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 Night Time

Drugs Facts

Active Ingredients & Purposes

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

Uses

For the temporary relief of the common cough and cold/flu symptoms:

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

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 10 days for pain unless directed by a doctor
- for more than 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 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 n heart disease
- high blood pressure
- thyroid disease
- diabetes n glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- a persistent or chronic cough as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin

When using this product
- may cause drowsiness; alcohol, sedatives and tranquilizers may increase drowsiness
- 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
- 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. 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. 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;** unless directed by a doctor
children under 6 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, artificial flavor, aspartame, citric acid, colloidal silicon dioxide, isopropyl alcohol, maltodextrin, tribasic calcium phosphate, sodium citrate, sucrose, water

Questions & comments?

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

PRINCIPAL DISPLAY PANEL

Oral Powder Solution/Solución oral de Polvo

NDC 55758-313-18

ANTIGRIP®

Nighttime/Noche

Cold & Cough/Gripe y Tos

Lemon/Limón

- Nasal Congestion/Congestión nasal
- Sore Throat Pain/Dolor de Garganta
- Body Ache/Dolor de Cuerpo
- Headache/Dolor de Cabeza
- Runny Nose/Secreción Nasal
- Sneezing/Estornudos
- Cough/Tos
- Fever/Fiebre

Acetaminophen/Acetaminofeno

Dextromethorphan HBr/Dextromethorphan HBr

Chlorpheniramine maleate/Maleato de clorfeniramina
Phenylephrine HCl/Fenilefrina HCL

18 Daytime Packets/Sobres de Día
per packet/por paquete 10g

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
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0KO0R)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	LEMON	**Imprint Code**	
Contains			

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: 3/2019 Pharmadel LLC