**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.*

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**Desenfriol-D**

**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

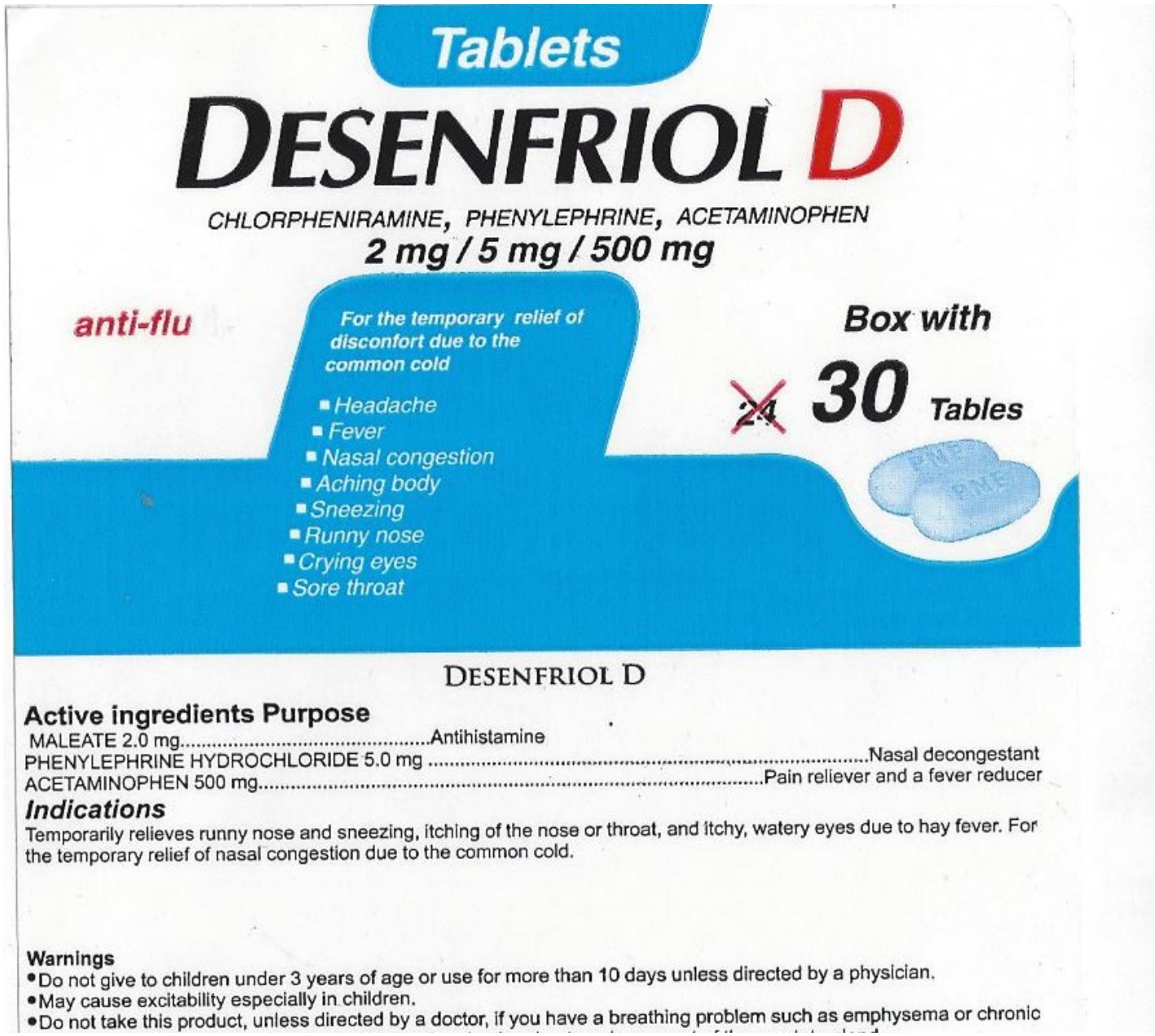
children under 12 years

- 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

**Desfriol-D**



bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.
**May cause drowsiness;** alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child's doctor.
**Do not exceed recommended dosage.** If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor. If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor. Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor.Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor. Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor. Do not use 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.
**Directions**
Adults and children 12 years of age and over: oral dosage is 4 milligrams every 4 to 6 hours, not to exceed 24 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: oral dosage is 1 milligram every 4 to 6 hours, not to exceed 6 milligrams in 24 hours.

CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE, ACETAMINOPHEN.

**MADE IN MEXICO BY:**
*SCHERING-PLOUGH, S.A. DE C.V.*
*AV. 16 DE SEPTIEMBRE NO. 301*
*COL. XALTOCAN, MEXICO D.F.*
*16090 MEXICO. REG. NO. 55563 SSA VI*

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# DESENFRIOL-D

chlorpheniramine maleate, phenylephrine hydrochloride, acetaminophen tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:53666-417 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CHLORPHENIRAMINE MALEATE** (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 0.002 g in 1 g |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 0.005 g in 1 g |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 0.5 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** | blue | **Score** | no score |
| **Shape** | OVAL | **Size** | 18mm |
| **Flavor** | | **Imprint Code** | PME |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:53666-417-01 | 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(53666-417) |

Revised: 12/2020 Salimex, S.A.