

SANATOS DAY AND NIGHT MULTI SYMPTOM- acetaminophen,dextromethorphan hbr,doxylamine succinate

Pharmadel

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Sanatos Daytime & Nighttime Liquicaps 12/12

Drug Facts

Active ingredients and Purposes

Daytime Relief

Active ingredients (in each liquicap)	Purposes
Acetaminophen 325 mg.....	Pain reliever/ fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Phenylephrine HCl 5 mg.....	Nasal decongestant

Nighttime Relief

Active ingredients (in each liquicap)	Purposes
Acetaminophen 325 mg.....	Pain reliever/ fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine

Use

Daytime Relief

Temporarily relieves common cold/flu symptoms:

- headache
 - minor aches and pains
 - sore throat
 - nasal and sinus congestion
 - stuffy nose
- Temporarily reduces fever

Nighttime Relief

Temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- headache
- minor aches and pains
- sneezing
- sore throat
- runny nose
- itchy nose or throat
- itchy, watery eyes due to hay fever
- Temporarily reduces fever

Warnings

Liver Warning:

Daytime & Nighttime

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
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy Alert: Acetaminophen

Daytime & Nighttime

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:

Daytime & Nighttime

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

Daytime & Nighttime

- 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.

- for more than 3 days for fever, unless directed by a doctor

Ask a doctor before use if you have

Daytime

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a cough that is accompanied by excessive phlegm(mucus)
- a persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to enlarged prostate gland

Nighttime

- liver disease
- glaucoma
- a cough that is accompanied by excessive phlegm (mucus)
- a breathing problem, persistent or chronic cough 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

Daytime

- taking the blood thinning drug warfarin

Nighttime

- taking sedatives or tranquilizers
- taking bloodthinning drug warfarin

Stop use and ask a doctor if

Daytime

- symptoms do not improve within 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache.
- new symptoms occur
- redness or swelling is present
- nervousness, dizziness, or sleeplessness occur. These could be signs of a serious condition.

Nighttime

- pain or cough gets worse or lasts more than 5 days
- redness or swelling is present
- new symptoms occur
- cough comes back, occurs with rash or a persistent headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

Daytime & Nighttime

ask a health professional before use.

Keep out of reach of children.

Daytime & Nighttime

In case of accidental 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

Daytime & Nighttime

- take only as directed
- do not exceed 4 doses in a 24-hour period
- even if taking both Daytime and Nighttime, total limit per day is 4 doses per 24 hour period
- adults & children 12 years & over: take two (2) liquicaps with water every 4 hours
- children 4 to under 12 years consult a doctor
- children under 4 years: do not use

Other information

Daytime & Nighttime

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

Inactive ingredients

Daytime

FD&C yellow #6, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol,

Nighttime

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, sorbitan, titanium dioxide.

Principal Display Panel

Sanatos ®

MULTI SYMPTOM / MULTI SÍNTOMAS

Daytime Relief / Alivio Durante el Día

Acetaminophen, Dextromethorphan HBr,
Phenylephrine HCl/Acetaminofén, Dextrometorfano HBr, Fenilefrina HCl

- Sore Throat / Dolor de Garganta
- Nasal Congestion / Congestión Nasal
- Aches & Fever / Dolores y Fiebre
- Headache / Dolor de Cabeza
- Cough / Tos

Non-Drowsy

No causa sueño

Daytime Liquicaps

12 Liquicaps de Dia

Sanatos ®

Nighttime Relief/Alivio Durante la Noche

Acetaminophen, Dextromethorphan HBr,
Doxylamine Succinate
Acetaminofén, Dextrometorfano HBr,
Sucinato de Doxilamina

- Sore Throat / Dolor de Garganta
- Aches & Fever / Dolor y Fiebre
- Runny Nose / Secreción Nasal
- Sneezing / Estornudos
- Cough / Tos

Nighttime Liquicaps

12 Liquicaps de Noche



SANATOS DAY AND NIGHT MULTI SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-142
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-142-24	1 in 1 CARTON	09/30/2018	
1		1 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2

SANATOS DAYTIME MULTI SYMPTOM

acetaminophen,dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	orange (Liquicap)	Score	score with uneven pieces
Shape	OVAL	Size	21mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		12 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/30/2018	

Part 2 of 2

SANATOS NIGHTTIME MULTI SYMPTOM

acetaminophen,dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green (Liquicap)	Score	score with uneven pieces
Shape	OVAL	Size	21mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		12 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

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OTC monograph not final	part343	09/30/2018	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part341	09/30/2018	

Labeler - Pharmadel (030129680)

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