GILTUSS SEVERE SINUS- oxymetazoline hcl spray
Gil Pharmaceutical Corp

Giltuss Severe Sinus Nasal Spray

Drug Facts

Active ingredient

Oxymetazoline HCl 0.05%

Purpose

Nasal decongestant

Uses
temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- temporarily relive sinus congestion and pressure
- shrinks swollen nasal membrances so you can breathe more freely

Warnings

Ask a doctor before use if you have
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product
- **do not use more than directed**
- do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- use of this container by more than one person may spread infection

Stop use and ask a doctor ifsymptoms persist

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- **adults and children 6 to under 12 years of age (with adult supervision):**2 or 3 sprays in each nostrill. Not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- **children under 6 years of age:**ask a doctor.
- Shake well before use. To open, rotate cap to align the marks. Squeeze cap on both

sides in a counter-clockwise turn and pull off to remove. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting the head, insert nozzle into nostril. Fully depress with a firm, even stroke and sniff deeply. Wipe nozzle clean after use and snap cap back onto the bottle.

Other information

- store between 20° to 25°C (68° to 77° F)
- retain carton for future reference on full labeling

Inactive Ingredients

benzalkonium chloride, dibasic sodium phosphate, edetate disodium dihydrate, glycerin, monobasic sodium phosphate, polyethylene glycol, propylene glycol, povidone, purified water.

Tamper evident: do not use if safety seal is broken or missing

MANUFACTURED FOR GIL PHARMACEUTICAL CORP.

PONCE, PUERTO RICO 00717-1565

giltuss.com

FAST AND POWERFUL

Giltuss®

SEVERE SINUS

UP TO 12 HOURS RELIEF

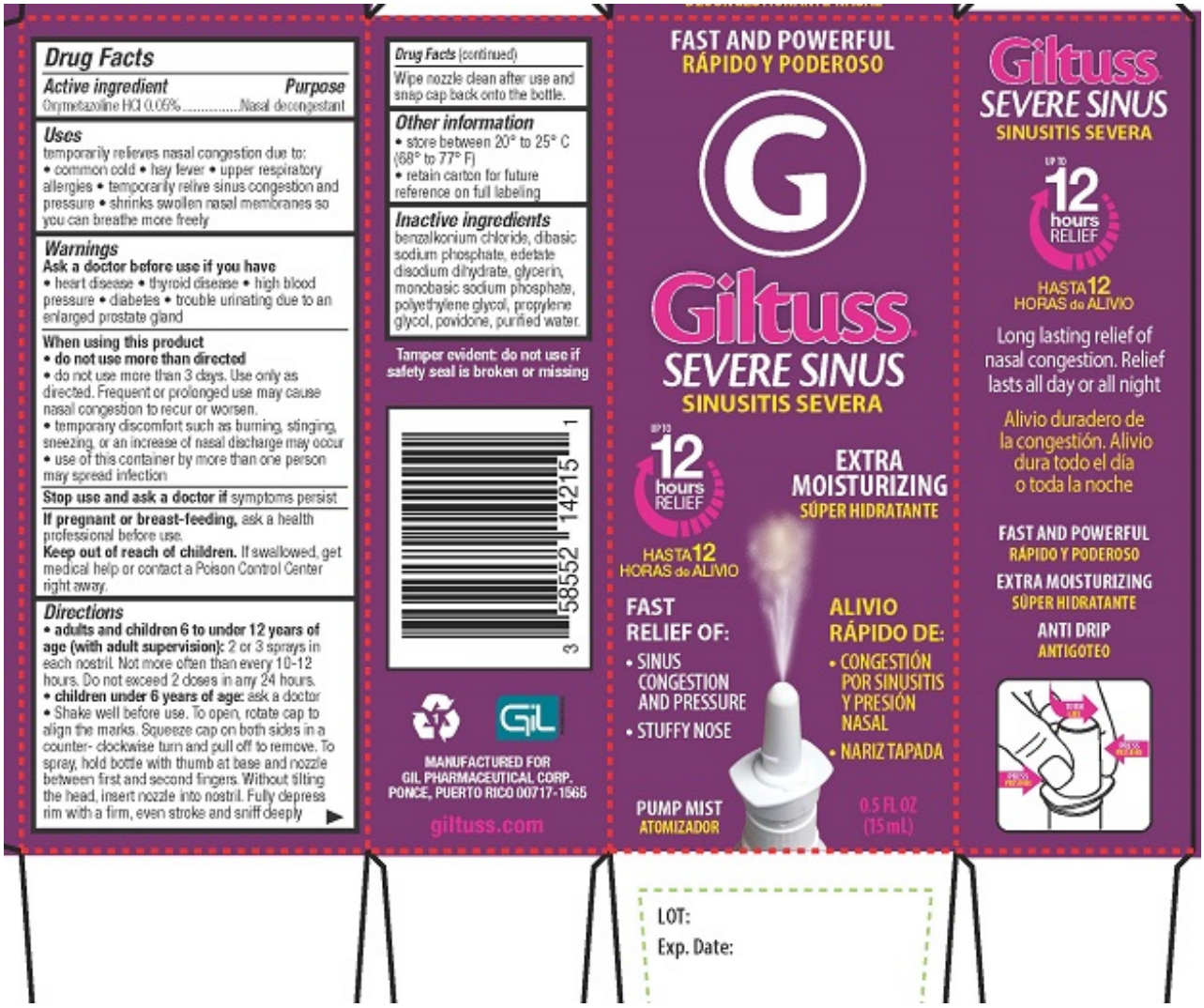
EXTRA MOISTURIZING

FAST RELIEF OF:

- SINUS CONGESTION AND PRESSURE
- STUFFY NOSE

PUMP MIST

0.5 FL OZ (15 mL)



GILTUSS SEVERE SINUS

oxymetazoline hcl spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58552-142
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-142-15	1 in 1 CARTON	07/28/2020	
1		15 mL in 1 BOTTLE, SPRAY; 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	07/28/2020	

Labeler - Gil Pharmaceutical Corp (176826592)

Establishment

Name	Address	ID/FEI	Business Operations
SEAWAY PHARMA		117218785	manufacture(58552-142)

Revised: 10/2025 Gil Pharmaceutical Corp