

ORTIZOL OTIC SOLUTION- antipyrine, benzocaine, phenylephrine hydrochloride liquid
Bayer HealthCare LLC, Consumer Care

Ortizol-Otic Solution

Each ml contains :

Antipyrine USP 50 mg

Benzocaine USP 50 mg

Phenylephrine HCL USP 1.25 mg

The analgetic action of antipyrine and benzocaine to relief pressure. reduce inflammation and congestion. and alleviate pain and discomfort in acute otitis media.

For the relief of pain and the reduction of inflammation in acute otitis media. It is also useful in the removal of excessive or impacted cerumen.

Hipersensitivity to any of the components or substances related to them. In the presence of spontaneous perforation or discharge.

Warm to body temperature and fill the ear canal with 2 to 4 drops. Moisten cotton pledget with the solution and gently insert into the ear canal.

Repeat 3 or 4 times daily.

Store at controlled room temperature 25 °C (77 °F).

Protect from freezing.

Keep tightly closed.

Keep this and all medications out of reach of children.

Sodium

Metabisulfite NF 1 mg.

Propylene Glycol USP 897.75 mg.



ORTIZOL OTIC SOLUTION

antipyrine, benzocaine, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61841-180
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		50 mg

ANTIPYRINE (UNII: T3CHA1B51H) (ANTIPYRINE - UNII:T3CHA1B51H)	ANTIPYRINE	50 mg in 1 mL
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	50 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61841-180-05	1 in 1 CARTON	12/19/2014	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		12/19/2014	

Labeler - Bayer HealthCare LLC, Consumer Care (785159372)

Revised: 2/2015

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