8% and nasal dryness occurring in 11.3 % of patients many of the side effects reported are also symptoms of common cold.
Very common side effects (may affect more than 1 in 10 people):
- Nose bleeding, nasal dryness

Common side effects (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, nausea
- Altered smell sensation, dizziness, shakiness
- Discomfort, tiredness
- Sleeplessness
- Irritation of the eyes, dry eyes

Rare (may affect up to 1 in 1,000 people):
- Runny nose

Frequency not known (cannot be estimated from available data):
- Rash, hives
- Discomfort around the nose
- Discomfort in the chest, thirst
- Sudden spam of throat muscle
- Irregular pulse
- Difficulties focusing with the eyes, dilation of the pupils
- Itching
- Difficulties emptying the bladder
- Atrial fibrillation
- Paranasal sinus discomfort
- Pharyngeal oedema

In order to minimize the risk of side effects such as nose bleeding and other effects on the nose, it is recommended that you stop treatment with Otrivin Dual Relief when your symptoms improve even if this is sooner than 7 days.
* 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.

HOW TO STORE OTRIVIN DUAL RELIEF?

Keep out of the reach and sight of children.
Do not use Otrivin Dual Relief after the expiry data which is stated on the label. The expiry date refers to the last day of that month. After the first opening, the nasal spray can be used until the end of the shelf life.
Do not freeze.
Don't Store above 30 °C
Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

FURTHER INFORMATION

What Otrivin Dual Relief contains:
The active substances are xylometazoline hydrochloride and ipratropium bromide.
Each 1ml contains 0.5mg xylometazoline hydrochloride and 0.6mg ipratropium bromide.
1 puff contains:
70 micrograms xylometazoline hydrochloride and 84 micrograms ipratropium bromide.
Other excipients: disodium edetate, glycerol (85%), purified water, sodium hydroxide and hydrochloric acid (for pH adjustment).

What Otrivin Dual Relief looks like and contents of the pack
Otrivin Dual Relief is a clear colourless solution.
The 10 ml pack contains approx 70 puffs.
Otrivin Dual Relief is available as a 10 ml nasal spray with metered-dose spray pump.
Trade marks owned or licensed by GSK

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Manufactured by: GSK Consumer Healthcare SARL Nyon, Switzerland.

MAH: GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Middlesex, UK

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THIS IS A MEDICAMENT
a. Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
b. Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
c. The doctor and the pharmacist are experts in medicine, its benefits and risks.
d. Do not by yourself interrupt the period of treatment prescribed.
e. Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach and sight of children
Council of Arab Health Ministers
Union of Arab Pharmacists

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