

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 SIGN OF TAMPERING

REV. 01/26

Barcode: 3 83059 00017 8

Manufactured by: Shield Pharmaceuticals Corp.
Ronkonkoma, NY 11779

Drug Facts (continued)

ValuRx®
mini softgels
smaller size, same strength

Nighttime Cold & Flu Maximum Strength

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

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

Barcode: 000178

Drug Facts (continued)

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

Active Ingredients (in each Softgel)

Pain Reliever/Fever Reducer: Acetaminophen 25 mg
Cough Supressant: Dextromethorphan HBr 15 mg
Antihistamine: Doxylamine succinate 6.25 mg
Nasal Decongestant: Phenylephrine HCl 5 mg

Drug Facts (continued)

Uses

This product is not manufactured or distributed by The Bayer Health LLC, United States of America. Alka-Seltzer Plus® PowerMax™ Gels

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: Do not take 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 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

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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) | 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: PDC6A3C00X) | |
| 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