

ZICAM- oxymetazoline hydrochloride spray
Matrixx Initiatives, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Zicam® Sinus Relief

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
 - the common cold
 - hay fever
 - upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- helps clear nasal passages
- shrinks swollen membranes

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- 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 result
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms 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 nostril 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

To use pump:

- to open, hold the actuator to squeeze and turn cap
- hold with thumb at bottom of bottle and nozzle between fingers
- before using the first time, prime pump by depressing several times
- place tip of nozzle just past nasal opening (approximately 1/8")
- pump 2 or 3 times in each nostril without tilting your head. Sniff deeply.
- wipe nozzle clean after use
- to close, turn cap until it 'clicks'

Other information

- store between 15-29°C (59-84°F)
- retain carton for future reference on full labeling

Inactive ingredients

aloe barbadensis gel, benzalkonium chloride, benzyl alcohol, disodium EDTA, disodium phosphate, dl-alpha tocopherol, eucalyptol, glycerin, hydroxyethylcellulose, hydroxylated lecithin, menthol, monosodium phosphate, polysorbate 80, purified water

Questions? Comments? Side Effects?

call 877-942-2626 toll free

**Distributed by Matrixx Initiatives, Inc.
Scottsdale, Arizona 85260.**

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

NDC 62750-006-10

ZICAM®

INTENSE

SINUS

RELIEF

NASAL DECONGESTANT
OXYMETAZOLINE HCl

12

HOUR

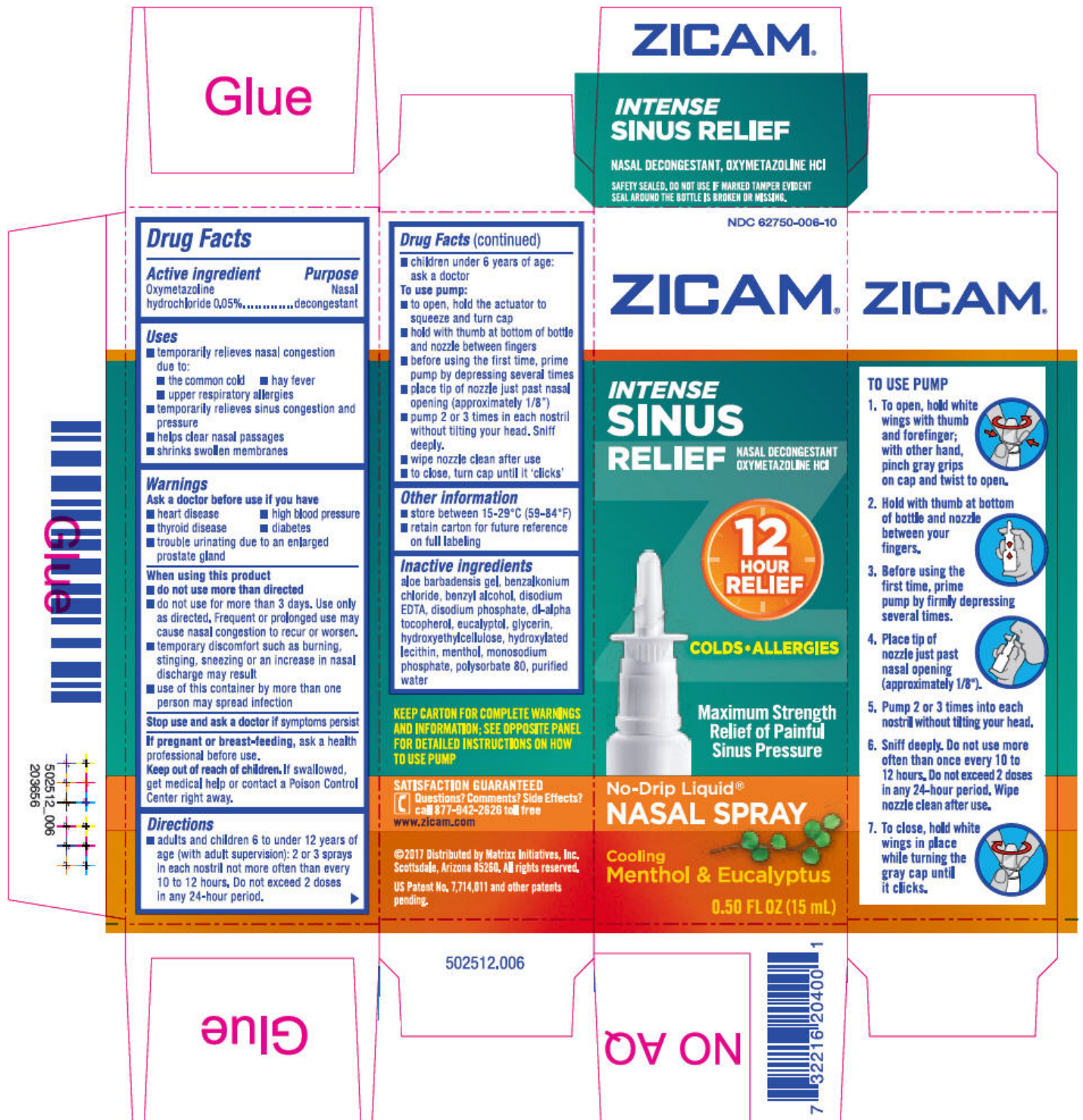
RELIEF

COLDS*ALLERGIES

Maximum Strength
Relief of Painful
Sinus Pressure

No-Drip Liquid®
NASAL SPRAY

Cooling
Menthol & Eucalyptus
0.50 FL OZ (15 mL)



ZICAM

oxymetazoline hydrochloride spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:62750-006

Route of Administration	NASAL
--------------------------------	-------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
oxymetazoline hydrochloride (UNII: K89MJ0S5VY) (oxymetazoline - UNII:8VLN5B44ZY)	oxymetazoline hydrochloride	.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
benzalkonium chloride (UNII: F5UM2KM3W7)	
benzyl alcohol (UNII: LKG8494WBH)	
edetate disodium (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
eucalyptol (UNII: RV6J6604TK)	
glycerin (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62750-006-10	1 in 1 CARTON	05/29/2002	
1		15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/29/2002	

Labeler - Matrixx Initiatives, Inc. (790037253)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac, Inc.		071609663	MANUFACTURE(62750-006)