PERCOGESIC EXTRA STRENGTH- acetaminophen and diphenhydramine capsule, coated
Medtech Products Inc.

Percogesic Extra Strength 63029-054

Drug Facts

Active Ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Active Ingredient (in each caplet)

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 6 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 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 your 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 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.

Do not exceed recommended dosage.

Directions

Adults and children 12 years of age and older: take 2 caplets every 6 hours. Maximum daily dose is 6 tablets. **Children under 12 years of age:** ask a doctor.

Other information

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

Inactive ingredients

croscarmellose sodium, FD&C yellow no. 6 lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyvinylpyrrolidone, silica, sodium carboxymethyl starch, starch, stearic acid, talc, titanium dioxide, triacetin

Questions?

1-800-443-4908

PRINCIPAL DISPLAY PANEL

EXTRA STRENGTH
Percogesic®
Acetaminophen/
Diphenhydramine

Fever Reducer/ Antihistamine

40 COATED CAPLETS

Drug facts (continued)

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Questions? 1-800-443-4908

Keep carton for complete information.

Tamper Evident: Do not use if imprinted safety seal under cap is broken or missing.

Drug Facts

Active ingredients *(in each tablet)* **Purposes**

Acetaminophen 500 mg.....Pain reliever/Fever reducer

Diphenhydramine HCl 12.5 mg.....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

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PERCOGESIC EXTRA STRENGTH

acetaminophen and diphenhydramine capsule, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63029-054
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	orange (peach colored)	**Score**	no score
Shape	CAPSULE	**Size**	10mm
Flavor		**Imprint Code**	ES;PER
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-054-60	1 in 1 CARTON	07/07/2010	
1		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63029-054-40	1 in 1 CARTON	07/07/2010	
2		40 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	07/07/2010	

Labeler - Medtech Products Inc. (122715688)

Revised: 2/2024 Medtech Products Inc.