DAY AND NIGHT MULTI SYMPTOM COLD AND FLU RELIEF- day and night multi symptom cold and flu relief
Intrivo Diagnostics Inc.

Day and Night Multi Symptom Cold and Flu Relief

Active ingredient(s)

Active Ingredients (in each softgel)
Nighttime only
Acetaminophen 325mg
Dextromethorphan HBr 15mg
Doxylamine succinate 6.25mg

Active Ingredients (in each softgel)
Daytime only
Acetaminophen 325mg
Dextromethorphan HBr 10mg

Phenylephrine HCl 5mg

Purpose

Nighttime only
Pain reliever/fever reducer
Cough suppressant
Antihistamine

Daytime only
Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Use(s)

temporarily relieves common cold and flu symptoms:
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing
- nasal congestion (Daytime only)

Warnings

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

if you take

- more than 4 doses 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, lasts for more than 2 days, occurs with or followed by fever, headache, rash, nausea, or vomiting, see 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

- to make a child sleep (Nighttime only)

Ask a doctor before use if

- liver disease
- 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 an enlarged prostate gland
- glaucoma (Nighttime only)
- heart disease
- thyroid disease
- diabetes high blood sugar (Daytime only)

Ask a doctor or pharmacist before use if

you are taking the blood thinning drug warfarin

- taking sedatives or tranquilizers (Nighttime only)

When using this product

When using this product
- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drink
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if
- pain 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.
- you get nervous, dizzy or sleepless
- symptoms get worse or last more than 5 days (children) or 7 days (adults) (Daytime only)
  These could be signs of a serious condition.

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of reach of children

Taking more than directed can cause serious health problems. 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.

Directions

Directions (Nighttime only)
- take only as directed
- do not exceed 4 doses per 24 hours
  Adults and children 12 years and over: 2 softgels with water every 4 hours
  Children 4 to under 12 years: do not use
  Children under 4 years: ask a doctor

Directions (Daytime only)
- take only as directed
- do not exceed 4 doses per 24 hours
  Adults and children 12 years and over: 2 softgels with water every 6 hours
  Children 4 to under 12 years: do not use
  Children under 4 years: ask a doctor

Other information
- store at room temperature 20-25 °C (68-77° F)

- do not use if blister unit is torn or open

Inactive ingredients

Inactive ingredients (Nighttime only)

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white edible ink

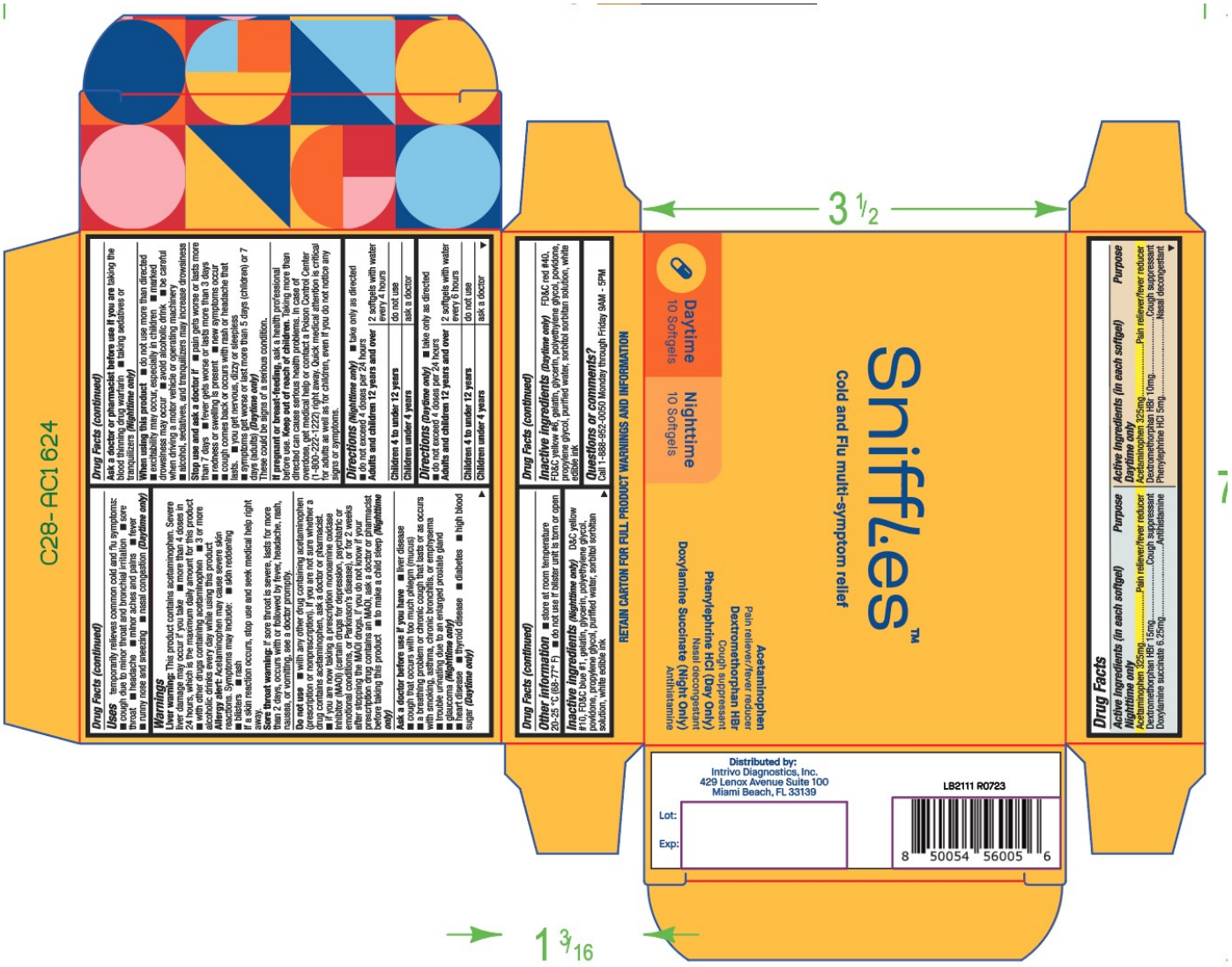
Inactive ingredients (Daytime only)

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white edible ink

Questions/Comments

Call 1-888-952-0050 Monday through Friday 9AM - 5PM

Principal Display Panel



Daytime and Nighttime softgels

DAY AND NIGHT MULTI SYMPTOM COLD AND FLU RELIEF

day and night multi symptom cold and flu relief kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83558-020

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83558-020-02	2 in 1 CARTON	10/28/2023	
1		1 in 1 CARTON; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity

Part 1	1 BLISTER PACK	10
Part 2	1 BLISTER PACK	10

Part 1 of 2

DAYTIME COLD AND FLU RELIEF

daytime cold and flu relief capsule, liquid filled

Product Information	
Item Code (Source)	NDC:83558-021
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	PC9
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:83558-	1 in 1 CARTON		

1	021-01	1 in 1 CARTON		
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	10/28/2023	

Part 2 of 2

NIGHTTIME COLD AND FLU RELIEF

nighttime cold and flu relief capsule, liquid filled

Product Information

Item Code (Source)	NDC:83558-022
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

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	green	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	PC10

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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	10/28/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/28/2023	

Labeler - Intrivo Diagnostics Inc. (118833259)

Revised: 10/2023 Intrivo Diagnostics Inc.