

**ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HCL-  
acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet  
OPMX LLC**

*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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**Pentrexilina - Daytime  
(Acetaminophen 500mg, Chlorpheniramine Maleate 4mg, Phenylephrine HCl  
10mg Tablet)**

***Drug Facts***

***Active Ingredients***

Acetaminophen 500mg

Chlorpheniramine Maleate 4mg

Phenylephrine HCl 10mg

***Purpose***

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***Active Ingredients (in each caplet)***

Acetaminophen 500 mg

Chlorpheniramine Maleate 4 mg

Phenylephrine HCl 10 mg

***Purpose***

Pain reliever

Antihistamine

Nasal decongestant

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***Uses***

Temporarily relieves these symptoms of hay fever or other respiratory allergies:

- Headache
- Nasal congestion
- Sinus congestion & pressure
- Runny nose and sneezing
- Minor aches & pain

Temporarily relieves these additional symptoms of hay fever:

- itching of the nose or throat
- itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus opening and passages

***Warnings***

## **Liver warning:**

This product contains acetaminophen. Severe liver damage may occur if you take :

- more than 6 tablets in 24 hours, which is the maximum daily amount for this product
- with other drugs contains 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.

## **Sore throat warning:**

if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult doctor promptly.

## **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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

## **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 use more than directed
- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness

- avoid drinks
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if:**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or last more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:**

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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
- Swallow whole; do not crush, chew or dissolve
- Do not exceed 6 tablets per 24 hours

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Adults and children 12 years of age & over	1 tablet with water every 4-6 hours as needed
Children 4 to 12 years of age	Ask a doctor
Children under 4 years of age	Do not use

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**Other information**

- Store at room temperature between 20-25°C (68-77°F)
- Avoid excessive heat and humidity
- Tamper Evident: do not use if package or blister unit is open or shows any sing of tampering

**Inactive ingredients**

magnesium stearate, povidone, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

**Questions or comments?**

Call: (619) 600-5632 (Mon-Fri 9am-5pm EST) or <https://www.opmx.us>

**Uses:** ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies ■ headache ■ sinus congestion & 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 6 tablets in 24 hrs, which is the maximum daily amount for this product ■ 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.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Directions:**  
 ■ Do not take more than directed - See Overdose warning  
 ■ Swallow whole; do not crush, chew or dissolve  
 ■ Do not exceed 6 tablets per 24 hours

Adults and children 12 years of age & over	1 tablet with water every 4-6 hours as needed
Children 4 to 12 years of age	Ask a doctor
Children under 4 years of age	Do not use

**Other information:** ■ Store at room temperature 20°-25°C (68°-77°F)  
 ■ Avoid excessive heat and humidity

**READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

Exclusively distributed by  
  
 San Diego, CA 92161  
 Phone: 619-400-5632

Made for:  
  
 San Diego, CA

REV. 09/2019

TAMPER EVIDENT: DO NOT USE IF POUCH IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING

**2 Tablets**

 **DAYTIME**

**PENTREXILINA®**

ACTIVE INGREDIENTS (in each tablet)	PURPOSE
Acetaminophen 500 mg	Pain reliever/fever reducer
Chlorpheniramine Maleate 4 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

Effective and quick relief from  
**cold & flu symptoms**

- ☀ **Headache**
- ☀ **Nasal Congestion**
- ☀ **Itchy, Watery Eyes**
- ☀ **Runny Nose & Sneezing**



**Drug Facts (continued)**

**Other information:** • Store at room temperature between 20° - 25° C (68° - 77° F) • Avoid excessive heat and humidity

**Inactive ingredients:** magnesium stearate, polydioxane, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

**Questions or comments?** Call: (619) 600-5632 (Mon-Fri 9am-5pm EST) or <https://www.opmx.us>

**TAMPER EVIDENT: DO NOT USE IF POUCH IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING**

12 Tablets (6 Pouches of 2 Tablets)

**Effective and Quick Relief from**

- Headache
- Nasal Congestion
- Itchy, Watery Eyes
- Runny Nose & Sneezing

**PENTREXILINA**

Acetaminophen 500 mg • Chlorpheniramine Maleate 4 mg • Phenylephrine HCl 10 mg

**COLD & FLU DAYTIME**

NDC 69729-223-37

8 55828 00024 000000

REG. 10/07/19 (REV. 1/16)

Made for: **OPMX** Pharmaceuticals, Inc. San Diego, CA

Exclusively distributed by: **OPMX** Pharmaceuticals, Inc. San Diego, CA

**READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT INFORMATION**

**Drug Facts**

ACTIVE INGREDIENTS (in each tablet)	PURPOSE
Acetaminophen 500 mg	Pain reliever/fever reducer
Chlorpheniramine Maleate 4 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

**Uses:**

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies: • headache • sinus congestion & 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 6 tablets in 24 hrs, which is the maximum daily amount for this product • with other drugs containing acetaminophen
- 2 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

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**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 sleep

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

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

**When using this product:** • do not use more than directed • drowsiness 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, nasal congestion, or cough 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

**If pregnant or breast-feeding:** ask a health professional before use. **Keep out of reach of children.**

**Overdose warning:** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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 of age & over	1 tablet with water every 4-6 hours as needed
• Swallow whole; do not crush, chew or dissolve	Children 4 to 12 years of age	Ask a doctor
• Do not exceed 6 tablets per 24 hours	Children under 4 years of age	Do not use





Acetaminophen 500 mg - Chlorpheniramine Maleate 4 mg - Phenylephrine HCl 10 mg

# PENTREXCILINA®

**Effective and Quick Relief from**

- Nasal Congestion & Runny Nose
- Sneezing & Watery Eyes
- Fever & Headache
- Muscle Pain
- Body Aches

**PENTREXCILINA®**

**6 Tablets**

**3 Packs of 2 Tablets**



**READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT INFORMATION**

Exclusively distributed by:



Made for:



REV. 08/2023 ITEM # RRX1131  
 LOT  
 EXP. DATE  
 8 10053 18126 3

**Drug Facts**

**Active Ingredients (in each caplet)**

Acetaminophen 500 mg  
 Chlorpheniramine Maleate 4 mg  
 Phenylephrine HCl 10 mg

**Purpose**

Pain reliever  
 Antihistamine  
 Nasal decongestant

**Uses**

temporarily relieves these symptoms of hay fever or other upper respiratory allergies: headache, sinus congestion & 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

rich, watery eyes

helps clear nasal passages

helps decongest sinus openings and passages

water-weight gain

water-weight gain

headache

backache

muscle aches

fatigue

**Warnings**

**Liver warning:** Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 6 tablets in 24 hrs, which is the maximum daily amount for this product

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

rash. If a skin reaction occurs, stop use and seek medical help right away

Skin reddening

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**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

glaucoma

diabetes

trouble urinating

due to an enlarged prostate gland

a breathing problem such as emphysema or chronic bronchitis

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

taking sedatives or tranquilizers

When using this product: do not use more than directed

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:

fever gets worse or lasts more than 3 days

redness or swelling is present

new symptoms occur

7 days

nauseous, dizziness, or sleeplessness occur

pain or nasal congestion gets worse or lasts more than 7 days

Keep out of reach of children

Overdose warning: taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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

Swallow whole, do not crush, chew or dissolve

Do not exceed 6 tablets per 24 hours

Children 4 to 12 years of age: Ask a doctor

Children under 4 years of age: Do not use

12 years of age & over: 4-6 hours as needed

1 tablet with water every 4-6 hours as needed

**Other information**

Store at room temperature between 20°-25°C (68°-77°F)

Avoid excessive heat and humidity

Keep container tightly closed

Do not use if package or blister unit is open or shows any sign of tampering

**Inactive ingredients**

magnesium stearate, povidone, silicon dioxide, sodium benzoate, sodium starch glycolate, starch, talc

**Questions or comments?** Call: (619) 600-5632 (Mon-Fri 9am-5pm EST) or <https://www.opmx.us>

**ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE**

# HCL

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-222
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg
<b>ACETAMINOPHEN</b> (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND (BICONVEX)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	S78
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-222-27	2 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	
2	NDC:69729-222-37	12 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	
3	NDC:69729-222-38	144 in 1 POUCH; Type 0: Not a Combination Product	08/26/2019	
4	NDC:69729-222-06	3 in 1 CARTON	09/04/2023	
4		2 in 1 POUCH; 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	08/26/2019	

**Labeler** - OPMX LLC (029918743)

## Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LIMITED		677385498	manufacture(69729-222)

Revised: 9/2023

OPMX LLC