PERCOGESIC ORIGINAL STRENGTH- acetaminophen and diphenhydramine hcl tablet, coated
Medtech Products Inc.

Percogesic Original 63029-053

Drug Facts

Active Ingredients (in each tablet)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Active Ingredients (in each tablet)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

for temporary relief of minor aches and pains due to:

- headache
- backache
- muscular aches
- arthritis pain
- colds
- flu
- fever
- toothache
- premenstrual and menstrual cramps

Temporarily relieves

- runny nose
- sneezing
- itchy nose and throat

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur

if you take
- more than 8 tablets in 24 hours, which is the maximum daily amount
- 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.

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.
- with any other product containing diphenhydramine, even one used on skin
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor or pharmacist before use if you have
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

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

When using this product
- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may cause drowsiness
- may cause excitability, especially in children
- be careful driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- pain persists for more than 10 days
- fever persists for more than 3 days (unless directed by a doctor)
- condition worsens or new symptoms occur
- redness or swelling is present. These may be signs of a serious condition.

If you are pregnant or breast-feeding, ask a health care professional before use.

Keep out of the reach of children.

Overdose warning:

Taking more than the recommended dose (overdose) could cause serious health problems, including liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 dosage. Adults and children 12 years and older: take 2 tablets every 4-6 hours. Maximum daily dose is 8 tablets.

Children under 12 years of age: ask a doctor

Other Information

- store at controlled room temperature 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive Ingredients

Croscarmellose Sodium, FD&C Yellow #6 Lake, Hypromellose, Magnesium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Mineral Oil, Polyethylene Glycol, Polyvinylpyrrolidone, Pregelatinized Starch, Silica, Sodium Starch Glycolate and Stearic Acid

Questions?

1-800-443-4908

PRINCIPAL DISPLAY PANEL

ORIGINAL STRENGTH
Percogesic®
Acetaminophen/Diphenhydramine HCl

Aspirin-Free, Pain Reliever,
Fever Reducer/ Antihistamine

50 COATED TABLETS

PERCOGESIC ORIGINAL STRENGTH

acetaminophen and diphenhydramine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63029-053
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	Percogesic
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-053-90	1 in 1 BOX	03/19/2010	
1		90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63029-053-50	1 in 1 BOX	03/19/2010	
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:63029-053-24	1 in 1 BOX	03/19/2010	
3		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/19/2010	

Labeler - Medtech Products Inc. (122715688)

Revised: 3/2024 Medtech Products Inc.