

**NIGHTTIME COLD AND FLU MINI SOFTGELS- acetaminophen,
dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule,
liquid filled
Shield Pharmaceuticals Corp**

Nighttime Cold and Flu Mmini Softgels

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl - 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache • minor aches & pains • fever • runny nose & sneezing

Warnings

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

- more than 8 Softgels 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 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.

Ask a doctor before use if you have

- liver disease •glaucoma •cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema •trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not use more than directed n excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain 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
- 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 (1-800-222-1222) right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

- **take only as directed • do not exceed 8 softgels per 24 hrs**
- adults & children 12 yrs & over 2 Softgels with water every 6 hrs
- children 4 to under 12 yrs ask a doctor
- children under 4 yrs do not use

Other information

- store between 20-25°C (68-77°F).
- Avoid high humidity and excessive heat.
Protect from light.

Questions or comments?

1-800-373-6981 (toll-free)

Inactive ingredients

FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 10, gelatin, glycerin, isopropyl alcohol, MCT Oil, polyethylene glycol-400, propylene glycol, povidone, purified water, silver sheen, sorbitol solution

Distributed by:

Shield Pharmaceuticals Corp.

Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL

Nighttime

Cold & Flu Minni

Softgels

Carton

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER
UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

REV. 01/26
Made in India

Distributed by: **Shield Pharmaceuticals Corp.**
Ronkonkoma, NY 11779

Drug Facts (continued)

Other information

- store between 20°-25°C (68°-77°F)
- Avoid high humidity and excessive heat

ValuRx®

Compare to the
Active Ingredients
in Alka-Seltzer Plus®
Maximum Strength Nighttime
Cold & Flu PowerMax™ Gels*

mini softgels
smaller size, same strength

**Nighttime
Cold & Flu**

Maximum Strength

Acetaminophen - Pain reliever/fever reducer
Dextromethorphan HBr - Cough suppressant
Doxylamine succinate - Antihistamine
Phenylephrine HCl - Nasal decongestant

Relieves:

- Nasal Congestion
- Cough
- Sore Throat
- Headache & Body Ache
- Sinus Pressure
- Runny Nose

12 mini softgels

Actual Size

Drug Facts

Active ingredients (in each Softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg
Nasal decongestant

Purpose

Pain reliever/fever reducer

*This product is not
manufactured or
distributed by the
owner of the registered
trademarks
Alka-Seltzer Plus®
PowerMax™ Gels

Drug Facts (continued)

Uses

- temporarily relieves these symptoms due to a cold or flu:
■ minor aches and pains ■ headache ■ cough ■ nasal and sinus congestion ■ sore throat
■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
■ more than 8 Softgels 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 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
■ in children under 12 years of age

Ask a doctor before use if you have

- liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ cough with
excessive phlegm (mucus) ■ a breathing problem such as emphysema or chronic bronchitis
■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough
such as occurs with smoking, asthma, or emphysema

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 ■ may cause marked
drowsiness ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase
drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may
occur, especially in children

Stop use and ask a doctor if ■ 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 ■ nervousness, dizziness, or sleeplessness occurs

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 (1-800-222-1222) right away. Quick medical attention is critical for adults & for children
even if you do not notice any signs or symptoms.

Directions ■ do not take more than the recommended dose
■ adults & children 12 yrs & over: take 2 Softgels with water every 4 hrs. Do not exceed
10 softgels in 24 hours or as directed by a doctor ■ children under 12 yrs: do not use

FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 10, gelatin, glycerin,
isopropyl alcohol, MCT Oil, polyethylene glycol-400, propylene glycol, purified water, silver
sheen, sorbitol solution

Drug Facts (continued)

Inactive ingredients

isopropyl alcohol, MCT Oil, polyethylene glycol-400, propylene glycol, purified water, silver
sheen, sorbitol solution

Questions or comments? 1-800-373-6981

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NIGHTTIME COLD AND FLU MINI SOFTGELS

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83059-0129
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	SDM
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0129-1	1 in 1 CARTON	02/03/2026	
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	02/03/2026	

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 2/2026

Shield Pharmaceuticals Corp