BERKLEY AND JENSEN NASAL- oxymetazoline hydrochloride spray BJWC

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.

BJWC Nasal Spray Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

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

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 occur
- 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 (1-800-222-1222).

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: Shake well before use. Hold white tabs, <u>SQUEEZE</u> grooved area of cap <u>FIRMLY</u> and turn counter clockwise. Before using the first time, prime metered pump by depressing pump firmly several times. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use. Secure cap after use.

Other information

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

Inactive ingredients

benzalkonium chloride solution, benzyl alcohol, camphor, dibasic sodium phosphate, edetate disodium, eucalyptol, menthol, microcrystalline cellulose and carboxymethylcellulose sodium, monobasic sodium phosphate, polyethylene glycol, povidone, propylene glycol, purified water

Questions or comments?

1-800-934-1204

Package/Label Principal Display Panel

Compare to the active ingredient in Afrin[®] No Drip MAXIMUM STRENGTH PLUS MENTHOL NO DRIP NASAL SPRAY OXYMETAZOLINE HCI 0.05% NASAL DECONGESTANT WON'T DRIP FROM NOSE OR DOWN THROAT SEVERE CONGESTION COLDS – ALLERGIES 12 HOUR RELIEF FAST, POWERFUL CONGESTION RELIEF TWO 1 FL OZ (30 mL) BOTTLES PUMP MIST

TOTAL 2 FL OZ (60 mL)



BERKLEY AND JENSEN NASAL

Product Info	rmation						
Product Type				(Source)	NDC:68391-721		
			item code	Code (Source) NDC:6		30391-721	
Route of Admiı	nistration NAS	ΑL.					
Active Ingred	lient/Active Moi	ety					
	Ingredient	: Name		Basis of Stre	ngth S	strengtl	
OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYME - UNII:8VLN5B44ZY)			YMETAZ OLINE	LINE OXYMETAZOLINE .05 g		-	
nactive Ingr	edients						
		Ingredient Name	•		S	trength	
BENZYL ALCOHO	L (UNII: LKG8494WBH)						
	IATE, DIBASIC, UNSP		: GR686LBA74)				
	UM (UNII: 7FLD91C86k	()					
EUCALYPTOL (UN	-						
	ECIFIED FORM (UNII:						
	INE CELLULOSE (UNI						
	IATE, MONOBASIC, U			IS W)			
		-	4)				
	PECIFIED (UNII: FZ989						
	COL (UNII: 6DC9Q167)	(3)					
	CHLORIDE (UNII: F5UI						
BENZALKONIOM							
Product Cha	racteristics						
Color	WHITE (off v	vhite)	Score	e			
Shape			Size				
Flavor			Impri	nt Code			
Contains			· ·				
Packaging							
# Item Code	Packa	ge Description	M	arketing Start Date	Market Da	ing End Ite	
	2 in 1 CARTON		06/0	04/2021			
1 NDC:68391- 721-16							
	30 mL in 1 BOTTLE, 5 Combination Product	SPRAY; Type 0: Not a					
1 721-16		SPRAY; Type 0: Not a					
1 721-16 1		SPRAY; Type 0: Not a					

Category	Citation	Date	Date
OTC monograph final	part341	06/04/2021	

Labeler - BJWC (159082692)

Revised: 6/2021

BJWC