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

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**Sanatos Daytime Softgels (HHH)**

## *Drug Facts*

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## *Active ingredients and Purposes*

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| ***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 cough-cold symptoms
- cough due to minor throat and bronchial irritation
- headache
- minor aches and pains
- nasal congestion
- sinus congestion and pressure
- stuffy nose
- temporarily reduces fever

## *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
- 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.

**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
- difficulty urinating due to enlargement of the prostate gland

**When using this product**

**do not exceed recommended dosage**

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, cough or nasal congestions 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 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 4 doses in a 24 hour period

| Age | Dose |
|---|---|
| adults and children 12 years and older | 2 softgels every 4 hours, **do not exceed 6 doses in a 24 hour period** |
| 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, glycerol, polyethylene glycol 400, povidone k30, propylene glycol, sorbitol sorbitan solution, water

**Questions or comments?**

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

**Dist by/ por:**

**PHARMADEL LLC**

New Castle, DE 19720

www.pharmadel.com

**Principal Display Panel**


# SANATOS DAYTIME

acetaminophen, dextromethorphan, phenylephrine capsule, liquid filled

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:55758-508 |
| **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) | |
| **SORBITAN** (UNII: 6O92ICV9RU) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | red | **Score** | score with uneven pieces |
| **Shape** | CAPSULE | **Size** | 21mm |
| **Flavor** | | **Imprint Code** | CF01 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:55758-508-08 | 1 in 1 CARTON | 08/08/2025 | |
| **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 | 08/08/2025 | |

## Labeler - Pharmadel LLC (030129680)

Revised: 8/2025 Pharmadel LLC