TYLENOL EXTRA STRENGTH / TYLENOL PRECISE COOLING PAIN RELIEF- acetaminophen, lidocaine, menthol
Kenvue Brands LLC

TYLENOL® EXTRA STRENGHT / TYLENOL® PRECISE COOLING PAIN RELIEF

Drug Facts

Drug Facts

Active ingredient (in each gelcap)

Acetaminophen 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

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 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 between 20-25°C (68-77°F). Avoid high humidity.
■ **do not use if carton is opened. Do not use if foil inner seal imprinted with**

“TYLENOL” is broken or missing.

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, D&C yellow no. 10, edetate calcium disodium, FD&C blue no. 1, FD&C red no. 40, gelatin, hypromellose, iron oxide, magnesium stearate, methylparaben, modified starch, polyethylene glycol, polysorbate 80, powdered cellulose, pregelatinized starch, propylene glycol, propylparaben, red iron oxide, sodium lauryl sulfate, sodium propionate, sodium starch glycolate, titanium dioxide, yellow iron oxide

Questions or comments?

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

Drug Facts

Active Ingredient

Lidocaine 4%

Menthol 1%

Purpose

Topical analgesic

Topical analgesic

Uses

For the temporary relief of pain

Warnings

For external use only.

Do not use

■ in large quantities, particularly over raw surfaces or blistered areas

When using this product

■ avoid contact with eyes

Stop use and ask a doctor if

■ condition worsens or symptoms persist for more than 7 days

■ symptoms clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ use only as directed
■ adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
■ children under 12 years of age: ask a doctor

Other Information

store at 15 ° to 30 ° C (59 ° to 86 ° F)

Inactive Ingredients

carbomer copolymer, cetearyl olivate, cetyl alcohol, fragrance, glycerin, isopropyl palmitate, phenoxyethanol, sodium polyacrylate, sorbitan olivate, water

Questions?

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PRINCIPAL DISPLAY PANEL

NDC 50580-142-01

Extra Strength

TYLENOL ®

FOR ADULTS

Acetaminophen
Pain Reliever
Fever Reducer

RAPID RELEASE GELS

Actual Size

225 Gelcaps*
500 mg each

*Gelatin-Coated Tablets

+ FREE BONUS ITEM

TYLENOL ®

PRECISE ™

Cooling†

Pain Relieving Cream

Lidocaine 4% **Menthol** 1%

Fast acting †

Targeted penetrating

pain relief

Maximum Strength Lidocaine

without a prescription

LIGHTLY SCENTED

For external use only

NET WT. 0.5 OZ (14.2 g)

TYLENOL EXTRA STRENGTH / TYLENOL PRECISE COOLING PAIN RELIEF

acetaminophen, lidocaine, menthol kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-142

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-142-01	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	11/25/2024	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	225
Part 2	1 TUBE	14.2 g

Part 1 of 2

TYLENOL EXTRA STRENGTH

acetaminophen tablet, coated

Product Information	
Item Code (Source)	NDC:50580-490
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM PROPIONATE (UNII: DK6Y9P42IN)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

Product Characteristics

Color	blue, red, gray	**Score**	no score
Shape	OVAL	**Size**	21mm
Flavor		**Imprint Code**	TY;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-490-25	1 in 1 CARTON		
1		225 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	04/30/2021	

Part 2 of 2

TYLENOL PRECISE COOLING PAIN RELIEVING

lidocaine, menthol cream

Product Information

Item Code (Source)	NDC:69968-0793
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69968-0793-1	1 in 1 CARTON		
1		14.2 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	M017	11/25/2024	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	M013	11/25/2024	

Labeler - Kenvue Brands LLC (118772437)

Revised: 11/2024 Kenvue Brands LLC