FLONASE HEADACHE AND ALLERGY RELIEF- acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet
GlaxoSmithKline Consumer Healthcare Holdings (US) 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.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/Fever reducer

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
- sinus congestion and pressure
- runny nose and sneezing
- minor aches and pains
- nasal congestion
- headache
- temporarily relieves these additional symptoms of hay fever:
- itching of the nose or throat
- itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus openings and passages

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage

may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
    - 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:

- blisters
- rash
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- high blood pressure
- a breathing problem such as emphysema or chronic bronchitis
- heart disease
- liver disease
- thyroid disease
- glaucoma
- diabetes

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- drowsiness may occur

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur

- pain or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
  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 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 use more than directed
- adults and children 12 years of age and over:
  - take 2 caplets every 4-6 hours
  - swallow whole – do not crush, chew, or dissolve
  - do not take more than 10 caplets in 24 hours
- children under 12 years of age: ask a doctor

Other information

- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

benzyl alcohol, crospovidone, magnesium stearate, microcrystalline cellulose, modified corn starch, natural flavor, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, purified water, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-855-328-5259

Additional Information

KEEP CARTON FOR COMPLETE INFORMATION

Do not use if blister is broken or damaged.

Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

Principal Display Panel

NDC 0135-0578-03

FLONASE

HEADACHE &

ALLERGY RELIEF

NEW INGREDIENTS

Acetaminophen 325 mg Pain Reliever/Fever Reducer

Chlorpheniramine Maleate 2 mg Antihistamine

Phenylephrine HCl 5 mg Nasal Decongestant

FAST RELIEF FROM

- Allergy Symptoms
- Headache Pain
- Nasal Congestion

96 CAPLETS

B-0630-778-46 ORG – Front Carton

FLONASE HEADACHE AND ALLERGY RELIEF

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0578
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CROSPOVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	FRH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0578-01	1 in 1 CARTON	03/10/2022	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0578-02	4 in 1 CARTON	03/10/2022	
2		48 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0578-03	8 in 1 CARTON	03/10/2022	
3		96 in 1 BLISTER PACK; 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	03/10/2022	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Kangle Pharmaceutical Co., Ltd		421341487	API MANUFACTURE(0135-0578)