TOPCARE PAIN RELIEF PM EXTRA STRENGTH NON HABIT FORMINGacetaminophen, diphenhydramine hcl tablet, film coated Topco Associates LLC

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.

Topco Associates LLC. Pain Relief PM 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

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 l	pedtime
	•	than 2 caplets of this product in 24 hours

Inactive ingredients

carnauba wax, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions?

1-888-423-0139

Principal Display Panel

TopCare_® health

COMPARE TO EXTRA STRENGTH TYLENOL[®] PM ACTIVE INGREDIENTS

EXTRA STRENGTH

NIGHTTIME

Pain Relief PM

ACETAMINOPHEN 500 mg, DIPHENHYDRAMINE HCl 25 mg

PAIN RELIEVER • NIGHTTIME SLEEP-AID

Non-Habit Forming

50 CAPLETS

For Adults

actual size

ΡM



TOPCARE PAIN RELIEF PM EXTRA STRENGTH NON HABIT FORMING									
acetaminophen, diphenhydramine hcl tablet, film coated									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-437						
Route of Administration	ORAL								

Ingredient Name Basis of Strength Strength ACETAMINOPHEN (UMI: 36209TLD) (ACETAMINOPHEN - UMI:36209TLD) (DIPHENHYDRAMINE + VORCHLORIDE (UMI: TC2D6JAD40) ACETAMINOPHEN (DIPHENHYDRAMINE + VORCHLORIDE (UMI: TC2D6JAD40) Strength Inactive Ingredients Ingredient Name Strength Strength CARMAUBA WAX (UMI: R12CBM0EIZ) Ingredient Name Strength CARMAUBA WAX (UMI: R12CBM0EIZ) CROSPOVIDONE (15 MPA:S AT 5%) (UMI: 68401960MK) FORC BLUE NO. 1 (UMI: H3R47K3TBD) FORC BLUE NO. 1 (UMI: H3R47K3TBD) FORC BLUE NO. 1 (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 30XW25V3W0) POLYSORATE 80 (UMI: 60ZP392G8H) FOROUSONE, UMSPECIFIED (UMI: 30XW25V3W0) FOROUSONE, UMSPECIFIED (UMI: 30XW25V3W0) MAGNESIUM STEARATE (UMI: 328961948) Strength FOROUSONE, UMSPECIFIED (UMI: 30XW25V3W0) POLYSORATE 80 (UMI: 15F1X9V2)P) Strength FOROUSONE, UMI: 15F1X9V2)P) Product Ch	Active Ingredi	ent/Active Moiet	У					
AC ETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 500 mg DIPHENHYDRAMINE - UNII:8GT582583M) DIPHENHYDRAMINE - UNII:8GT5832583M) DIPHENHYDRAMINE - UNII:8725679/ FD6C BLUE NO. 1 (UNII: H3R47K3TBD) FD6C BLUE NO. 1 (UNII: 30097M6I30) MICROCRYSTALLINE CELUL05E (UNII: 300%255WLA) DIPHENHYDRAMINE - UNII: 6027392 G8H) DOVIDOR, UNSPECIFIED (UNII: 300%255WLA) DOVYSORBATE 80 (UNII: 6027392 G8H) DOVIDOR, UNSPECIFIED (UNII: 300%255WLA) DIPHENHYDRAMINE - UNII: 6027392 G8H) DOVIDOR, UNSPECIFIED (UNII: 300%255WLA) DIPHENHYDRAMINE GLYCOL UNII: 15F1X9V2P) DIFFACUE CLOURS - UNII: 6027392 G8H) DOVIDOR, UNSPECIFIED (UNII: 300%255WLA) DIPHENHYDRAMINE - UNII: 6027392 G8H) DOVIDOR, UNSPECIFIED (UNII: 300%255WLA) DIPHENHYDRAMINE (UNII: 6027392 G8H) DOVIDOR, UNSPECIFIED (UNII: 300%255WLA) DIPHENHYDRAMINE - UNII: 6027392 G8H) DOVIDOR, UNSPECIFIED (UNII: 300%255WLA) DIPHENHYDRAMINE - UNII: 6027392 G8H) DIPHENHYDRAMINE - UNII: 60276 DIFHENHYDRAMINE - UNII: 6027392 DIPHENHYDRAMINE - UNII: 6027392 DIPHENHYDRAMINE - UNII: 6027392 DIPHENHYDRAMINE - UNII: 602721/1992 DIPHENHYDRAMINE - UNII: 602721/19			-		Basis of St	renath	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6jAD40) DIPHENHYDRAMINE - UNII:8GTS82583M) Inactive Ingredients Ingredient Name Strength CARNAUBA WAX (UNII: R12CBM0EIZ) CROSPOVIDONE (LS MPA.S AT 3%) (UMI: 68401960MK) FD6C BLUE NO. 2 (UNII: R147/STBD) FD6C BLUE NO. 2 (UNII: D6K8R7DQK) HYPROMELLOSE, UNSPECIFIED (UNII: 3NX9293WO) MGCROCRYSTALLINE CELLULOSE (UNII: 091R32D610) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 8X900293WO) MGCROCRYSTALLINE CELLULOSE (UNII: 72989GH94E) STEARTE (UNII: 628932G8H) POLYODAE, UNSPECIFIED (UNII: 72989GH94E) STEARTE CALID (UNII: 8127265AP) TITANIUM DIOXIDE (UNII: 1578932J9) FOAC BLUE NO. 2 (UNII: 1578932J9) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 72989GH94E) STEARIC ACID (UNII: 4EUV7265AP) TITANIUM DIOXIDE (UNII: 1578932J9) POLYENBATE SUCULI: 5027932G8H) POLYENBATE SUCULI: 502793Z6H) POLYENBATE SUCULI SUCULI SUCULIAR SUCU	ACETAMINOPHEN							
Ingredient Name Strength CARNAUBA WAX (UNII: R12CEMOEIZ) Strength CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK) Strength Fb6C BLUE NO. 1 (UNII: H3R47K3TBD) Strength Fb6C BLUE NO. 2 (UNII: L3RX/237800) Strength Fb6C BLUE NO. 2 (UNII: L3RX/237800) Strength MCROCRYSTALLINE CELLUOSE (UNII: 3NX/29V3WO) MMGNESIUM STEARATE (UNII: 7097MGI30) MICROCRYSTALLINE CELLUOSE (UNII: 0P1R32D61U) POLYSORBATE 80 (UNII: 60ZP392G8H) POLYSORBATE 80 (UNII: 60ZP392G8H) Strength POVIDOE, UNISECFIEED (UNII: 3P393G1H3E) Strength STEARIC ACID (UNII: 4ELV7Z65AP) Strength TITTANIUM DIOXIDE (UNII: 15FIX9V2JP) Strength Product Characteristics Size Contains VAL Imprint Code L437;PM Packaging Marketing Start Marketing End Date 1 In 1 CARTON 07/21/1992 08/08/2015 1 S0 in 1 BOTTLE; Type 0: Not a Combination Product OTC: 36800-437. 1 in 1 CARTON 2 NOC:36800-437. 1 in 1 CARTON 07/21/1992 08/08/2015 2 </td <td colspan="3">DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)</td> <td></td> <td colspan="2">DIPHENHYDRAMINE</td> <td></td>	DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)				DIPHENHYDRAMINE			
Ingredient Name Strength CARNAUBA WAX (UNII: R12CEMOEIZ) Strength CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK) Strength Fb6C BLUE NO. 1 (UNII: H3R47K3TBD) Strength Fb6C BLUE NO. 2 (UNII: L3RX/237800) Strength Fb6C BLUE NO. 2 (UNII: L3RX/237800) Strength MCROCRYSTALLINE CELLUOSE (UNII: 3NX/29V3WO) MMGNESIUM STEARATE (UNII: 7097MGI30) MICROCRYSTALLINE CELLUOSE (UNII: 0P1R32D61U) POLYSORBATE 80 (UNII: 60ZP392G8H) POLYSORBATE 80 (UNII: 60ZP392G8H) Strength POVIDOE, UNISECFIEED (UNII: 3P393G1H3E) Strength STEARIC ACID (UNII: 4ELV7Z65AP) Strength TITTANIUM DIOXIDE (UNII: 15FIX9V2JP) Strength Product Characteristics Size Contains VAL Imprint Code L437;PM Packaging Marketing Start Marketing End Date 1 In 1 CARTON 07/21/1992 08/08/2015 1 S0 in 1 BOTTLE; Type 0: Not a Combination Product OTC: 36800-437. 1 in 1 CARTON 2 NOC:36800-437. 1 in 1 CARTON 07/21/1992 08/08/2015 2 </td <td>Inactivo Ingro</td> <td>dianta</td> <td></td> <td></td> <td></td> <td></td> <td></td>	Inactivo Ingro	dianta						
CARNAUBA WAX (UNII: R12CBM0EIZ) CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK) FD&C BLUE NO. 1 (UNIII: H3RATK3TBD) FD&C BLUE NO. 2 (UNII: ICARRATX3TBD) FD&C BLUE NO. 2 (UNII: ICARRATX3TBD) FDAC BLUE NO. 2 (UNII: ICARRATX3TBD) POLYSORBATE 30 (UNII: 602P392G8H) POLYSORBATE 30 (UNII: 612P392G8H) POLYSORBATE 30 (UNII: 612P392G8H) POLYSORBATE 30 (UNII: 15FIX9V2JP) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Product Characteristics Color BLUE (Light blue) Score no score Shape OVAL Size 18mm Flavor Contains PACKaging # Item Code Package Description Marketing Start Marketing End Date Marketing Information Product Marketing Information Marketing Information Marketing Information Marketing Start Marketing Start Marketing End DOI: 0.00 in 1.BOTTLE; Type 0: Not a Combination Product Marketing Information Marketing Start Marketing Start Marketing End DOI: 0.00 in 1.BOTTLE; Type 0: Not a Combination Product Marketing Information Marketing Start Marketing Start Marketing End Date MARANA END DATE MARKET MARANA END DAT	mactive mgre					-		
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK) Image: Cross of the second seco		-	redient Name			5	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD) Image: Status of the status of th			I: 68401960MK)					
FD&C BLUE NO. 2 (UNII: L06K8R7DQK) Improduct L06K2 Improduct L06K2 Improduct L06K2 Improduct L06K2 Improduct L06K2 Improduct L0K2 Improduct								
MAGNESIUM STEARATE (UNII: 70097M6i30) MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U) POLYSORBATE 80 (UNII: 60ZP392G8H) POVIDONE, UNSPECIFIED (UNII: 25989GH94E) STEARIC ACID (UNII: 4ELV7Z65AP) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) POUTOCHARACETISTICS Color BLUE (Light blue) Score no score Shape OVAL Size 18mm Flavor OVAL Size 18mm Flavor Contains PACKaging # Item Code Package Description 07/21/1992 NDC:36800-437- 1 in 1 CARTON 07/21/1992								
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) POLYSORBATE 80 (UNII: 60ZP392G8H) POVIDONE, UNSPECIFIED (UNII: F2989GH94E) STEARIC ACID (UNII: 4ELV7Z65AP) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Product Characteristics Color BLUE (Light blue) Score no score Shape OVAL Size 18mm Flavor Internet State State 1437;PM Contains Internet State State 1437;PM Packaging Marketing Start Date Marketing End Date 1437;PM Marketing End Date 11 in 1 CARTON 07/21/1992 08/08/2015 2 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 2 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 2 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 3 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 4 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 3 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 3 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 3 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 4 NDC:36800-437- 1 in 1 CARTON 07/21/1992 08/08/2015 3 NDC:	HYPROMELLOSE, U	JNSPECIFIED (UNII: 3N	1XW29V3WO)					
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDWLA) Image: Content of the system o	MAGNESIUM STEA	RATE (UNII: 70097M6I3	0)					
POLYSORBATE 80 (UNII: 60ZP392G8H) Image: Control of the system of th	MICROCRYSTALLIN	E CELLULOSE (UNII: (OP1R32D61U)					
POVIDONE, UNSPECIFIED (UNII: F2989GH94E) Image: Constant of the	POLYETHYLENE GI	YCOL, UNSPECIFIED	(UNII: 3WJQ0SDW1A)					
STEARIC ACID (UNII: 4ELV7265AP) Image: constant of the state o								
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Interface Interface <thinterface< th=""> Interface Interface</thinterface<>			H94E)					
Product Characteristics Color BLUE (Light blue) Score no score Shape OVAL Size 18mm Flavor Imprint Code L437;PM Contains Packaging Marketing Start Marketing End Date Packaging In 1 CARTON 07/21/1992 08/08/2015 1 NDC:36800-437- 1 1 in 1 CARTON 07/21/1992 08/08/2015 2 NDC:36800-437- 78 1 in 1 CARTON 07/21/1992 08/08/2015 2 NDC:36800-437- 78 1 in 1 CARTON 07/21/1992 08/08/2015 3 DOT ILE; Type 0: Not a Combination Product 07/21/1992 08/08/2015 4 Dot in 1 BOTTLE; Type 0: Not a Combination Product 07/21/1992 08/08/2015 3 DOT in 1 BOTTLE; Type 0: Not a Combination Product 07/21/1992 08/08/2015 4 Dot in 1 BOTTLE; Type 0: Not a Combination Product Marketing Start Date Marketing End Date 5 Application Number or Monograph Citation Marketing Start Date Marketing End Date	•							
Color BLUE (Light blue) Score no score Shape OVAL Size 18mm Flavor Imprint Code L437;PM Contains Packaging Marketing Start Date MDC:36800-437- 1 in 1 CARTON 07/21/1992 MDC:36800-437- 1 in 1 CARTON Marketing End Date MDC:36800-437- 1 in 1 CARTON 07/21/1992 MDC:36800-437- 1 in 1 CARTON Mar	ITTANIUM DIOXIDE	: (UNII: 15FIX9V2JP)						
NDC:36800-437- 71 Marketing Start Date Marketing End Date NDC:36800-437- 71 1 in 1 CARTON 07/21/1992 Marketing End Date NDC:36800-437- 71 1 in 1 CARTON 07/21/1992 08/08/2015 NDC:36800-437- 71 1 in 1 CARTON 07/21/1992 08/08/2015 NDC:36800-437- 78 1 in 1 CARTON Marketing End Date NDC:36800-437- 78 Application Number or Monograph Marketing Start Marketing End Date	Color Shape	BLUE (Light blue) Score OVAL Size		-			18mm	
# Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:36800-437- 71 1 in 1 CARTON 07/21/1992 07/21/1992 2 NDC:36800-437- 78 1 in 1 CARTON 07/21/1992 08/08/2015 3 100 in 1 BOTTLE; Type 0: Not a Combination Product 07/21/1992 08/08/2015 Marketing Information Marketing Start Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date OTC monograph not part343 07/21/1992 07/21/1992	Contains				-	2137,1		
# Item Code Package Description Date Date 1 NDC:36800-437- 71 1 in 1 CARTON 07/21/1992 07/21/1992 2 NDC:36800-437- 78 1 in 1 CARTON 07/21/1992 08/08/2015 3 NOC:36800-437- 78 1 in 1 CARTON 07/21/1992 08/08/2015	Packaging							
1 71 1 III T CARTON 07/21/1992 07/21/1992 1 50 in 1 BOTTLE; Type 0: Not a Combination Product 07/21/1992 08/08/2015 2 NDC:36800-437- 78 1 in 1 CARTON 07/21/1992 08/08/2015 2 100 in 1 BOTTLE; Type 0: Not a Combination Product 07/21/1992 08/08/2015 2 100 in 1 BOTTLE; Type 0: Not a Combination Product 07/21/1992 08/08/2015 Marketing Information Marketing Category OTC monograph not part343 07/21/1992		Package	Package Description		-		-	
Image: Product in the product in th	1	. in 1 CARTON 07/21/19		92				
2 78 1 III 1 CARTON 07/21/1992 06/06/2013 2 100 in 1 BOTTLE; Type 0: Not a Combination Product 100 in 1 BOTTLE; Type 0: Not a Combination 100 Marketing Information Application Number or Monograph Citation Marketing Start Date Marketing End Date OTC monograph not part343 07/21/1992 07/21/1992	1							
Product Product Marketing Information Marketing Start Citation Number or Monograph Citation Marketing Start Date Marketing End Date OTC monograph not part343 07/21/1992 07/21/1992				07/21/19	221/1992 08/08/		8/2015	
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not or mart343part34307/21/1992	2							
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph not or mart343part34307/21/1992								
CategoryCitationDateDateOTC monograph not DTC monograph notpart34307/21/1992	Marketing I	nformation						
					-		-	
	OTC monograph not final	part343		07/21/	1992			

Labeler - Topco Associates LLC (006935977)

Revised: 4/2023

Topco Associates LLC