ACETAMINOPHEN, DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen, diphenhydramine hydrochloride tablet, film coated
Major Pharmaceuticals

0752-Major

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep-aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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: ■ skin reddening ■ blisters ■ rash

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

Do not use

■ with any other product containing diphenhydramine, even one used on skin

■ in children under 12 years of age

■ 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 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

■ difculty in urination due to enlargement of the 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

■ avoid alcoholic beverages

■ do not drive a motor vehicle or operate machinery

■ drowsiness will occur

Stop use and ask a doctor if

■ sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness. ■ new symptoms occur

■ redness or swelling is present

■ pain gets worse or lasts more than 10 days

■ fever gets worse or lasts more than 3 days

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

Directions

■ **do not take more than directed (see overdose warning)**

■ **adults and children 12 years and over:** take 2 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours. ■ **children under 12 years:** do not use

Other information

store in a dry place at 15° – 30°C (59° – 86°F).

croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, mineral oil, polyvinylpyrrolidone, pregelatinized starch, silica, sodium starch glycolate, stearic acid, talc, titanium dioxide and triacetin

Questions or comments?

Call (800) 231-4670

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol®.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by:
MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
Questions or comments?
Call (800) 616-2471
www.majorpharmaceuticals.com

NDC 0904-6731-51

MAJOR

Extra Strength Acetaminophen PM Caplets

Acetaminophen and Diphenhydramine HCl

500mg/25mg

Pain Reliever/ Nighttime Sleep Aid

Compare to active ingredient oin Extra Strength TYLENOL PM*

50 Caplets

Drug Facts (continued)

Do not use ■ with any other product containing diphenhydramine, even one used on skin ■ in children under 12 years of age ■ 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 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 ■ difficulty in urination due to enlargement of the 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 ■ avoid alcoholic beverages ■ do not drive a motor vehicle or operate machinery ■ drowsiness will occur

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Drug Facts (continued)

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Inactive ingredients croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, mineral oil, polyvinylpyrrolidone, pregelatinized starch, silica, sodium starch glycolate, stearic acid, talc, titanium dioxide and triacetin

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Distributed by:
MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268

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MAJOR®

NDC 0904-6731-51

Compare to the active ingredients in Extra Strength Tylenol® PM*

Extra Strength

Acetaminophen PM

Acetaminophen and Diphenhydramine HCl

500 mg/25 mg

Pain reliever / Nighttime sleep-aid

50 Caplets

Rev. 10/23 M-29 Re-Order No. 700920

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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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ACETAMINOPHEN, DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen, diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6731
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POVIDONE K30 (UNII: U725QWY32X)	
TRIACETIN (UNII: XHX3C3X673)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	CPC752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6731-51	1 in 1 CARTON	12/26/2018	
1		50 in 1 BOTTLE; 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	12/26/2018	

Labeler - Major Pharmaceuticals (191427277)

Revised: 1/2024 Major Pharmaceuticals