1. NAME OF THE MEDICINAL PRODUCT

Vibrocil□

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Phenylephrine base and Dimetindene (INN).
Chemical designation:
Phenylephrine: (S)-1-(3-Hydroxyphenyl)-2-methylaminoethanol
Dimetindene: 2-(2-dimethylaminoethyl)-3-[2-(2-pyridyl)ethyl]-(1H)-indene maleate.

Vibrocil® Nasal Drops, Spray:
Phenylephrine 0.25% w/v, dimetindene 0.025% w/v

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Vibrocil® Nasal Drops, Spray

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Symptomatic treatment of common cold, nasal congestion, acute and chronic rhinitis, seasonal (hay fever) and non-seasonal allergic rhinitis, acute and chronic sinusitis, vasomotor rhinitis. Adjunctive therapy in case of acute otitis media.

Pre- and post-operative care (nasal surgery).

4.2. Posology and method of administration

Nasal drops:
Infants up to 1 year of age (with medical advice):
1 drop into each nostril 3 to 4 times a day
Children 1 to 6 years of age:
1 to 2 drops into each nostril 3 to 4 times a day
Adults and children over 6 years of age:
3 to 4 drops into each nostril 3 to 4 times a day

APPROVED BY SCDMTE JSC
Expert / Date 09.10.18
Applicant / Date 15.10.2018

Nasal Spray *Adults and children over 6 years of age*:
1 to 2 sprays in each nostril 3 to 4 times a day.

4.3. Contra-indications

Known hypersensitivity to any of the ingredients.

Like other vasoconstrictors, phenylephrine is contra-indicated in case of atrophic rhinitis and in patients who are receiving monoamine oxidase inhibitors or who have received them in the previous 14 days.

4.4. Special warnings and precautions for use

Vibrocil® should not be used continuously for more than 1 week: prolonged or excessive use may induce tachyphylaxis and rebound congestion (rhinitis medicamentosa).
As with other topical vasoconstrictors, do not exceed the recommended dosage; excessive use may lead, especially in small children and in the elderly, to systemic effects of vasoconstrictors.
Caution is recommended in patients with cardiovascular disease, hypertension, thyroid disease or closed angle glaucoma.
Vibrocil drops should not be used without medical advice in infants below 1 year of age.

4.5. Interactions with other medicinal products and other forms of interaction

Phenylephrine is contra-indicated in patients taking monoamine oxidase inhibitors or who have received them in the previous 14 days.

Vasoconstrictors should be used with caution in patients receiving tricyclic antidepressants and antihypertensives such as □-adrenergic blocking agents.

4.6. Pregnancy and lactation

In view of the potential systemic vasoconstrictor effect of phenylephrine, it is advisable to take the precaution of not using Vibrocil® during pregnancy and breast-feeding.

APPROVED BY SCDMTE JSC
Expert / Date 09.10.18
Applicant / Date
15.10.2018

4.7. Effects on ability to drive and use machines

None

4.8. Undesirable effects

Vibrocil® is usually very well tolerated.

Rare cases of mild and transient local reactions (burning sensation or dryness of the nasal mucosa) may be observed.

4.9. Overdose

Serious effects of the accidental ingestion of Vibrocil® by small children have never been reported. The majority of cases were symptom-free but, rarely, tiredness, stomach ache, slight tachycardia, increased blood pressure, excitation, sleeplessness and pallor have been reported.

Gastric lavage is not usually required even after swallowing a full bottle of drops. The use of charcoal and possibly a laxative may be indicated in young children. For older children and adults, the administration of large quantities of fluid is usually sufficient.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group

Sympathomimetics, combination excl. corticosteroids. ATC: R01AB

Mechanism of action and pharmacodynamic effects

The active ingredients of Vibrocil® clear the nasal passages and dry up secretions. Vibrocil® does not interfere with the activity of the nasal cilia.

Phenylephrine is a sympathomimetic amine. Used as a nasal decongestant, it is a mild vasoconstrictor acting selectively on α_1-adrenergic receptors in erectile venous capacitance vessels of the nasal mucosa. It thus produces a rapid and lasting decongestion of the nasal fossae.

5.2. Pharmacokinetic properties

Vibrocil® is intended for topical application and its activity is therefore not correlated with plasma levels of the active ingredients.

If accidentally orally absorbed, phenylephrine has reduced bioavailability (approximately 38%) because of first pass metabolism in the gut and liver. The apparent half-life of elimination is about 2.5 hours.

Systemic availability of dimetindene in oral solution is around 70%. The apparent half-life of elimination is about 6 hours.

5.3 Preclinical safety data

Animal studies with dimetindene have shown neither teratogenic potential nor other adverse effects on the embryo and/or foetus relevant to the safety assessment of the product.

APPROVED BY SCDMTE JSC
Expert / Date 09.10.18
Applicant / Date 15.10.2018

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Vibrocil® Drops, Spray:

Benzalkonium chloride (preservative), disodium phosphate, citric acid monohydrate, sorbitol, deterpenated essence of lavender, purified water.

Four drops of Vibrocil® Nasal Drops contain up to 5 micrograms Sorbitol.

6.2. Incompatibilities

None known to date.

6.3. Shelf life

Drops: 3 years.

Spray : 2 years.

6.4. Special precautions for storage

Drops:Do not store above 30°C.

Spray: Do not store above 25°C.

6.5. Nature and contents of container

Vibrocil® Nasal Drops: 15 ml amber glass bottle, fitted with a polypropylene cap which includes a polypropylene pipette with a chlorobutyl elastomer bulb.

Vibrocil® Nasal Spray: 25 ml low density polyethylene squeeze bottle (filled with 10 ml of product) fitted with a polyethylene spray nosepiece with a polyethylene protection cap.

6.6. Instructions for use/handling

Vibrocil® should be used after blowing the nose.

Vibrocil® Nasal Drops:

Tilt the head back while standing or sitting up. Or, if lying on a bed, hang the head over the side. Place the drops into each nostril and keep the head tilted back for a few minutes to allow the medicine to spread throughout the nose.

For infants with congestion, it is recommended to use the nasal drops before feeding in order to help when breast-feeding.

Vibrocil® Spray:

To produce a fine spray, the nebuliser should be held upright with the nozzle pointing upwards. With head upright, insert the nozzle into the nostril, give the nebuliser one short and sharp squeeze, and then withdraw it from the nostril before releasing the pressure. Breathing a little air through the nose during the spraying process ensures optimal distribution of the spray.

7. MARKETING AUTHORISATION HOLDER

Novartis Consumer Health SA, Switzerland,

Address: Route de l'Etraz, Case postale 269,1260 Nyon, Switzerland

APPROVED BY SCDMTE JSC
Expert / Date 09.10.18
Applicant / Date 15.10.2018

8. MARKETING AUTHORISATION NUMBER

To be completed locally

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

APPROVED BY SCDMTE JSC
Expert / Date 09.10.18
Applicant / Date 15.10.2018

10. DATE OF REVISION OF THE TEXT