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

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.

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 at room temperature

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) 616-2471

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM.

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

Distributed by:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

See New Warnings Information and Directions

NDC 0904-6731-51

MAJOR

Extra Strength Acetaminophen PM Caplets

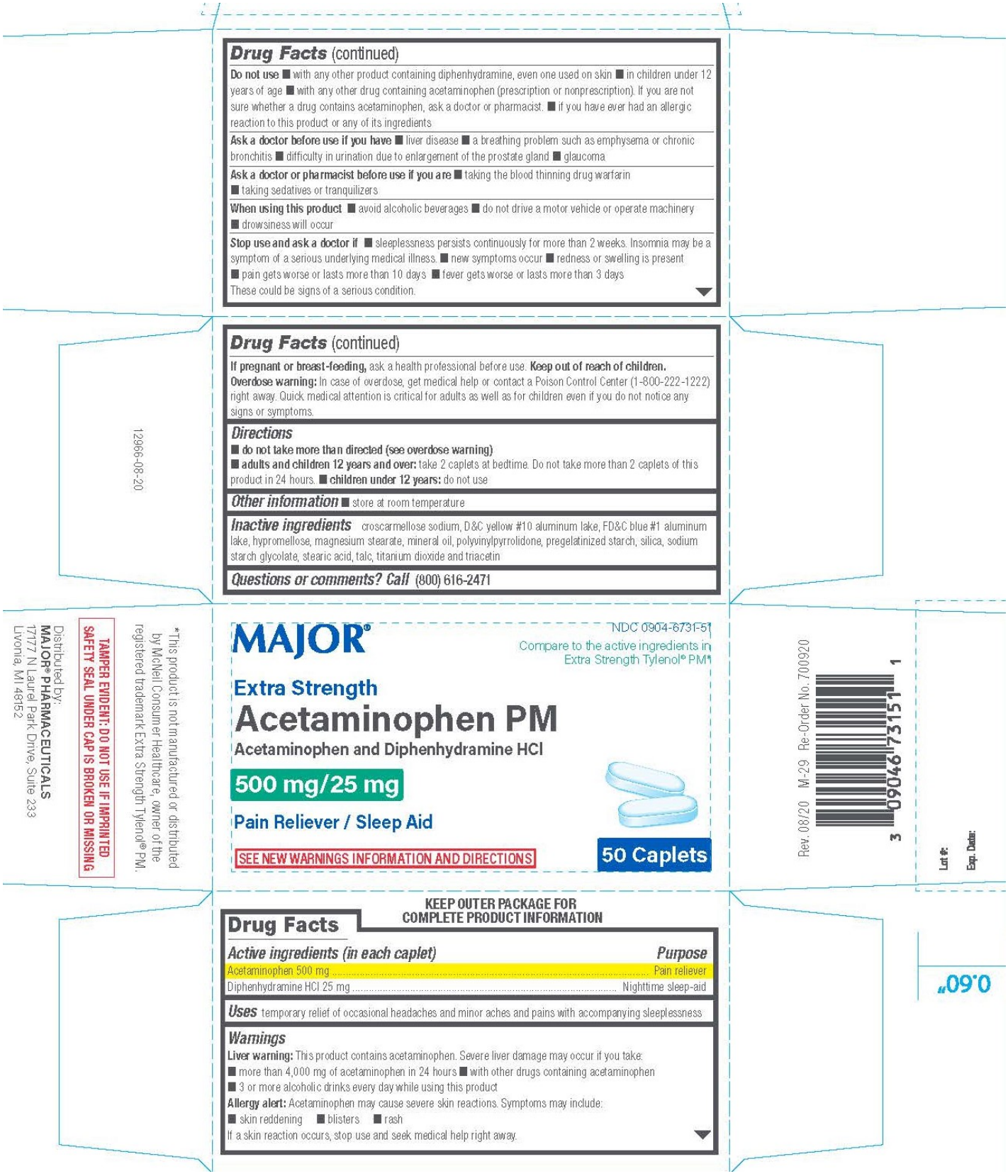
Pain Reliever

Sleep Aid

Acetaminophen 500 mg and **Diphenhydramine** HCl 25 mg each

Compare to active ingredient oin Extra Strength TYLENOL PM*

50 Caplets



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
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 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 not final	part343	12/26/2018	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2021 Major Pharmaceuticals