SOUND BODY 12 HOUR NASAL ORIGINAL- oxymetazoline hydrochloride spray
Lee Pharmaceuticals

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.

Drug Facts

Active ingredient

Oxymetazoline Hydrochloride, 0.05%

Purpose

Nasal Decongestant

Uses

- Temporarily relieves nasal congestion due to: common cold, hay fever, sinusitis, upper respiratory allergies.
- Shrinks swollen membranes so you can breathe more freely.

Warnings

Ask a doctor before use if you have

- Heart disease
- High blood pressure
- Diabetes
- Thyroid disease
- 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 if symptoms persists.

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 ofter than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- Children under 6 years of age: consult a doctor.
- To spray, squeeze bottle quickly and firmly. Do not tilt head backwards while spraying. Wipe nozzle clean after use.

Other information
- Store between 20° - 25° C (68° - 77° F)
- Retain carton for future reference on full labeling.

Inactive ingredients

Benzalkonium chloride, edetate disodium, glycerin, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water

3.8x5.7cm

Oxymetazoline HCl
Nasal Solution

12 Hour Relief

1 FL OZ (30mL)

Distributed by:
Lee Pharmaceuticals, South El Monte, CA 91733 USA
Questions or Comments? 800-950-5337

16051120 Rev. 4/13

SIZE: 5.4x3.2x13.2cm

Cat. No. 5120-000
1505120
Rev. 4/13

CMYK PANTONE 287C

SOUND BODY 12 HOUR NASAL ORIGINAL

oxymetazoline hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:23558-5120

Route of Administration	NASAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	50.0 mg in 100.0 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23558-5120-0	1 in 1 CARTON		
1	NDC:23558-5120-1	30 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2008	

Labeler - Lee Pharmaceuticals (056425432)

Registrant - Lee Pharmaceuticals (056425432)

Establishment

Name	Address	ID/FEI	Business Operations
Samson Pharmaceuticals		088169581	manufacture(23558-5120)

Revised: 6/2013 Lee Pharmaceuticals