DOLEX ACETAMINOPHEN 500MG EXTRA STRENGTH- acetaminophen capsule, coated
Pharmadel 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.

Rapidol Acetaminophen 500 (HPharma)

Drug Facts

Active ingredient & Purpose

Active ingredient (in each caplet)	***Purpose***
Acetaminophen 500 mg	Pain reliever/ fever reducer

Uses

For the temporary relief of minor aches and pains due to:

- the common cold
- headache
- backache
- muscular aches
- toothache
- minor pain of arthritis
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

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

- more than **4000mg in 24 hours**, which is the maximum daily amount
- with other drugs containing acetaminophen

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 allergic to 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
- redness or swelling is present
- any new symptoms occur

These could be signs of a serious condition.

If pregnant or breast feeding,

Keep out of reach of children.

Keep out of reach of children.

Overdose warning:

In case of an accidental 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

- **do not take more than directed (see OVERDOSE WARNING)**

Age	Dose
adults and children 12 years of age 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 of age	• **consult a doctor**

Other information

- store at room temperature 77-86°F (25-30°C)

Inactive ingredients

corn starch,hypromellose,magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone k90, stearic acid, titanium dioxide

Distributed by:

PHARMADEL LLC.

New Castle, DE 19720

1-866-359-3478

Prinicipal Display Panel

DOLEX ACETAMINOPHEN 500MG EXTRA STRENGTH

acetaminophen capsule, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-372
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM CITRATE (UNII: RHO26O1T9V)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL (Capsule-Shaped Tablet)	**Size**	18mm
Flavor		**Imprint Code**	AP500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-372-24	1 in 1 CARTON	04/07/2023	
1		24 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 not final	part343	04/07/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 4/2023 Pharmadel LLC