

ANTIGRIP DAYTIME- acetaminophen, 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 Daytime

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 HCl 10 mg.....	Nasal decongestant
.....	

Uses

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

- sore throat
- headache
- muscular aches
- backaches
- minor aches and pains
- nasal congestion due to hay fever
- other respiratory allergies
- sinus congestion and pressure
- 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 and 3 days or 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

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin

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 occur
- a persistent cough or symptoms persist 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

adults and children 12 years of age and over

Dose

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 14 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, silicone dioxide, sodium citrate, sucrose, tribasic calcium phosphate, water

Questions & comments?

PRINCIPAL DISPLAY PANEL

NDC 55758-314-18

ANTIGRIP® Daytime/Día

Cold & Cough/Gripe y Tos

Lemon/Limón

Product packaging for ANTIGRIP Daytime/Día Oral Powder Solution. Includes side panels with 'Datos Farmacológicos', 'Indicaciones', 'Contraindicaciones', and 'Efectos secundarios'. The main panel features the product name and 'Cold & Cough/Gripe y Tos'.

ANTIGRIP DAYTIME

acetaminophen, dextromethorphan hbr , phenylephrine hci powder, for solution

Table with 4 columns: Product Type (HUMAN OTC DRUG), Item Code (Source) (NDC:55758-314), Route of Administration (ORAL), and Strength (650 mg).

Table with 3 columns: Ingredient Name (ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)), Basis of Strength (ACETAMINOPHEN), and Strength (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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0K00R)	
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:55758-314-18	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)