

DOLEX FORTE- acetaminophen, aspirin, caffeine tablet

Pharmadel LLC

Dolex Forte (HHH Pharma)

Active ingredients and Purposes

.

Active ingredients	Purposes
Acetaminophen 250 mg.....	Pain reliever
Aspirin 250 mg (NSAID*).....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid

* nonsteroidal anti-inflammatory drug

Drug Facts

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Uses

Temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- toothache
- premenstrual and menstrual cramps and bloating

Warnings

Reye's syndrome:Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

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.

Allergy alert: Aspirin (NSAID) may cause severe allergic reactions. Symptoms may include:

- hives

- facial swelling
- asthma (wheezing)
- shock

Liver warning: This product contains **Acetaminophen**. Severe liver damage may occur if you take

- more than **8 tablets in 24 hours**, which is the maximum daily amount
- with other drugs containing **acetaminophen**
- 3 or more alcoholic drinks everyday while using this product

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (**NSAID**), which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription **NSAIDs** (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks everyday while using this product
- take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally a rapid heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing **acetaminophen** (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- you have asthma
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood

- have bloody or black stools
- have stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms appear.

These could be signs of a serious condition.

If pregnant or breastfeeding,

ask a health professional before use. It is especially important not to use **aspirin** during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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 WARNINGS)**
- **adults and children 12 years of age and older:** take two (2) tablets every 6 hours with a full glass of water. Do not take more than **8 tablets** in 24 hours.
- **children under 12 years of age:** consult a doctor

Other information

- store between 68-77°F (20-25°C)
- keep box for important information
- read all product information before use

Inactive ingredients

corn starch, hypromellose, microcrystalline cellulose, polyethylene glycol 400, povidone k30, silicon dioxide, stearic acid, talc, water

Dist. by/ por:

Pharmadel LLC

New Castle, DE 19720

Questions? +1-866-359-3478

**This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength

Principal Display Panel

DOLEX[®]

FORTE

EXTRA STRENGTH

- Headache
- Fever reducer
- Muscular Aches



24 TABLETS†

†Capsule-Shaped Tablet

NDC 55758-509-24



COMPARE TO THE ACTIVE INGREDIENTS
IN EXCEDRIN[®] EXTRA STRENGTH**

Acetaminophen,

Aspirin (NSAID), Caffeine

DOLEX FORTE

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-509
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE K30 (UNII: U725QWY32X)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	CAPSULE ((Capsule-Shaped Tablet))	Size	17mm
Flavor		Imprint Code	HH6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-509-24	1 in 1 CARTON	08/12/2025	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55758-509-50	25 in 1 BOX	08/12/2025	
2	NDC:55758-509-02	2 in 1 PACKET; 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	08/12/2025	

