SANATOS DAYTIME- acetaminophen, dextromethorphan, phenylephrine capsule, liquid filled
Pharmadel LLC

Sanatos Day Softgels (HL)

Drug Facts

Active ingredients and Purposes

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

Uses

Temporarily relieves common cold/flu symptoms
- headache
- minor aches and pains
- nasal congestion due to hay fever or other upper respiratory allergies
- sinus congestion and pressure
- and reduces fever

Warnings

Liver warning: This product contains **acetaminophen.** Severe liver damage may occur if you take
- more than 4 doses 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.

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

Ask a doctor before use if you have
- 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 an enlarged prostate gland

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

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

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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
- **do not exceed recommended dosage (see Liver warning)**
- do not exceed 4 doses in a 24 hour period

Age	**Dose**
adults and children 12 years and older	2 softgels every 6 hours
children 4 to under 12 years	consult a doctor
children under 4 years	do not use

Other information
- store between 68-77°F (20-25°C)

- avoid excessive heat
- do not use if blister pack unit is punctured or torn

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, methylparaben, polyethylene glycol 400, povidone k-30, propylene glycol, propylparaben, sorbitol, titanium dioxide, water.

Questions or comments?

+1-866-359-3478 (M-F) 9 AM - 5 PM EST or www.pharmadel.com

Distributed by:

Distributed by:

PHARMADEL LLC

New Castle, DE, 19720

/PHARMADELUSA

Principal Display Panel

NDC 5578-041-08

SanaTos®

Daytime Relief
Alivio Durante el Día

Acetaminophen
Dextromethorphan HBr,Phenylephrine HCl

Acetaminofén,
Dextrometorfano HBr, Fenilefrina HCl

- Cough / Tos
- Aches & Fever / Dolor y Fiebre
- Nasal & Sinus Congestion / Congestión Nasal

NON-DROWSY
NO CAUSA SUEÑO

Alcohol Free · Antihistamine Free
Sin Alcohol • Sin Antihistamínico

8 Softgels
8 Capulas blandas

SANATOS DAYTIME

acetaminophen, dextromethorphan, phenylephrine capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-041
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	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 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	SN2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-041-08	1 in 1 CARTON	04/04/2023	
1		8 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	04/04/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 9/2024 Pharmadel LLC