TYLENOL PM EXTRA STRENGTH- acetaminophen, diphenhydramine hydrochloride tablet, film coated
Jones Contract Packaging Services

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.

Tylenol PM Extra Stength

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

Warnings

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 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
- in children under 12 years of age
- 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 you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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 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 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 between 20-25°C (68-77°F)
- **do not use if carton is opened, or neck wrap or foil inner seal imprinted with "TYLENOL" is broken or missing**

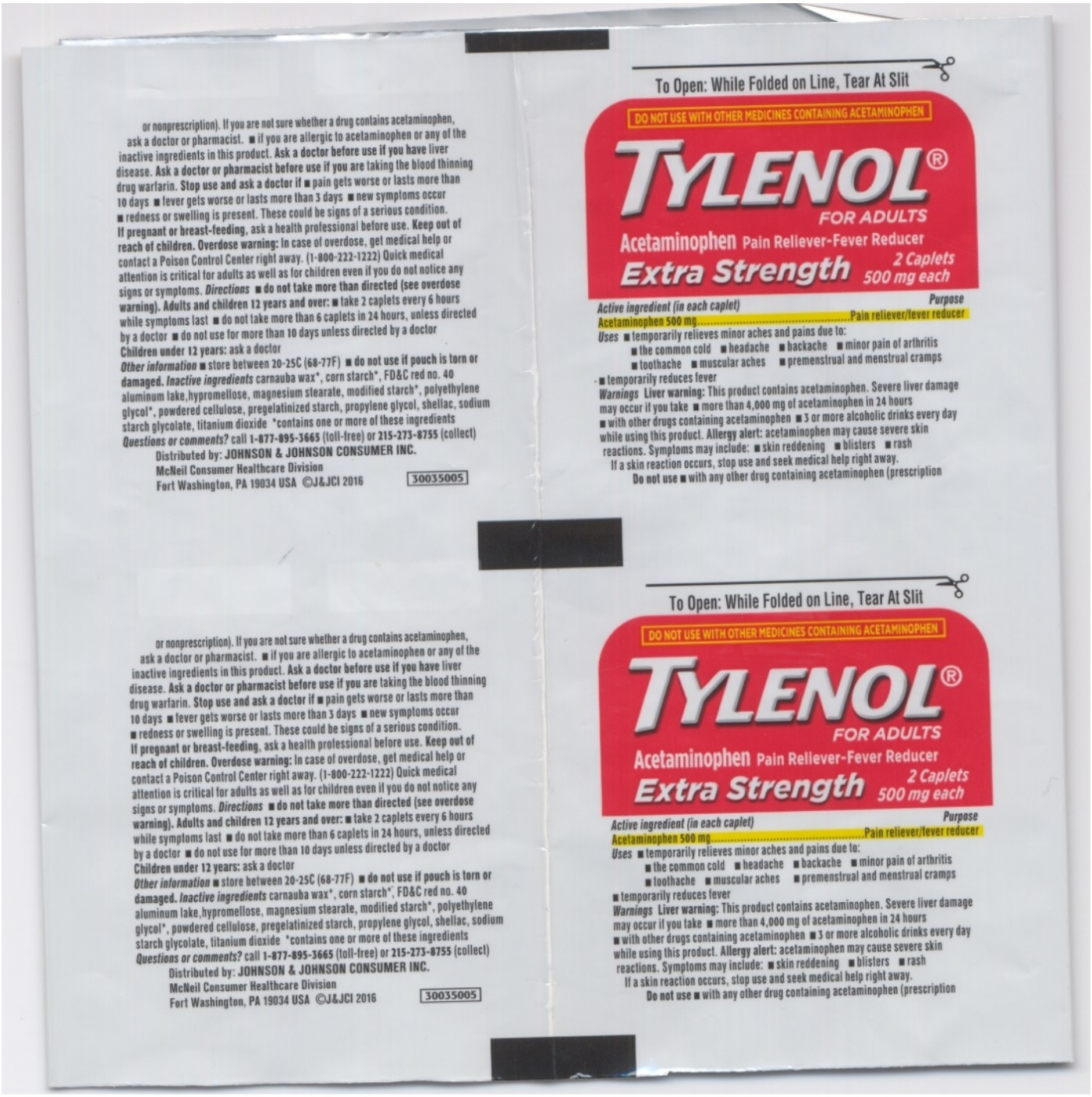
Inactive ingredients

carnauba wax, crospovidone, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

Tylenol 50 Pouches Tray



or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are allergic to acetaminophen or any of the inactive ingredients in this product. **Ask a doctor before use if you have liver disease. Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin. Stop use and ask a doctor if** ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present. 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 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 or symptoms. ***Directions*** ■ **do not take more than directed (see overdose warning). Adults and children 12 years and over:** ■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor **Children under 12 years:** ask a doctor ***Other information*** ■ store between 20-25C (68-77F) ■ **do not use if pouch is torn or damaged.** ***Inactive ingredients*** carnauba wax*, corn starch*, FD&C red no. 40 aluminum lake,hypromellose, magnesium stearate, modified starch*, polyethylene glycol*, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide *contains one or more of these ingredients ***Questions or comments?*** call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

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McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA ©J&JCI 2016 30035005

To Open: While Folded on Line, Tear At Slit

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

TYLENOL®
FOR ADULTS
Acetaminophen Pain Reliever-Fever Reducer
Extra Strength 2 Caplets 500 mg each

Active ingredient (in each caplet)	*Purpose*
Acetaminophen 500 mg	Pain reliever/fever reducer

Uses ■ temporarily relieves minor aches and pains due to:
■ the common cold ■ headache ■ backache ■ minor pain of arthritis
■ toothache ■ muscular aches ■ premenstrual and menstrual cramps
■ temporarily reduces fever

Warnings **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 drug containing acetaminophen (prescription

or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are allergic to acetaminophen or any of the inactive ingredients in this product. **Ask a doctor before use if you have liver disease. Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin. Stop use and ask a doctor if** ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present. 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 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 or symptoms. ***Directions*** ■ **do not take more than directed (see overdose warning). Adults and children 12 years and over:** ■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor **Children under 12 years:** ask a doctor ***Other information*** ■ store between 20-25C (68-77F) ■ **do not use if pouch is torn or damaged.** ***Inactive ingredients*** carnauba wax*, corn starch*, FD&C red no. 40 aluminum lake,hypromellose, magnesium stearate, modified starch*, polyethylene glycol*, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide *contains one or more of these ingredients ***Questions or comments?*** call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

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TYLENOL PM EXTRA STRENGTH

acetaminophen, diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67414-608
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (Light Blue)	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	TY;PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67414-608-06	50 in 1 TRAY	01/25/2018	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67414-608-00	2500 in 1 BOX	01/25/2018	
2		2 in 1 POUCH; 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	01/25/2018	

Labeler - Jones Contract Packaging Services (243697187)

Registrant - Jones Contract Packaging Services (243697187)

Establishment

Name	Address	ID/FEI	Business Operations
Jones Contract Packaging Services		243697187	pack(67414-608)

Establishment

Name	Address	ID/FEI	Business Operations
McNeil Healthcare LLC.		831188763	manufacture(67414-608)