AGRIFEN- acetaminophen, dextomethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled
OPMX LLC

AGRIFEN

Active ingredient

Active ingredients (in each Softgel)	***Purposes***
Acetaminophen 325 mg	Pain reliever/Fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5mg	Nasal descongestant

Uses

Temporarily relieves common cold/flu symptoms:

- Nasal congestion
- Cough due to minor throat & bronchial irritation
- Sore throat
- Headache
- Minor aches and pains
- Fever

Uses

- Pain reliever/Fever reducer
- Cough suppressant
- Nasal descongestant

Warnings

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

- More than 4 doses in 24 hrs, which is the maximum daily amount for this product.
- With other drugs containing acetaminophen.
- 3 or more alcoholic drinks daily while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- Skin reddening
- Blisters
- Rash
- If a skin reactions occurs, stop use and seek medical help right away

Sore throat warning: If sore throat is severe, lasts for more than 2 days, is accompained 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.

Ask a doctor before use if you have

- Liver disease
- Hear disease
- Diabetes
- High blood pressure
- Trouble urinating due to enlarged prostate gland
- Cough that occurs with too mcuh plegm (mucus)
- Persistent or chronic cough occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are:

Taking the blood thinning drug warfarin.

When using this product,

do not use more than directed.

Stop use and ask a doctor if

- You get nervous, dizzy or sleepless
- Symptoms get worse or last more than 5 days (children) or 7 days (adults)
- Fever gets worse or lasts more than 3 days
- Redness or swelling is present
- New symptoms occur
- Cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition

Keep out of reach of children

If pregnant or breast-feeding

ask a health professional before use.

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.

Quick medical attention is critical for adults as well as for children even if you dot notice any signs or symptoms.

Directions

- Take only as directed.
- Do not exceed 4 doses per 24 hours.

Adults & children 12 yrs & over	2 softgels with water every 4 hrs
Children 4 to under 12 yrs	Ask a doctor
Children under 4 yrs	Do not use

Other information

- Store at room temperature.

Inactive ingredients

FD&C Red No.40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide.

Questions?

Call toll free 619-600-5632

Monday through Friday 9AM - 5PM EST

NDC 69729-802-10

AGRIFEN

Acetaminophen 325 mg

Dextomethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Dolor de Cabeza

Headache

Congestión Nasal

Nassal Congestion

Ojos llorosos

Itchi, Watery eyes

Escurrimiento Nasal y Estornudos

Runny Nose & Sneezing

10 Soft Gels

Exclusively distributes by:

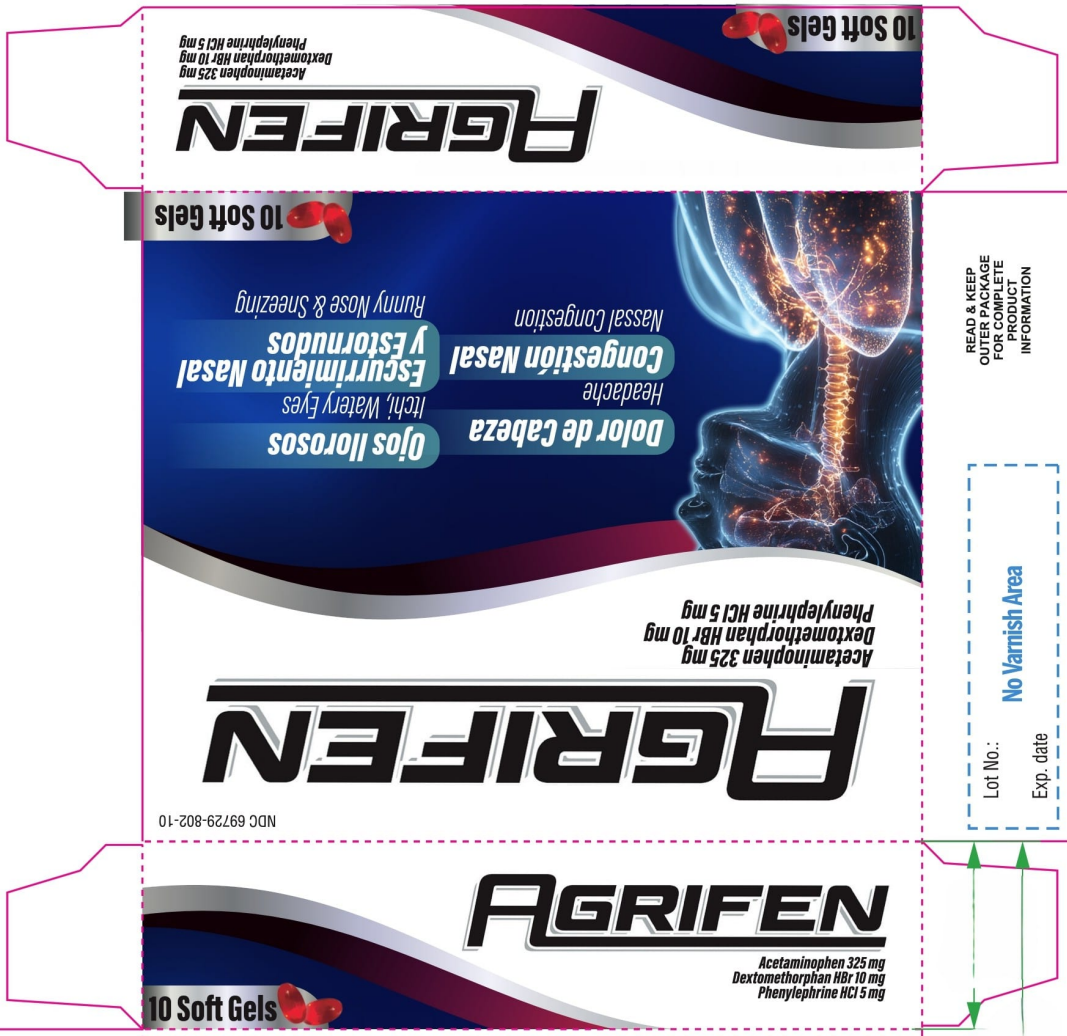
OPMX

Chula Vista, CA 91910

Phine: 619-600-5632

TAMPER EVIDENT:

Do not use if package is opened or if blister unit is torn, broken or shows any sign of tampering



Drug Facts

Active ingredients (in each Softgel) — **Purposes**

Acetaminophen 325 mg ..... Pain reliever/Fever reducer
Dextromethorphan HBr 10mg ..... Cough suppressant
Phenylephrine HCl 5 mg ..... Nasal decongestant

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Ask a doctor before use if you have
• Liver disease • Heart disease • Diabetes • High blood pressure • Trouble urinating due to enlarged prostate gland • Cough that occurs with too much phlegm (mucus) • Persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis or emphysema.

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

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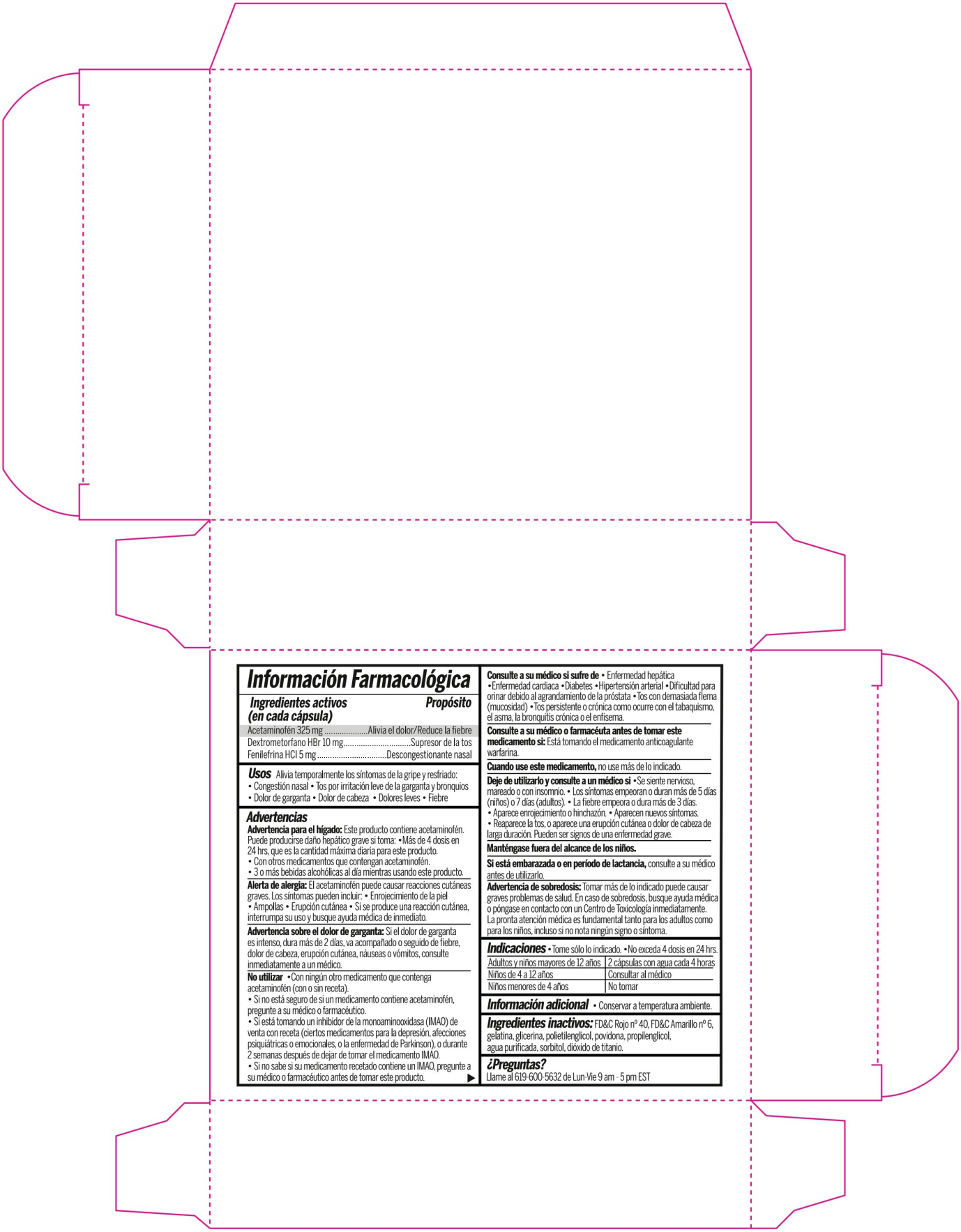
Monday through Friday 9AM - 5PM EST

REV. 03.2025
ITEM #RRX1157

8 10053 18164 5

Exclusively distributed by:
OPMX
Chula Vista, CA 91910
Phone: 619-600-5632

TAMPER EVIDENT: Do not use if product is opened or if blister unit is torn, broken or shows any sign of tampering



Información Farmacológica

Ingredientes activos (en cada cápsula)	Propósito
Acetaminofén 325 mg	Alivia el dolor/Reduce la fiebre
Dextrometorfano HBr 10 mg	Supresor de la tos
Fenilefrina HCl 5 mg	Descongestionante nasal

Usos Alivia temporalmente los síntomas de la gripe y resfriado:
- Congestión nasal • Tos por irritación leve de la garganta y bronquios
- Dolor de garganta • Dolor de cabeza • Dolores leves • Fiebre

Advertencias

Advertencia para el hígado: Este producto contiene acetaminofén. Puede producirse daño hepático grave si toma: • Más de 4 dosis en 24 hrs, que es la cantidad máxima diaria para este producto.
- Con otros medicamentos que contengan acetaminofén.
- 3 o más bebidas alcohólicas al día mientras usando este producto.

Alerta de alergia: El acetaminofén puede causar reacciones cutáneas graves. Los síntomas pueden incluir: • Enrojecimiento de la piel • Ampollas • Erupción cutánea • Si se produce una reacción cutánea, interrumpa su uso y busque ayuda médica de inmediato.

Advertencia sobre el dolor de garganta: Si el dolor de garganta es intenso, dura más de 2 días, va acompañado o seguido de fiebre, dolor de cabeza, erupción cutánea, náuseas o vómitos, consulte inmediatamente a un médico.

No utilizar • Con ningún otro medicamento que contenga acetaminofén (con o sin receta).
- Si no está seguro de si un medicamento contiene acetaminofén, pregunte a su médico o farmacéutico.
- Si está tomando un inhibidor de la monoaminooxidasa (IMAO) de venta con receta (ciertos medicamentos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson), o durante 2 semanas después de dejar de tomar el medicamento IMAO.
- Si no sabe si su medicamento recetado contiene un IMAO, pregunte a su médico o farmacéutico antes de tomar este producto. ▶

Consulte a su médico si sufre de • Enfermedad hepática • Enfermedad cardiaca • Diabetes • Hipertensión arterial • Dificultad para orinar debido al agrandamiento de la próstata • Tos con demasiada flema (mucosidad) • Tos persistente o crónica como ocurre con el tabaquismo, el asma, la bronquitis crónica o el enfisema.

Consulte a su médico o farmacéuta antes de tomar este medicamento si: Está tomando el medicamento anticoagulante warfarina.

Cuando use este medicamento, no use más de lo indicado.

Deje de utilizarlo y consulte a un médico si • Se siente nervioso, mareado o con insomnio. • Los síntomas empeoran o duran más de 5 días (niños) o 7 días (adultos). • La fiebre empeora o dura más de 3 días.
- Aparece enrojecimiento o hinchazón. • Aparecen nuevos síntomas.
- Reaparece la tos, o aparece una erupción cutánea o dolor de cabeza de larga duración. Pueden ser signos de una enfermedad grave.

Manténgase fuera del alcance de los niños.

Si está embarazada o en período de lactancia, consulte a su médico antes de utilizarlo.

Advertencia de sobredosis: Tomar más de lo indicado puede causar graves problemas de salud. En caso de sobredosis, busque ayuda médica o póngase en contacto con un Centro de Toxicología inmediatamente. La pronta atención médica es fundamental tanto para los adultos como para los niños, incluso si no nota ningún signo o síntoma.

Indicaciones • Tome sólo lo indicado. • No exceda 4 dosis en 24 hrs.

Adultos y niños mayores de 12 años	2 cápsulas con agua cada 4 horas
Niños de 4 a 12 años	Consultar al médico
Niños menores de 4 años	No tomar

Información adicional • Conservar a temperatura ambiente.

Ingredientes inactivos: FD&C Rojo nº 40, FD&C Amarillo nº 6, gelatina, glicerina, polietilenglicol, povidona, propilenglicol, agua purificada, sorbitol, dióxido de titanio.

¿Preguntas?
Llame al 619-600-5632 de Lun-Vie 9 am - 5 pm EST

AGRIFEN

acetaminophen, dextomethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69729-802
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	**Score**	score with uneven pieces
Shape	OVAL (Oblong)	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-802-10	1 in 1 CARTON	03/31/2025	
1		10 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 Drug	M012	03/31/2025	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
SOFTECH PHARMA PRIVATE LIMITED		677111277	manufacture(69729-802) , label(69729-802) , pack(69729-802)

Revised: 3/2025 OPMX LLC