# DAY TIME GELCAP- acetaminophen, dextromethorphan, phenylephrine capsule, liquid filled Navarro Discount Pharmacies,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.

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#### **Drug Facts**

#### Active ingredients (in each GelCap)

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Phenylephrine HCl 5mg

#### **Purpose**

Pain reliever/fever reducer Cough suppressant Nasal decongestant

#### Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- nasal congestion

#### 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

**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 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
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phegm(mucus)
- Persistent or chronic cough as occurs with smoking, asthma, emphysema

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

taking the blood thinning drug warfarin.

When using this product, do not exceed the recommended dosage.

#### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- 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

#### Overdose warning:

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical to adults and children even if you do not notice any signs or symptoms.

#### **Directions**

- take only as directed-see Overdose warning
- do not exceed 4 doses per 24 hours

adults and children 12 yrs and over	2 GelCaps with water every 4 hrs	
children 4 to under 12 yrs	ask a doctor	
children under 4 yrs	do not use	

#### Other information

• store at room temperature

#### **Inactive ingredients**

FDC red no. 40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and sobitol special

Multi-Symptom

20 FL

Múltiples de Gripe/Influenza Cold

para el Día Relie Time



NDC #59970-077-12



Compare to active ingredients in Dayquil®\* Compare con los ingredientes activos en DayQuil®\*

Para Información en Español lea el Inserto

Non-Drowsy!

Alivia Síntomas Múltiples de Gripe / Influenza para el Día

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl Acetaminofeno, Dextrometorfano HBr, Clorhidrato de fenilefrina

- Relieves Fever Headache Sore Throat Stuffy Head Coughing

Alivia • Fiebre • Dolor de cabeza • Dolor de garganta • Cabeza congestionada • Dolor • Tos

Cápsulas de Gel

LOT & FXP LOTE & FECHA DE VENCIMIENTO



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Uses temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation sore throat headache minor aches and pains fever

#### nasal congestion

### Warnings

prostate gland

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with other drugs containing acetaminophen

3 or more alcoholic drinks daily while using this product

Sore throat warning: If sore throat is severe, lasts for more than 2 days occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use with any other drug containing acetaminophen(prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a ductor or pharmacist. If you are now taking a prescription monoamine oxidase inhibitor (MAOII)(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 ■ thyroid disease ■ diabetes ■ high blood pressure ■ cough that occurs with too much phlegm (mucus) a a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema ■trouble urinating due to enlarged

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#### Drug Facts (continued)

Stop use and ask a doctor if - you get dizzy, nervous or sleepless

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Directions
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children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information store at room temperature

Inactive ingredients FD&C red no. 40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and

- \*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Dayquile.
  \*Este product on oe stabricado ni distribuido por Procter & Gamble, propietario de la marca registrada Dayduile.

Exclusively distributed by: Distribuido exclusivamente po





Made In Korea

TAMPER EVIDENT: This package is safety sealed and child resistant. Use only if blisters are intact. If difficult to open, use scissors. Evidencia de alteración: Este paquete está sellado p mayor seguridad y es a prueba de niños. Utilice sólo si las ampollas están intactas. Si es dificil de abrir, use tijeras. Failure to follow these warnings could result in serious consequer El incumplimiento de estas advertencias puede resultar en consecuencias serias.

para

### DAY TIME GELCAP

acetaminophen, dextromethorphan, phenylephrine capsule, liquid filled

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59970-077
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	24mm
Flavor		Imprint Code	DYTIME
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:59970-077-12	1 in 1 BOX		
1	12 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 1/18/20 13	

## Labeler - Navarro Discount Pharmacies,LLC (094930963)

Revised: 1/2013 Navarro Discount Pharmacies,LLC