**SANATOS NIGHT- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid**
**Pharmalab Enterprises Inc**

*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.*

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**Drug Facts**

**Active Ingredients** **Purpose**

**(in each 15 mL tablespoon)**

Acetaminophen 500mg..... Pain Reliever/Fever Reducer

Dextromethorphan HBr 15mg..... Cough Suppressant

Doxylamine succinate 6.25mg.....Antihistamine

**Uses**: temporarily relieves common cold/flu symptoms:

- Cough due to Minor Throat and Bronchial Irritation
- Sore Throat
- Headache
- Minor Aches and Pains
- Fever
- runny nose and sneezing

**Warnings**: Do not exceed recommended dosage.

**Do not give to children under 12 years of age.**

Liver Toxicity may occur if:

- Recommended dosage is exceeded
- Used with other products containing acetaminophen
- Used with moderate amounts of alcohol

**Alcohol Warning**: If you consume 3 or more alcoholic drinks, ask your doctor whether you should take acetaminophen or other pain relievers. Acetaminophen may cause liver damage.
**Sore Throat Warning**: If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

**Do not use 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 two 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

**Stop Use and ask a doctor if you have:**

- Glaucoma
- Trouble urinating due to enlarged prostate gland
- Cough that occurs with too much phlegm(mucus)
- Persistent or chronic cough as occurs with smoking, asthma or emphysema
- Ask a doctor before use if you are taking sedatives or tranquilizers

**Ask a doctor before use if you** are taking sedatives or tranquilizers.

**When using this product, do not use more than directed**

- Excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- 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 or cough 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. This could be signs of a serious condition.

**If pregnant of breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning**: Taking more than the recommended dose can cause serious health problems. In case of 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:** Take only as recommended. See Overdose Warning.

- use dose cup or tablespoon(TBSP). **Do not use more than 4 doses in 24 hours**

Adults and children 12 years and older: Take 2 TBSP(30ml) every 6 hours, while symptoms persist or as directed by a doctor

Children under 12 years of age: Consult a doctor. Do not use this adult extra strength product in children under 12 years of age. This will provide more than the recommended dose(overdose) of acetaminophen and cause serious problems.

**Other information:**

- Store at controlled room temperature 15-30 C (59-86F)
- **each tablespoon contains: potassium 5 mg, sodium 18 mg.** Contains 10% alcohol.


Tos™

Flu

m Relief

Reducer

**Drug Facts** (continued)

**Alcohol warning:** If you consume 3 or more alcoholic drinks everyday, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

**Sore throat warning:** If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

**Do not use 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 two 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.

**Stop use and ask a doctor if you have**
■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ A breathing problem that lasts or occurs with smoking, asthma, chronic bronchitis or emphysema ■ trouble urinating due to enlarged prostate gland

**Ask a doctor before use if you** are taking sedatives or tranquilizers

**When using this product ■ do not use more than directed** ■ excitabilty may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ 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 or cough gets worse or lasts more than 7 days

**Drug Facts** (continued)

■ 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. This could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.**

**Overdose warning:** Taking more than the recommended dose can cause serious health problems. In case of 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:*** Take only as recommended. See Overdose Warning ■ use dose cup or tablespoon ( TBSP ). **Do not take more than 4 doses in 24 hours.**

**Drug Facts** (continued)

| | |
|---|---|
| Adults and children 12 years and older | Take 2 TBSP (30 mL) every 6 hours while symptoms persist or as directd by a doctor |
| Children under 12 years of age | Consult a doctor. Do not use this adult extra strength product in children under 12 years of age. This will provide more than the recommended dose (overdose) of acetaminophen and cause serious health problems. |

***Other information*** ■ store at controlled room temperature 15°-30°C ( 59°-86° F) ■ **Each tablespoon contains: potassium 5 mg, sodium 18 mg.** Contains 10% alcohol.

***Inactive ingredients*** Alcohol, citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate.

***Questions?*** (302) 725-0692

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# SANATOS NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:14505-399 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 500 mg in 15 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg in 15 mL |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg in 15 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C GREEN NO. 3** (UNII: 3P3ONR6O1S) | |
| **HIGH FRUCTOSE CORN SYRUP** (UNII: XY6UN3QB6S) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | green | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | ANISE (ANISE) | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:14505-399-06 | 177 mL in 1 BOTTLE, PLASTIC | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 02/04/2010 | |

## Labeler - Pharmalab Enterprises Inc (174401088)

## Registrant - Pharmalab Enterprises Inc (174401088)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Pharmalab Enterprises Inc | | 174401088 | manufacture |

Revised: 9/2010 Pharmalab Enterprises Inc