DESENFRIOL-D- chlorpheniramine maleate, phenylephrine hydrochloride, acetaminophen tablet
Salimex, S.A.

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.

Desenfriol-Ito

Active ingredient (in each caplet)

CHLORPHENIRAMINE MALEATE 2.0 mg

PHENYLEPHRINE HYDROCHLORIDE 5.0 mg

ACETAMINOPHEN 500 mg

Purpose

Pain reliever

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
- headache
- sinus congestion and pressure
- nasal congestion
- runny nose and sneezing
- minor aches and pains
- temporarily relieves these additional symptoms of hay fever:
- itching of the nose or throat
- itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus openings and passages

Warnings

- Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product
- Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may

include:
- skin reddening
- blisters
- rash
- If a skin reaction occurs, stop use and seek medical help right away.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- to make a child sleepy

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- do not exceed recommended dosage
- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- new symptoms occur

These could be signs of a serious condition.otc

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

do not take more than directed (see overdose warning)

adults and children 12 years and over
- take 2 caplets every 4-6 hours
- swallow whole – do not crush, chew or dissolve
- do not take more than 10 caplets in 24 hours

children under 12 years
- ask a doctor

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, D&C red #33, FD&C blue #1, FD&C red 40, flavors, glycerin, microrocrystalline cellulose, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum

Desfiol-Ito

DESENFRIOL-D

chlorpheniramine maleate, phenylephrine hydrochloride, acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53666-517
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	0.001 g in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.0025 g in 1 g
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	0.08 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
GLYCERIN (UNII: PDC6A3C0OX)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	PNE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53666-517-01	30 in 1 BOX	10/18/2017	
1		0.05 g in 1 BLISTER PACK; 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	10/18/2017	

Labeler - Salimex, S.A. (589201581)

Registrant - Salimex, S.A. (589201581)

Establishment

Name	Address	ID/FEI	Business Operations
Bayer de México, S.A. de C.V.		588165709	manufacture(53666-517)

Revised: 6/2021 Salimex, S.A.