KGS ALLERGY SOOTHING- acetaminophen chlorpheniramine maleate capsule, delayed release pellets
Kingsway

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 capsule)

Acetaminophen 250 mg
Chlorpheniramine Maleate 2 mg

Purpose

Pain reliever

Antihistamine

Uses

■temporarily relieves these symptoms of hay fever and other upper respiratory allergies:

■runny nose and sneezing ■itchy, watery eyes

■temporarily relieves these additional symptoms of hay fever or other respiratory allergies:

■headache ■minor aches and pains

Warnings

Liver warning This product contains acetaminophen. The maximum daily dose of this product is 12 capsules in 24 hours. Severe liver damage many occur if you take ■ more than 4,000 mg of acetaminophen in 24 hours ■with other drugs containing acetaminophen ■3 or more alcoholic drinks daily while using this product.

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 have ever had an allergic reactionto this product or any of its ingredients

■to make a child sleepy

Ask a doctor before use if you have

■ liver disease ■ trouble urinating due to an enlarged prostate gland

■ a breathing problem such as emphysema or chronic bronchitis ■ Glaucoma

Ask a doctor or pharmacist if you are

■ taking the blood thinner drug, warfarin

■ taking sedatives or tranquilizers

When using this product

■ **do not exceed recommended dosage**

■ drowsiness may occur ■alcohol, sedatives and tranquilizers may increase drowsiness

■ avoid alcoholic drinks ■be careful when driving a motor vehicle or operating machinery

■ excitability may occur, especially in children

Stop use and ask a doctor if

■ nervousness, dizziness, or sleepleessness occur ■ pain 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

This could be signs of a serious condition

If pregnant or breast-feeding

ask a health professional before

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs of symptoms.

Directions

■ do not take more than directed (see Liver warning)

adults and children 12 years of age and over

■ take 2 caplets every 4 hours. ■swallow whole-do not crush, chew dissolve

■ do not take more than 12 capsules in 24 hours. ■ children under 12 years ask a doctor

Inactive ingredients

Caffeine, Carmine, Corn Starch, FDC Yellow 5, FDC Blue 1,hydroxy methylcellulose, Sugar

Package Label

KGS ALLERGY SOOTHING

acetaminophen chlorpheniramine maleate capsule, delayed release pellets

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63922-605
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE	CHLORPHENIRAMINE	

CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CAFFEINE (UNII: 3G6A5W338E)	
COCHINEAL (UNII: TZ8Z31B35M)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	white (clear)	**Score**	2 pieces
Shape	CAPSULE (Capsule)	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63922-605-01	1 in 1 BOX		
1	NDC:63922-605-12	12 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/30/2014	

Labeler - Kingsway (780573205)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Baiyunshan Guanghua Pharmacy Co.,Ltd.		527226626	manufacture(63922-605)

Revised: 2/2014 Kingsway