EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY- acetaminophen, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide tablet, film coated
Johnson & Johnson Consumer Inc.

Extra Strength TYLENOL Cold + Flu Multi-Action

Day

Drug Facts

Active ingredients (in each caplet)	***Purpose***
Acetaminophen 500 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Pseudoephedrine HCl 30 mg	Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- promotes nasal and sinus drainage
- 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.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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 now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dose

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

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 - 25°C (68 - 77°F).
- **do not use if blister unit is torn or broken**

Inactive ingredients

carnauba wax, hypromellose, magnesium stearate, microcrystalline cellulose, powdered cellulose, pregelatinized starch, propylene glycol, sodium starch glycolate, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-344-01

Extra Strength

TYLENOL ®

FOR ADULTS

COLD + FLU MULTI-ACTION

Acetaminophen,

Dextromethorphan HBr, Pseudoephedrine HCl

Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant

DAY

NON-DROWSY

- HEAD + BODY ACHES
- FEVER + SORE THROAT
- COUGH
- NASAL CONGESTION

Actual Size

24 CAPLETS

EXTRA STRENGTH TYLENOL COLD PLUS FLU MULTI-ACTION DAY

acetaminophen, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide tablet, film

coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-344
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	TY;COLD;1408
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-344-01	2 in 1 CARTON	06/21/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/21/2021	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.