EQUALINE FAST ACTING- phenylephrine hydrochloride spray SUPERVALU 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.

Drug Facts

Active ingredient

Phenylephrine hydrochloride 1%

Purpose

Nasal decongestant

Uses

for the temporary relief of nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies

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 exceed recommended dosage
- do not use for more than 3 days. Use only as directed
- temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- the use of this container by more than one person may spread infection
- 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 out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions

- adults and children 12 years of age and over: 2 or 3 sprays in each nostril not more than every 4 hours
- children under 12 years of age: ask a doctor
- Use instructions: with head in a normal, upright position, put atomizer tip into nostril. Squeeze bottle with firm, quick pressure while inhaling. Wipe nozzle clean after each use.

Other information

- store between 20°-25°C (68°-77°F)
- container is filled to proper level for best spray action

Inactive Ingredients

benzalkonium chloride, benzyl alcohol, citric acid, purified water, sodium chloride, sodium citrate

Questions

1-877-932-7948

IMPORTANT: Keep this carton for future reference on full labeling

DO NOT USE IF PRINTED SEAL OVER CAP IS TORN OR MISSING

Distributed By: Supervalu Inc.

Eden Prairie, MN 55344

This product is not manufactured or distributed by Novartis Consumer Health Inc., the owner of the registered trademark 4-Way Fast Acting Nasal Spray.

Principal Display

NDC 41163-728-01

Equaline

Fast Acting

Nasal Spray

Phenylephrine hydrochloride 1%

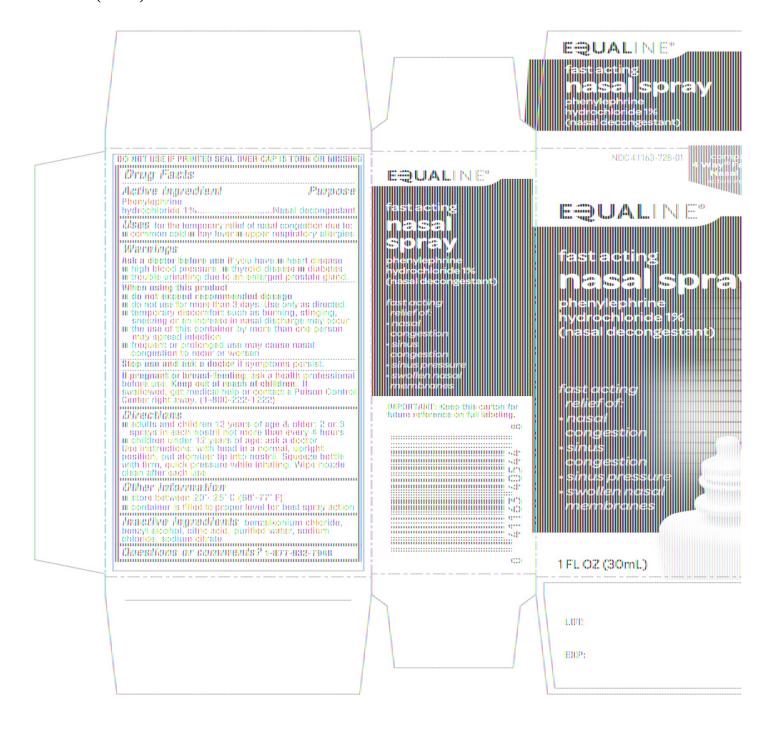
(nasal decongestant)

fast acting relief of

- nasal congestion
 - sinus congestion
 - sinus pressure

swollen nasal passages

1 FL OZ (30mL)



Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:41163-728

NASAL

Route of Administration

| Active Ingredient/Active Moiety | | | | | |
|--|--------------------------------|------------------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 1 mL | | | |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) | | | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | | | |
| CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | | | | |

| P | Packaging | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:41163-728- 01 | 1 in 1 CARTON | | | | |
| 1 | | 30 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 final | part341 | 10/30/2014 | | | |
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Labeler - SUPERVALU INC. (006961411)

Revised: 11/2014 SUPERVALU INC.