# ANTIGRIP NIGHTTIME- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hci powder, for solution 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.

-----

## ANTIGRIP Cold & Cough Nighttime

#### **Drugs Facts**

#### **Active Ingredients & Purposes**

Active ingredients (in each packet)	Purposes	
Acetaminophen 650	Pain reliever/ fever	
mg	reducer	
Dextromethorphan HBr 20	Cough suppressant	
mg	Cough suppressant	
Phenylephrine HCI 10 mg	Nasal decongestant	
Chlorpheniramine maleate 4 mg	Antihistamine	

#### Uses

Temporary relieves common cold/flu symptoms:

- sore throat
- headache
- muscular aches
- backaches
- minor aches and pains
- runny nose
- sneezing
- itching of the nose or throat
- stuffy nose
- itchy, watery eyes due to hay fever or other upper respiratory allergies
- nasal & sinus congestion
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

#### **Warnings**

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

- more than 6 packets in 24 hours, which is the maximum daily amount for this product
- 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 other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for more than 7 days for pain or 3 days for fever unless directed by a doctor
- if you are now taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask doctor or pharmacist before taking this product
- to sedate a child

## Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to enlargement of the prostate gland
- taking sedatives or tranquilizers
- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a cough is accompanied by excessive phlegm (mucus)

# Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

#### When using this product

- may cause drowsiness; alcohol, sedatives and tranquilizers may increase drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

#### Stop use and ask doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- redness or swelling is present
- nervousness, dizziness, or sleeplessness occurs
- a persistent cough or symptoms persists for more than 7 days, gets worse, tends to recur, or is accompanied by a fever, rash or persistent headache. 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 an 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 DOSE
- take every **4 hours**; **do not exceed 6 packets** in a 24 hour period
- dissolve the contents of one packet into 8 oz. glass of hot water and sip while hot; consume entire drink within 10-15 minutes
- if using a microwave; add contents of one packet to 8 oz. glass of cool water, stir briskly before and after heating. Do not overheat.

Age	Dose
adults and children 12 years of age and over	one packet every 4 hours
children under 12 years of age	do not use

#### Other information

- each packet contains: sodium 26.73 mg, potassium 9.71 mg
- **phenylketonurics:** contains phenylalanine 13 mg per packet
- store at room temperature 68-77°F (20-25°C)
- avoid excessive heat and moisture

**TAMPER EVIDENT:** Do not use if carton or packets are torn or punctured.

#### **Inactive ingredients**

acesulfame potassium, aspartame, citric acid, flavor, isopropyl alcohol, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate, water

#### Questions & comments?

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

#### PRINCIPAL DISPLAY PANEL

NDC 55758-313-18

ANTIGRIP® Nighttime Cold & Cough









# **ANTIGRIP NIGHTTIME**

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hci powder, for solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-313	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	650 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
WATER (UNII: 059QF0KO0R)			
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)			
ASPARTAME (UNII: Z0H242BBR1)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SUCROSE (UNII: C151H8 M554)			
TRIBASIC CALCIUM PHO SPHATE (UNII: 91D9 GV0 Z28)			

Product Characteristics			
Color		Score	
Shape		Size	

Flavor	LEMON	Imprint Code	
Contains			

I	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55758-313-18	18 in 1 CARTON	03/28/2019			
1		1 in 1 POUCH; 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	03/28/2019		

# Labeler - Pharmadel LLC (030129680)

Revised: 6/2020 Pharmadel LLC