

SANATOS MULTI SYMPTOM- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci tablet
Pharmadel LLC

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 MS Display 2x50 - Vovantis

Drug Facts

Active Ingredient & Purposes

Active ingredients (in each tablet)	Purposes
Acetaminophen 325 mg	Pain reliever/ fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

Temporarily relieves common cold/flu symptoms:

- minor aches & pains
- headache
- sore throat
- nasal congestion due to hay fever
- sinus congestion
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

Warnings

Liver Warning:

This product contains **acetaminophen**. Severe liver damage may occur if you take

- more than 8 tablets 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 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 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, ask a doctor or pharmacist before taking this product.
- for more than 7 days for pain and 3 days or fever, unless directed by a doctor.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin

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**
- **adults and children 12 years of age and over:**
- take 2 tablets every 6-8 hours; **do not exceed 8 tablets** in a 24-hour period
- **children under 12 years of age:** consult a doctor

Other information

- store at room temperature 59-86F (15-30C)
- avoid excessive heat and humidity

TAMPER EVIDENCE: Do not use if packet is open or torn.

Inactive ingredients

corn starch, microcrystalline cellulose, povidone-iodine, povidone k30, silicone dioxide, stearic acid, talc

Questions & comments?

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

Principal Display Panels

Display PDP



Packet PDP

NDC 55758-361-02 Contains 2 Tablets

SanaTos

COLD

MULTI -SYMPTOM

Acetaminophen,
Guaifenesin, Dextromethorphan HBr, Phenylephrine HCl

- Pain reliever / fever reducer
- Cough suppressant
- Expectorant
- Nasal decongestant



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-361
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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE-IODINE (UNII: 85H0HZU99M)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	A12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-361-02	2 in 1 PACKET; Type 0: Not a Combination Product	08/01/2020	
2	NDC:55758-361-99	50 in 1 CARTON	08/01/2020	
2	NDC:55758-361-02	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2020	

Labeler - Pharmadel LLC (030129680)

Revised: 5/2022

Pharmadel LLC