

**DOLEX FORTE- acetaminophen, aspirin, caffeine tablet**  
**Pharmadel LLC**

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**Dolex Forte (HPHARMA)**

**Drug Facts**

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**Active ingredients and Purposes**

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**Active ingredients**

Acetaminophen 250 mg.....  
Aspirin (**NSAID\***) 250 mg .....  
Caffeine 65 mg.....

**Purposes**

Pain reliever  
Pain reliever  
Pain reliever aid/ diuretic

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\* nonsteroidal anti-inflammatory drug

**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: Aspirin (NSAID)** may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

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

- adult takes more than **4 doses** in 24 hours, which is the maximum daily amount

- child takes more than **3 doses** in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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 the user:

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

**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 the user has 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 the user**

- has liver disease
- has a history of stomach problems, such as heartburn
- has high blood pressure, heart disease, liver cirrhosis, or kidney disease
- takes a diuretic
- has not been drinking fluids
- has lost a lot of fluid due to vomiting or diarrhea
- is a child with pain of arthritis
- has asthma

### **Ask a doctor before use if**

- a stomach bleeding warning applies to user

### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- users experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - has bloody or black stools
  - has stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- taking a prescription drug for diabetes, gout, or arthritis
- adult's pain gets worse or lasts for more than 10 days

- child's pain gets worse or lasts for more than 5 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- new symptoms occur

**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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

***Directions***

- **adults and children 12 years and over:** two (2) caplets every 6 hours with a full glass of water with each dose. Do not exceed; **adults 8 caplets** and **children 6 caplets** in 24 hours .
- **children under 12 years of age:** consult a doctor

***Other information***

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

**Inactive ingredients**

corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

**Questions?**

**1-866-359-3478** (M-F) 9AM to 5PM EST or [www.pharmadel.com](http://www.pharmadel.com)

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**PHARMADEL LLC**

New Castle, DE, 19720

**Principal Display Panel**

# DOLEX<sup>®</sup>

## FORTE

**EXTRA STRENGTH  
EXTRA FUERTE**



**Acetaminophen, Aspirin (NSAID), Caffeine**  
**Acetaminofén, Aspirina (AINE), Cafeína**

**Pain Reliever/ Alivia el Dolor**

- Headache
- Arthritis
- Muscular aches
- Premenstrual and Menstrual cramps
  
- Dolor de cabeza
- Artritis
- Dolores musculares
- Calambres premenstruales y menstruales



### DOLEX FORTE

acetaminophen, aspirin, caffeine tablet

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55758-306
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

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

## Inactive Ingredients

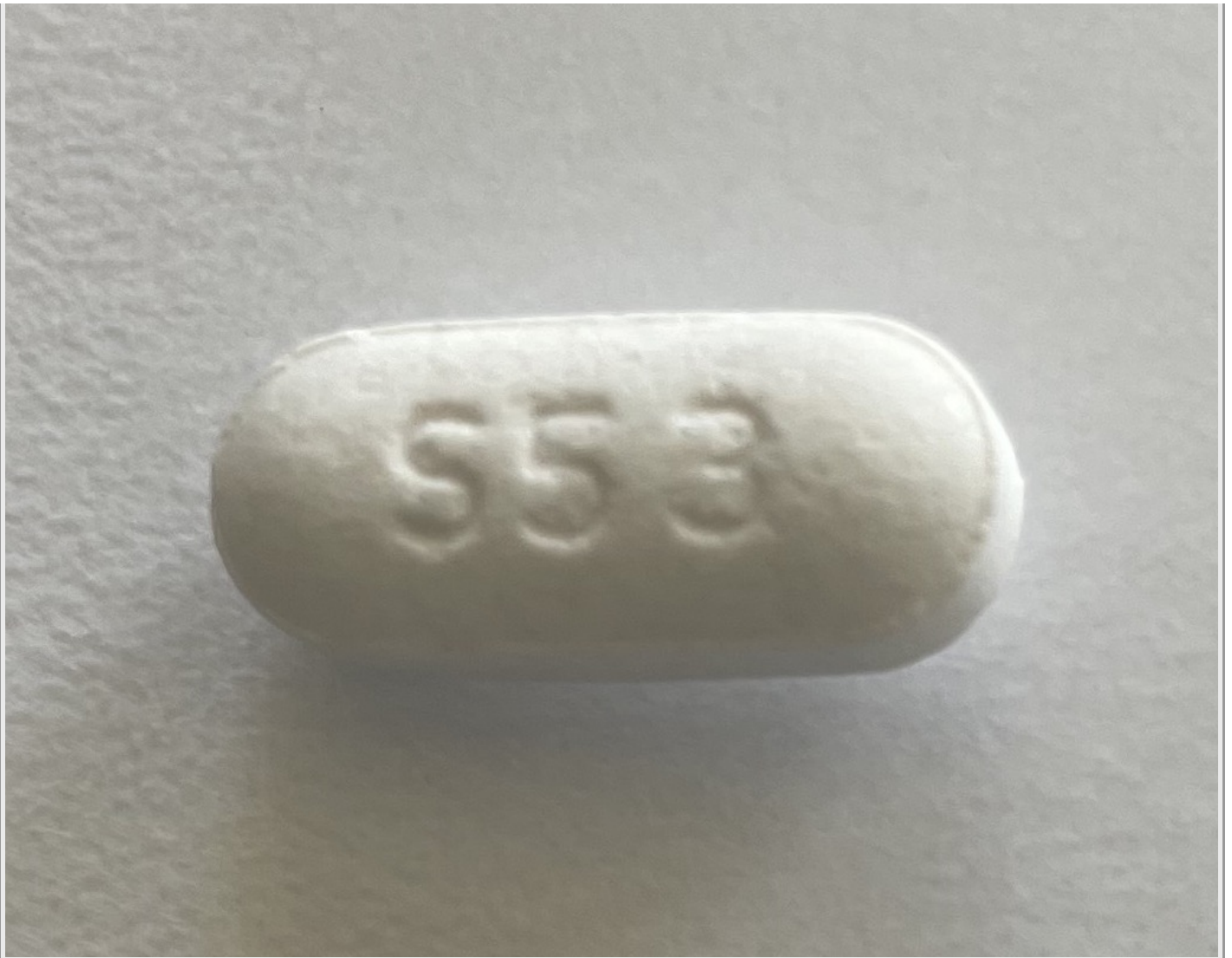
Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	score with uneven pieces
<b>Shape</b>	CAPSULE ((Capsule-Shaped Tablet))	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S53
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-306-24	1 in 1 CARTON	04/10/2023	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55758-306-50	25 in 1 BOX	04/25/2023	10/19/2023
2	NDC:55758-306-02	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:55758-306-99	50 in 1 CARTON	10/19/2023	
3	NDC:55758-306-02	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	03/24/2013	

**Labeler** - Pharmadel LLC (030129680)

Revised: 10/2023

Pharmadel LLC