<u>เอกสารกำกับยาภาษาอังกฤษ</u>

(เหมือนกันทุกขนาดบรรจุ)

Summary of Product Characteristics

GESTAL 0.025% DROPS

GESTAL 0.05% DROPS

GESTAL 0.05% SPRAY

1. Name of the medicinal product

GESTAL 0.025% DROPS: Oxymetazoline hydrochloride 0.025% W/V

clear, colorless solution for drops

GESTAL 0.05% DROPS: Oxymetazoline hydrochloride 0.05% W/V

clear, colorless solution for drops

GESTAL 0.05% SPRAY: Oxymetazoline hydrochloride 0.05% W/V

clear, colorless solution for spray

2. Qualitative and quantitative composition

GESTAL 0.025% DROPS:

Each 1 mL contains: Oxymetazoline hydrochloride 0.25 mg

GESTAL 0.05% DROPS:

Each 1 mL contains: Oxymetazoline hydrochloride 0.5 mg

GESTAL 0.05% SPRAY:

Each 1 mL contains: Oxymetazoline hydrochloride 0.5 mg

3. Pharmaceutical Form

Nasal drop, solution

Nasal spray, solution (non-pressurized)

4. Clinical Particulars

4.1 Therapeutic indications

Nasal decongestant, for the temporary relief of nasal congestion (stuffy nose), due to the common cold, hay fever or other upper respiratory allergies (allergic rhinitis), or associated with sinusitis.

4.2 Posology and method of administration

GESTAL 0.025% DROPS:

Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops in each nostril not more often than every 10 to 12 hours. **Use only recommended amount. Do not exceed 2 doses in any 24-hour period.**

GESTAL 0.05% DROPS:

Adult and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.

GESTAL 0.05% SPRAY:

Adult and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.

Elderly:

There is no need for dosage reduction in the elderly.

For nasal administration

4.3 Contraindication

- Hypersensitivity to any of the ingredients
- Have cardiovascular disease
- Have hyperthyroidism
- Have angle closure glaucoma
- Have prostatic enlargement
- Have phaeochromocytoma (a rare tumor of the adrenal glands)
- Have had an operation to remove your pituitary gland or you have recently had an operation on your nose or sinuses.
- Have inflamed skin or mucous membranes of your nostrils or have scabs in your nose
- Are already taking medicines to unblock your nose

4.4 Special warning and precautions for use

- Have high blood pressure
- Have diabetes
- Have kidney or liver problems
- Pregnancy and breastfeeding
- Taking or using, or have recently taken or used any other medicines
- Do not use this product for more than 3-7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.

4.5 Interactions with other medicinal products and other forms of interactions

GESTAL should not be given to patients being treated with monoamine oxidase inhibitors or within 14 days of ceasing such treatment.

4.6 Pregnancy and lactation

Due to insufficient evidence on the use of the product in pregnancy and lactation, use of the product should be avoided unless on the advice of a physician.

4.7 Effects on ability to drive and use machine

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

In general, no severe undesirable effects are expected.

Rare:	Eye disorders: Eye irritation, dryness, discomfort or redness
	Respiratory: Discomfort or irritation in the nose, mouth or throat; Sneezing
Very rare:	Cardiovascular: Tachycardia, palpitations, increased blood pressure
	CNS: Insomnia, nervousness, tremor, anxiety, restlessness, irritability, headache
	Gastrointestinal: Nausea

4.9 Overdose

Symptoms

The symptoms of moderate or acute overdosage can include mydriasis, nausea, cyanosis, fever, tachycardia, cardiac arrhythmia, hypertension, dyspnea, and cardiovascular failure.

CNS depression with symptoms such as decreased body temperature, bradycardia, hypotension, apnea or loss of consciousness is possible.

Treatment of overdose

Symptomatic treatment of the overdosage is required. In serious cases, intubation and artificial ventilation are required.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nasal preparations: Decongestants and other nasal preparations for topical use

ATC code: R01AA05

Oxymetazoline hydrochloride is a sympathomimetic amine having vasoconstrictor properties which are utilized in the relief of nasal congestion.

5.2 Pharmacokinetic properties

Oxymetazoline enters tissues rapidly and local vasoconstriction is normally achieved within 5-10 minutes of intranasal administration. The full effect lasts for 5-6 hours and then gradually subsides over the next 6 hours. Plasma half-life is 5-8 days with 30% of any absorbed drug being excreted in the urine unchanged and 10% being excreted in the feces.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6. Pharmaceutical Particulars

6.1 List of excipients

Benzalkonium chloride, Sodium phosphate dibasic, Sodium phosphate monobasic, Disodium EDTA, Propylene glycol, NaCl, Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Shelf life 2 years

6.4 Special precautions for storage

Store below 30^{O}C

Keep out of the sight and reach of children.

6.5 Nature and contents of container

GESTAL 0.025% DROPS:

Contain in amber glass bottle closed with PP bottle cap with glass dropper of 10 and 20 mL packed in paper box of 1, 10, 50, and 100 bottles.

GESTAL 0.05% DROPS:

Contain in amber glass bottle closed with PP bottle cap with glass dropper of 10 and 20 mL packed in paper box of 1, 10, 50, and 100 bottles.

GESTAL 0.05% SPRAY:

Contain in plastic bottle with spray nozzle cap of 10 and 15 mL packed in paper box of 1, 10, 50, and 100 bottles.

7. Marketing authorization holder

Millimed Co., Ltd.

193 Moo 1, Suksawad Road, Pak Khlong Bang Plakot, Phra Samut Chedi, Samut Prakan 10290, Thailand.

Tel: +66 2461 1027

8. Marketing authorization number(s)

XXXXXXXX

9. Date of first authorization/renewal of the authorization

XX.XX.XX

10. Date of revision of the text

20 Sep 2022