

SEDALMEX XL FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
Belmora LLC

Sedalmex 44-546

Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 100 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves these symptoms due to the common cold:
 - headache
 - nasal congestion
 - cough
 - minor aches and pains
 - sore throat
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily reduces fever

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.

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

Ask a doctor before use if you have

- diabetes
- liver disease
- heart disease
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such 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.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, cough, 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
- cough comes back or occurs with rash or headache that lasts. 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.

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**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **each caplet contains:** sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-779-2877

Principal display panel

NDC 27854-350-01

Belmora LLC

SEDALMEX XL

flu

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCl - Nasal Decongestant

24 CAPLETS

Actual Size

Relieves: Fever, Headache, Cough, Sore Throat, Sinus Pressure & Chest Congestion

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Questions or Comments Call.

1-888-779-2877 M-F 9AM-5PM EST

Distributed by Belmora LLC, 3033 Wilson Blvd.
Suite 700, Arlington, VA 22201

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



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 1-888-779-2877
 M-F 9AM-5PM EST
 Distributed by Belmora LLC, 3033 Wilson Blvd,
 Suite 700, Arlington, VA 22201

WARNING: TAMPER EVIDENT. DO NOT USE IF PACKAGING IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.
 EXPOSURE OF TAMPER-NO UTILICE SI EL PAQUETE ESTÁ ABERTO O SI LA UNIDAD BLISTER ESTÁ ROTA, ROTURA O MUESTRA CUALQUIER SEÑAL DE TAMPERING

Drug Facts (continued)

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
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.

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Ask a doctor before use if you have ■ diabetes ■ liver disease ■ heart disease ■ thyroid disease ■ high blood pressure ■ difficulty in urination due to enlargement of the prostate gland ■ cough that occurs with too much phlegm (mucus)

FPO

LEVANTE AQUÍ PARA VER MÁS INFORMACIÓN SOBRE EL MEDICAMENTO

Drug Facts (continued)

■ persistent or chronic cough such 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.

When using this product do not exceed recommended dosage.

Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur ■ pain, cough, 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 ■ cough comes back or occurs with rash or headache that lasts. 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. 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

■ adults and children 12 years and over
 ■ take 2 caplets every 4 hours
 ■ do not take more than 10 caplets in 24 hours
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Other information ■ each caplet contains: sodium 3 mg

PEEL HERE FOR MORE DRUG FACTS

PARENTS:
 Learn about item medicina para

PADRES:
 Obsequen más información sobre el abono de medicamentos.
www.StoppMedicinaAbuse.org

No Print / No Yarnish
 Lot no. & Exp. date

Drug Facts
 KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION
Active ingredients (in each caplet)
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Uses
 ■ temporarily relieves these symptoms due to the common cold:
 ■ headache ■ nasal congestion ■ cough ■ sore throat
 ■ temporarily relieves these symptoms due to the common cold:
 ■ temporarily reduces fever
 ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

8-0090-546-08
 FEB10/22/06/08



SEDALMEX XL

Flu/Gripe

Acetaminophen/Acetaminofén
Pain Reliever/Fever Reducer • Analgésico/Reductor de Fiebre
Dextromethorphan HBr - Cough Suppressant • Dextrometorfano HBr - Antitusígeno
Guaifenesin - Expectorant • Guaifenesina - Expectorante
Phenylephrine HCl - Nasal Decongestant • Fenilefrina HCl - Descongestionante Nasal



24 CAPLETS
 Tabletas
 Actual Size/Tamaño Real



Relieves: Fever, Headache, Cough, Sore Throat, Sinus Pressure & Chest Congestion
Alivia: Fiebre, dolor de cabeza, tos, dolor de garganta, presión intestinal y congestión en el pecho

Drug Facts (continued)
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ see end flap for expiration date and lot number
Inactive ingredients corn starch, croscopolvidone, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide
Questions or comments? 1-888-779-2877
Información sobre el medicamento
Ingredientes activos (en cada tableta) **Propósito**

Información sobre el medicamento (continuación)
Advertencias
Advertencia sobre el hígado: Este producto contiene acetaminofén. Se puede presentar daño hepático grave si usted toma ■ más de 4,000 mg de acetaminofén en 24 horas ■ este producto con otros medicamentos que contengan acetaminofén ■ 3 o más tragos diarios de bebidas alcohólicas mientras utiliza este producto
Alerta sobre alergia: El acetaminofén puede causar reacciones cutáneas graves. Los síntomas pueden incluir: ■ enrojecimiento de la piel ■ ampollas ■ erupciones cutáneas
 Si se produce una reacción cutánea, deje de usar el producto y busque atención médica de inmediato.
Advertencia sobre el dolor de garganta: Si el dolor de garganta es severo, persiste por más de 2 días, está acompañado por

LIVE AREA

LIVE AREA

ADHESIVE AREA



Sedalmex 44-546

SEDALMEX XL FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-350
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	17mm

Flavor		Imprint Code	44;546	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-350-01	2 in 1 CARTON	03/24/2022	
1		12 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	03/24/2022		

Labeler - Belmora LLC (112753244)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(27854-350) , pack(27854-350)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(27854-350)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(27854-350)

Revised: 3/2024

Belmora LLC