ACETAMINOPHEN 500MG, DEXTROMETHORPHAN HBR 10MG, GUAIFENESIN 200MG, PHENYLEPHRINE HCL 5MG- acetaminophen 500mg, dextromethorphan hbr 10mg, guaifenes in 200mg, phenylephrine hcl 5mg tablet Strive Pharmaceuticals 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.

Cold & Flu - Gripa (Acetaminophen 325mg; Dextromethorphan HBr 10mg, Guaifenes in 200mg, Phenylephrine HCl 5mg)

Acetaminophen 325mg; Dextromethorphan HBr 10mg; Gauifenesin 200mg; Phenylephrine HCl 5mg colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C yellow#6, magnesium staerate, mica, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, stearic acid, talc

- take with a full glass of water
- do not take more than directed
- do not exceed 8 caplets per 24 hours

adults & children 12 years of age & over	2 caplets with water every 4 hours
children 4 to 12 years of age	ask a doctor
children under 4 years of age	do not use

^{*}temporarily relief of occasional heaches and minor aches and pains with accompanying sleeplessness

Liver warning:

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

- more than 8 caplets 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
- 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 ths product
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostrate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthama, chronic bronchitis, or emphysema

Ask a doctor or a pharmacist before use if you are

• taking the blood thinning drug warfarin

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, 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

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

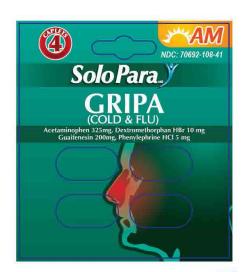
Overdose warning: In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

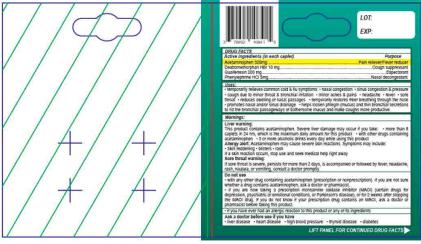
Keep out of reach of children

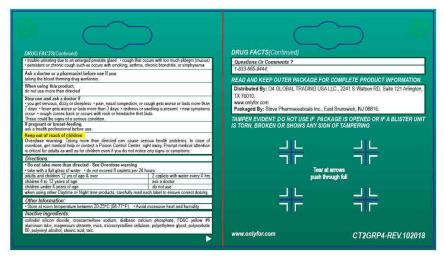
Overdose Warning: In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Pain reliever / fever reducer, cough suppressant, expectorant, nasal decongestant

- store at room temperature between 20 °C 25 °C (68 °F 77 °F)
- avoid excessive heat and humidity







GUAIFENESIN 200MG, PHENYLEPHRINE HCL 5MG

acetaminophen 500mg, dextromethorphan hbr 10mg, guaifenesin 200mg, phenylephrine hcl 5mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-108
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STEARIC ACID (UNII: 4ELV7Z65AP)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
MICA (UNII: V8A1AW0880)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
TALC (UNII: 7SEV7J4R1U)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		

Product Characteristics				
Color	orange	Score	no score	
Shape	CAPSULE	Size	19 mm	
Flavor		Imprint Code	S701	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:70692-108-41	4 in 1 PACKAGE; Type 0: Not a Combination Product	12/20/2018		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/20/2018	

Labeler - Strive Pharmaceuticals Inc (080028013)

Revised: 11/2020 Strive Pharmaceuticals Inc