ACETAMINOPHEN- acetaminophen tablet
TOPCO ASSOCIATES LLC

EXTRA STRENGTH
Pain Relief
ACETAMINOPHEN USP, 500 mg - PAIN RELIEVER / FEVER REDUCER
RAPID RELEASE

Active ingredient (in each gelcap)

Acetaminophen USP, 500 mg.

Purpose

Pain reliever/fever reducer

Uses

 temporarily relieves minor aches and pains due to:
 headache

 muscular aches
 backache

 minor pain of arthritis
 the common cold

 toothache
 premenstrual and menstrual cramps
 temporarily reduces fever

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

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

Drug Facts (continued)
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 gelcaps every 6 hours while symptoms last
 do not take more than 6 gelcaps 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 at 20°-25°C (68°-77°F)
 avoid high humidity
 see end panel for expiration date and lot number

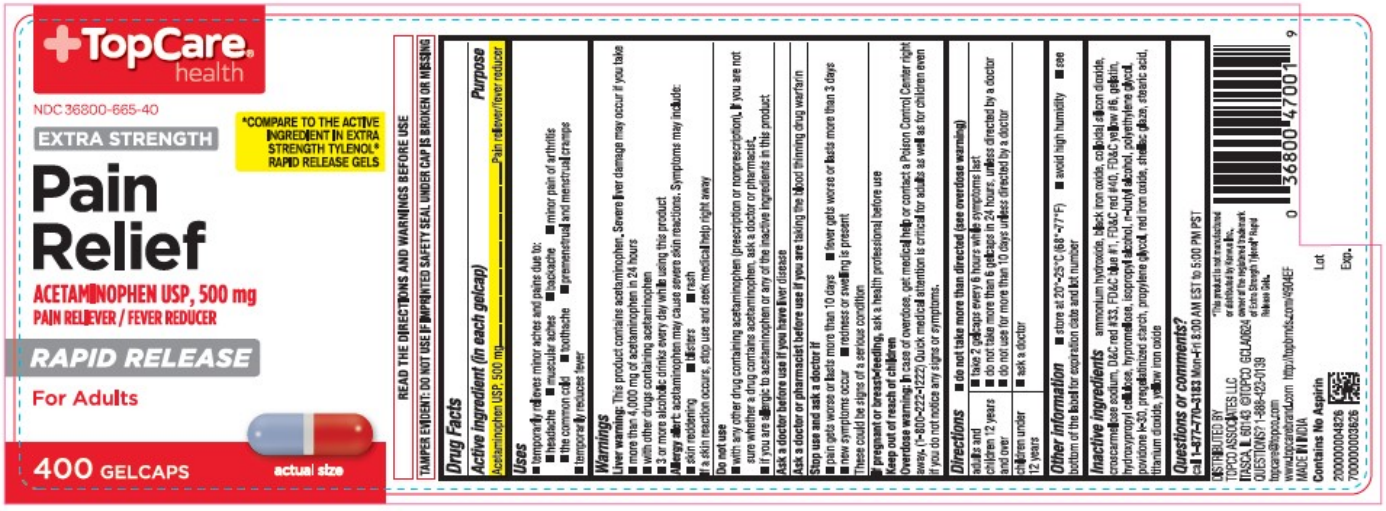
Inactive ingredients

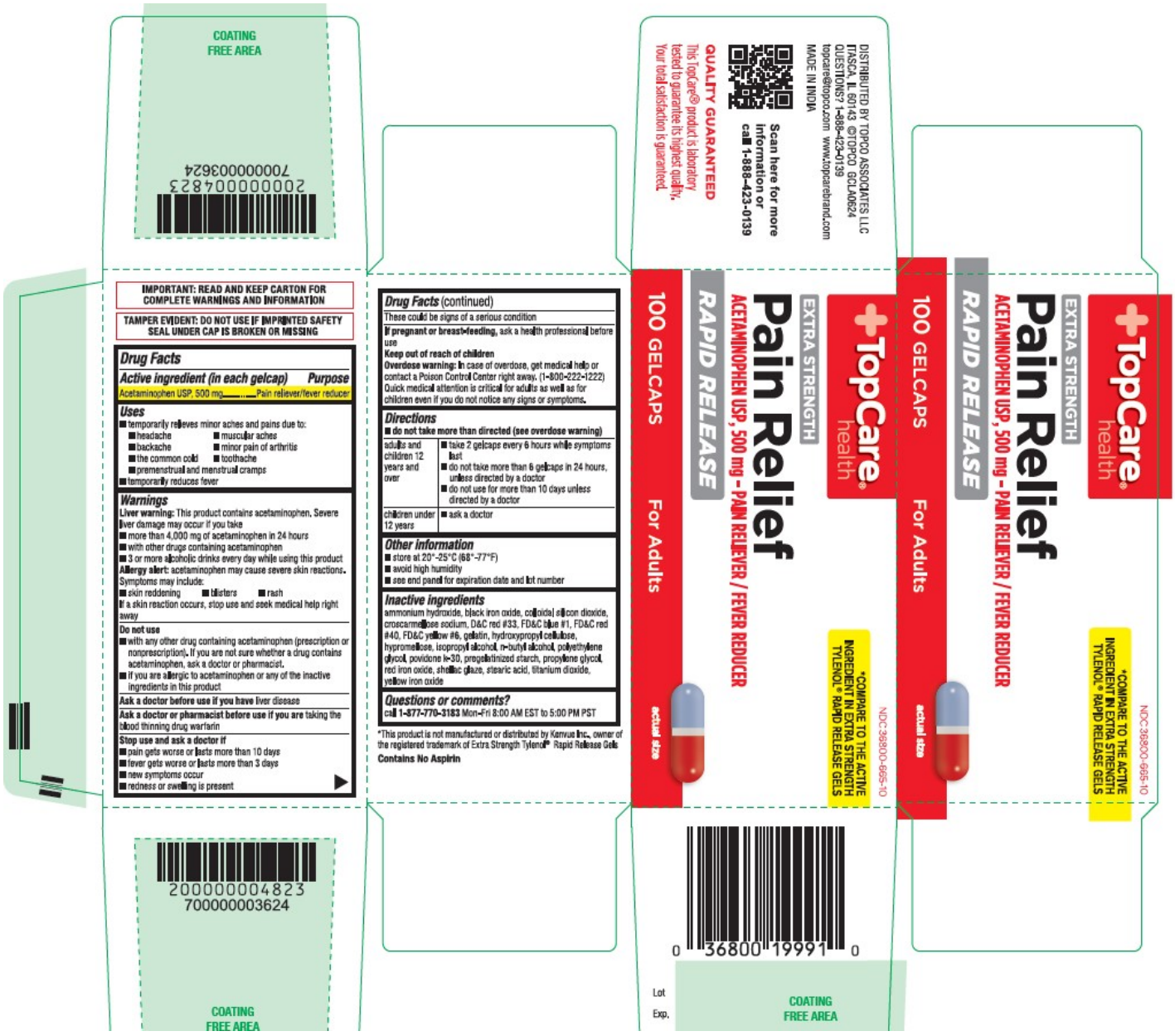
ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, p ovidone k-30, pregelatinized starch, propylene glycol, red iron oxide, shellac glaze, stearic acid, titanium dioxide, yellow iron oxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

Principal Display Panel





COATING
FREE AREA

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IMPORTANT: READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

Drug Facts

Active ingredient (in each gelcap) — **Purpose**

Acetaminophen USP, 500 mg ..... Pain reliever/fever reducer

Uses

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

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Drug Facts (continued)

These could be signs of a serious condition

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children under 12 years	■ ask a doctor

Other information

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ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone k-30, pregelatinized starch, propylene glycol, red iron oxide, shellac glaze, stearic acid, titanium dioxide, yellow iron oxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark of Extra Strength Tylenol® Rapid Release Gels

Contains No Aspirin

TopCare® health

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN USP, 500 mg – PAIN RELIEVER / FEVER REDUCER

RAPID RELEASE

100 GELCAPS

For Adults

actual size

*COMPARE TO THE ACTIVE INGREDIENT IN EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS

NDC:36800-665-10

TopCare® health

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Pain Relief

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100 GELCAPS

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NDC:36800-665-10

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QUALITY GUARANTEED

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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Lot

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COATING
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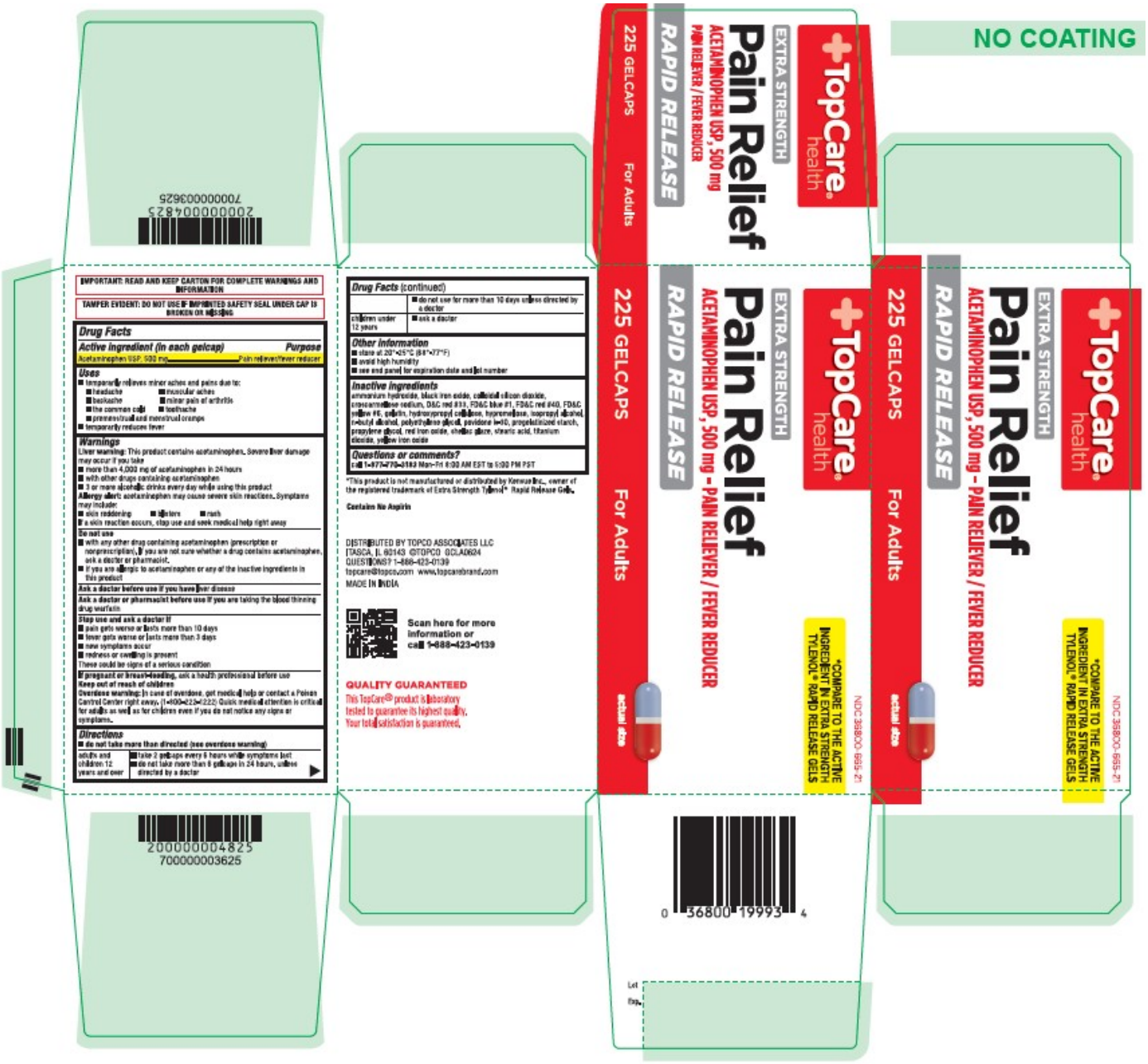

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-665
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SHELLAC (UNII: 46N107B71O)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	
AMMONIA (UNII: 5138Q19F1X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE K30 (UNII: U725QWY32X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	gray (Encapsulated with red opaque and blue gray opaque hard gelatin shells)	**Score**	2 pieces
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	G1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-665-21	225 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024	
2	NDC:36800-665-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024	
3	NDC:36800-665-40	400 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/14/2024	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 11/2024 TOPCO ASSOCIATES LLC