Summary of product characteristics

Xylo-COMOD®

1 NAME OF THE MEDICINAL PRODUCT

Xylo-COMOD® 1 mg/ml
Nasal spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Xylometazoline hydrochloride
1 spray of Xylo-COMOD® of 0.14 ml contains 0.14 mg of xylometazoline hydrochloride.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution

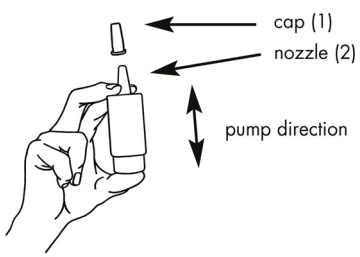
4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For short term treatment in case of congestion of the nasal mucosa.
Xylo-COMOD® is intended for use by adults and school children.

4.2 Posology and method of administration

One spray of Xylo-COMOD® is applied into each nostril two or three times a day. The single dose specified for Xylo-COMOD® must not be applied more than 3 times per day.
Xylo-COMOD® should not be used longer than 7 days. The recommended dose should not be exceeded.
Xylo-COMOD® is suitable for adults and school children over 6 years. It must not be used in children under the age of 6 years.



Remove the protective cap (1) before first use.
Hold the spray flask as shown and press the pump mechanism until a fine spray is emitted. Insert the nose adapter ("nozzle") (2) into each nostril and apply one spray into each nostril. In order to avoid solidification of the solution within the pump mechanism, the protective cover should be attached again after each usage.

4.3 Contraindications

This medicinal product should not be used in case of:
- hypersensitivity to xylometazoline hydrochloride or to any of the excipients of Xylo-COMOD®,
- dry inflammation of the nasal mucosa (rhinitis sicca),
- after pinealectomy through the nose or other surgical interventions laying bare the dura mater,
- babys and children under the age of 6 years.

4.4 Special warnings and precautions for use

Babies and young infants should be treated with special care. In single cases, severe side effects (particularly apnoea) have been reported after administration of the recommended dose in this age group. Overdose must unconditionally be avoided.

This medicament should only be used after a careful consideration of benefit and risk in case of:
- patients who are treated with mono-amino oxidase inhibitors (MAO inhibitors) or other drugs which potentially increase the blood pressure
- elevated intraocular pressure, particularly narrow-angle glaucoma
- severe cardiovascular diseases (e.g. coronary heart disease, hypertension)
- phaeochromocytoma
- metabolic disorders (e.g. hyperthyroidism and diabetes)
- porphyria
- prostata enlargement

Due to permanent use and overdosing of decongestive nasal preparations agents their effect can be diminished. The abuse of decongestive nasal preparations can result in:
- a reactive hyperaemia of the nasal mucosa (rhinitis medicamentosa)
- atrophy of the nasal mucosa.

In order to enable breathing through the nose at least in parts, the application of the sympathomimetic should be discontinued first in one nostril and, after the complaints have diminished, also on the other side.

4.5 Interaction with other medicinal products and other forms of interaction

The concomittant use of xylometazoline and
- tricyclic antidepressants,
- mono-amino oxidase inhibitors of the tranylcypromine type,
- hypertensive drugs

can lead to an increased blood pressure. The concomittant use should therefore be avoided.

4.6 Pregnancy and lactation

Pregnancy: Data, which were gained with a limited number of pregnant women who were exposed to xylometazoline in the first trimenon reveal no evidence of harmful effects of the substance on the pregnancy of the health of the foetus/newborn. For the time being, no other relevant epidemiologic data are available. Animal trials showed toxicity to reproduction after application of doses exceeding the therapeutic dosage regimen (see 5.3).
Xylo-COMOD® should only be used during pregnancy after a careful consideration of benefit and risk. The recommended dose must not be exceeded during pregnancy as overdosing can impair the blood supply of the unborn child.
Breast-feeding: It is not known if xylometazoline passes into breast milk. The use of Xylo-COMOD® should only be used during breast feeding after a careful consideration of benefit and risk. The recommended dose must no be exceeded during pregnancy as overdosing can reduce the production of breast milk.

4.7 Effects on ability to drive and use machines

If used as recommended, no adverse effects are to be expected.

4.8 Undesirable effects

The evaluation of side effects is based on the following frequency rates:

very common:	more than 1 in 10 patients
common:	less than 1 in 10, but more than 1 of 100 patients
uncommon:	less than 1 in 100, but more than 1 in 1,000 patients
rare:	less than 1 in 1,000, but more than 1 in 10,000 patients
very rare:	1 case or less in 10,000 patients
not known:	frequency not assessable on the basis of available data

Nervous system: Very rare: restlessness, insomnia, tiredness (sleepiness, sedation), headache, hallucinations (particularly in children)
Cardiovascular system: Rare: palpitations, tachycardia, increase in blood pressure
Very rare: cardiac arrhythmia
Respiratory tracts: Common: burning or dryness of the nasal mucosa, sneezing
Uncommon: experience of an increased swelling of the mucosa after subsiding of the effect, nose bleeding
Muscular and skeletal system: Very rare: convulsions (particularly in children)
Immune system: Uncommon: hypersensitivity reactions (angioedema, exanthema, itching)

4.9 Overdose

The clinical picture of intoxication with imidazole derivatives can be confusing: periods of stimulation can alternate with periods of depression of the central nervous system and of the cardiovascular system.
Signs of a stimulation of the central nervous system are anxiety, excitement, hallucinations and convulsions.
Signs of a depression of the central nervous system are: reduced blood heat, lethargy, sleepiness and coma.
The following other symptoms can occur: miosis, mydriasis, sweating, fever, paleness, cyanosis, sickness, tachycardia, bradycardia, cardiac arrhythmia, cardiac arrest, hypertonia, shock-like hypotonia, pulmonary oedema, respiratory disorders and apnoea.
Especially in children, overdose can cause dominating central effects with convulsions and coma, bradycardia, apnoea as well as hypertension, which can alternate with hypotension.
Therapeutic measures in case of overdose:
In case of severe overdose, immediate intensive care in a hospital is indicated. The administration of medical coal (absorbent), of sodium sulphate (laxative) or a gastric lavage (if high amounts were taken) should be done without delay as xylometazoline can be quickly absorbed. A non-selective alpha-blocking agent can be given in order to reduce the blood pressure.
Vasopression is contraindicated. If necessary, antipyretic / anticonvulsive therapy or artificial respiration with oxygen is indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Nasal preparation,
Alpha-sympathomimetic agent
ATC code: R01AA07

Xylometazoline, an imidazoline derivative, is an alpha-andrenergic sympathomimetic agent. It has vasoconstrictive properties and thus effects decongestion of the nasal mucosa. The effect usually commences within 5 - 10 minutes; the decongestion of the mucosa makes breathing through the nose easier and improves secretion.

5.2 Pharmacokinetic properties

The effect of Xylo-COMOD® commences within a few minutes and lasts for several hours, 6 - 8 hours on average. Occasionally, the amount absorbed after intranasal application can be sufficient to cause systemic effects, e.g. concerning the central nervous system and the cardiovascular system.
Data obtained with pharmacokinetic investigations in humans are not available.

5.3 Preclinical safety data

Investigation of the toxicity after repeated nasal application of oxymetazoline in dogs did not reveal any safety risks for humans. An in-vitro examination in bacteria regarding the mutagenicity yielded negative results. No data are available concerning the carcinogenic potential. No teratogenic effects were seen in rates and rabbits. Doses exceeding the therapeutic dosage regimen were lethal for the embryo or led to a reduced growth of the foetuses. In rats, the production of milk was inhibited. There are no indices of fertility disorders.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate (Ph.Eur.); sodium dihydrogen phosphate dihydrate; disodium phosphate dodecahydrate (Ph.Eur.); sorbitol (Ph.Eur.); purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

The shelf life is 3 years.
This medicinal product should not be used after the expiry date.
Shelf life after opening of the container: Do not use Xylo-COMOD® longer than 8 weeks after first opening.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Xylo-COMOD® is a clear, colourless solution, filled in a multiple dose container with gas-free pump-system. A pre-package contains one bottle with 15 ml of solution.

6.6 Special precautions for disposal <and other handling>

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

3004492.00.00

9 DATE OF RENEWAL OF AUTHORISATION

10 October 2003

10 DATE OF REVISION OF THE TEXT

November 2009

11 LEGAL STATUS

Available in pharmacies only.