NAZAL- naphazoline hydrochloride liquid
Sato Pharmaceutical Co., Ltd.

Nazal

Active ingredients
Naphazoline hydrochloride 0.05%

Purpose Nasal decongestant

Uses for the temporary relief of nasal congestion due to the common cold, hay fever, or associated with sinusitis

Warnings
For external use only

Do not use

■for more than 3 days

■in children under 12 years of age because it may cause sedation if swallowed

Ask a doctor before use if you have

■heart disease

■high blood pressure

■thyroid disease ■diabetes

■difficulty in urination due to enlargement of the prostate gland

When using this product

■do not exceed recommended dosage

■if may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge

■the use of this container by more than one person may spread infection

■use only as directed

■frequent or prolonged use may cause nasal congestion to recur or worsen

Stop use and ask a doctor if

■symptoms persist

If pregnant or breast-feeding, ask a health professional before use.

Keep our of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions
Adults and children 12 years of age and older - 1 or 2 sprays in each nostril not more often than every 6 hours
Children under 12 years of age - do not give unless directed by a doctor

Other information
■container is filled to proper level for best spray action

Inactive ingredients
benzalkonium chloride, citric acid, dibasic potassium phosphate, fragrance, monobasic potassium phosphate, simethicone, sodium chloride, water

nazalcart.jpg

NAZAL

naphazoline hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-057
Route of Administration	NASAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	50 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-057-01	1 in 1 CARTON	06/11/1990	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/11/1990	

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-057) , label(49873-057) , pack(49873-057)

Revised: 12/2023 Sato Pharmaceutical Co., Ltd.