

# VAPICIL

## Microdoser Nasal Spray

**Composition:** Each 1 ml Vapicil contains:  
 Dimetindene maleate 0.25 mg  
 Phenylephrine HCl 2.5 mg

**Preservative:** Benzalkonium chloride 0.1 mg

**Excipients:** Sodium phosphate dibasic, Sodium phosphate monobasic, Sodium chloride, Tween 80, Highly Purified water S. Q.

**Properties:** Vapicil clear the nose and up discharges while respecting the physiology of the vibratile cilia and the nasal mucosa. Phenylephrine is a sympathomimetic amine. Due to its selective action on  $\alpha_1$  adrenergic receptors of the cavernous venous tissue of the nasal mucosa, phenylephrine is a gentle vasoconstrictor which allows rapid and durable decongestion of the nasal fossae. Dimetindene maleate, a histamine antagonist acting on the  $H_1$  receptors is an antiallergic product which is effective at low doses and is well tolerated.

**Pharmacokinetics:** The product is intended for local application, and its activity is not correlated with the blood concentration of its active ingredients.

**Indications:** Common colds, acute and chronic rhinitis, seasonal (hay fever) and non-seasonal allergic rhinitis, acute and chronic sinusitis, pre and postoperative care, adjuvant in cases of acute otitis media.

### Dosage/Directions for use:

Children over 6 years and adults: 1 to 2 sprays in each nostril, 3 to 4 times a day (one spray provides a mean of 140 mg).

### Proceed as follows:-

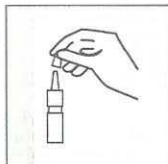
- 1- Blow the nose carefully.
- 2- Remove the protective cap.

Before using for the very first time, operate the microdoser several times to prime it, it is then ready for subsequent use.

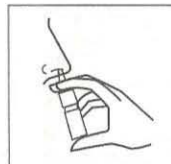
3- Insert the microdoser into one nostril and press it while breathing in through the nose at the same time.

Repeat this operation in the other nostril.

4- Replace the protective cap.



Remove the protective cap.



Hold the microdoser exactly as shown in the diagram. Press and breathe in at the same time.

### Restrictions on use:

**Contraindications:** Hypersensitivity to any of the constituents. Like other vasoconstrictors, phenylephrine is contraindicated in cases of simple atrophic rhinitis, atrophic rhinitis with foetid discharges (ozena) and in patients taking MAO inhibitors or who have received them during the previous two weeks.

**Precautions:** Vapicil must not be used continuously for more than 2 weeks if the symptoms persist, consult a doctor. Its prolonged or excessive use may lead to tachyphylaxis, rebound congestion or drug-induced rhinitis. As with all topical vasoconstrictors, do not exceed the prescribed doses, particularly in babies, young children and elderly persons; excessive use may lead to the appearance of systemic defects, especially in young children and the elderly.

Excessive doses must also be avoided in the case of hypertension or other cardiovascular diseases, hyperthyroidism or narrow angle glaucoma.

Like all products containing a topical vasoconstrictor, Vapicil must be used cautiously in the case of excessive reactions to sympathomimetics, expressed by insomnia or dizziness.

**Pregnancy, breast feeding:** Studies are not available in pregnant women, nursing mothers or animals.

Because of this, Vapicil should be administered only if the potential benefit justifies the potential risk to the foetus.

**Undesirable side effects:** A local and transient sensation of smarting or dryness of the nose may be observed in rare cases.

**Interactions:** Like all vasoconstrictors, phenylephrine is contraindicated in patients treated with MAO inhibitors, or who have received them in the previous two weeks.

Caution is required when taking tricyclic antidepressants or antihypertensives such as beta-blockers

**Overdosage:** The accidental ingestion of Vapicil by small children has never produced any serious side effects. The majority of cases were asymptomatic but tiredness, stomachache, mild tachycardia, increased blood pressure, excitation, insomnia and pallor have sometimes been reported.

There is no specific antidote in the case of overdosage with a combination of an antihistamine and a vasoconstrictor.

Gastric lavage is not required in principle, even after the ingestion of a full bottle (15 ml). In young children, the administration of activated charcoal and possibly a laxative may be indicated.

For older children (over 6 years) and adults, the administration of a large quantity of fluid is usually sufficient.

**Storage:** Protect from light and heat. Do not store above 30°C. The medicine may be used only up to the date (EXP) shown on the package.

**Presentation:** Microdoser of 15 ml.