SEVERE DAYTIME NIGHTTIME COLD AND FLU RELIEF MAX STRENGTH- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl, guaifenesin
YET HEALTH GROUP LLC

YET (as PLD) - BARE & BETTER SEVERE DAYTIME/NIGHTTIME COLD & FLU RELIEF - MAX STRENGTH (81179-804)

NIGHTTIME SEVERE COLD & FLU

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

DAYTIME SEVERE COLD & FLU

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

NIGHTTIME SEVERE COLD & FLU

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

DAYTIME SEVERE COLD & FLU

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

NIGHTTIME SEVERE COLD & FLU

Uses

Temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

DAYTIME SEVERE COLD & FLU

Uses

Temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (musus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
- more than 8 softgels in 24 hours, 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.

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

NIGHTTIME SEVERE COLD & FLU

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 emphasema
- trouble urinating due to an enlarged prostate gland

DAYTIME SEVERE COLD & FLU

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

NIGHTTIME SEVERE COLD & FLU

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

DAYTIME SEVERE COLD & FLU

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

NIGHTTIME SEVERE COLD & FLU

When using this product
- do not exceed recommended dosage
- 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, and tranquilizers may increase drowsiness

DAYTIME SEVERE COLD & FLU

When using this product

do not use more than directed.

NIGHTTIME SEVERE COLD & FLU

Stop use and ask a doctor if
- you gets nervous, dizzy or sleepless
- 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
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

DAYTIME SEVERE COLD & FLU

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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
- 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 as well as for children even if you do not notice any signs or symptoms.

NIGHTTIME SEVERE COLD & FLU

Directions

- take only as directed
- do not exceed 8 softgels per 24 hrs

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

DAYTIME SEVERE COLD & FLU

Directions

- take only as directed
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adults & children 12 yrs & over	take 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; do not exceed 25°C (77°F)

NIGHTTIME SEVERE COLD & FLU

Inactive ingredients

D&C YELLOW #10, FD&C BLUE #1, GELATIN, GLYCERIN, POLYETHYLENE GLYCOL, POLYSORBATE, POVIDONE, PROPYLENE GLYCOL, PURIFIED WATER, SODIUM HYDROXIDE, SORBITOL SORBITAN SOLUTION, TITANIUM DIOXIDE.

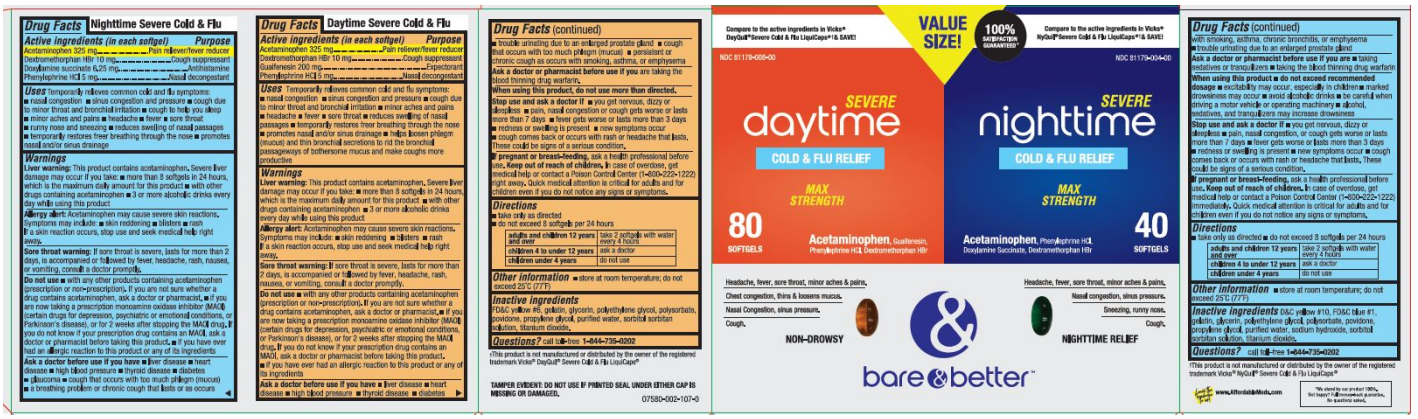
DAYTIME SEVERE COLD & FLU

Inactive ingredients

FD&C YELLOW #6, GELATIN, GLYCERIN, POLYETHYLENE GLYCOL, POLYSORBATE, POVIDONE, PROPYLENE GLYCOL, PURIFIED WATER, SORBITOL SORBITAN SOLUTION, TITANIUM DIOXIDE.

Questions?

CALL TOLL-FREE 1-844-735-0202



SEVERE DAYTIME NIGHTTIME COLD AND FLU RELIEF MAX STRENGTH

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl, guaifenesin kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81179-804

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81179-804-02	1 in 1 CARTON	09/02/2021	
1		1 in 1 BOTTLE; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	40 BOTTLE	40
Part 2	80 BOTTLE	80

Part 1 of 2

SEVERE NIGHTTIME COLD AND FLU RELIEF MAX STRENGTH

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

Product Information	
Item Code (Source)	NDC:81179-004
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
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**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 1000000 (UNII: HZ58M6D839)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics			
Color	green	**Score**	no score

Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	IS5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81179-004-00	1 in 1 BOTTLE; 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	09/02/2021	

Part 2 of 2

SEVERE DAYTIME COLD AND FLU RELIEF MAX STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source)	NDC:81179-008
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	IS4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81179-008-00	1 in 1 BOTTLE; 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	09/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/02/2021	

Labeler - YET HEALTH GROUP LLC (117763296)

Revised: 1/2024 YET HEALTH GROUP LLC