FLAXENDOL EXTRA STRENGTH ACETAMINOPHEN- acetaminophen capsule
Gelpharma S.A. de C.V.

Flaxendol Extra Strength Acetaminophen

Drug Facts

Active ingredient (in each softgel capsule)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

for the temporary relief of minor aches and pains associated with

- the common cold
- headache
- toothache
- muscular aches
- backache
- premenstrual and menstrual
- the minor pain from arthritis
- to reduce fever

Warnings

This product contains acetaminophen. Severe liver damage mayoccur if you take: **Liver warning:**

more than 8 softgel capsules in 24 hours, which is the maximum daily amount

with other drugs containing acetaminophen

3 or more alcoholic drinks every day while using this product

Acetaminophen may cause severe skin reactions. Symptoms may include: **Allergy alert:**

If a skin reaction occurs, stop use and seek medical help right away.

- skin reddening
- blisters
- rash

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.

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.

When using this product

- do not exceed recommended dosage
- do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition.
- if symptoms do not improve within 7 days or are accompanied by fever, consult a doctor

Stop using and ask a doctor if

- pain 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

If pregnant or breast-feeding,

ask a health professional before use.

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 children even if you do not notice any signs or symptoms 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: Take 2 capsules every 6 hours while symptoms last. Do not take more than 6 capsules in 24 hours unless directed by a doctor.
- Children under 12 years of age: consult a doctor.

Other information

- Store at 68-77°F (20-25°C)
- Avoid high humidity

Inactive ingredients

FD&C Red No. 40, gelatin, glycerin, polyethylene glycol 400, polyethylene glycol 600,

silicon dioxide, titanium dioxide, water

Questions or Comments?

(346) 326-1728 Mon-Fri 8:00a.m. EST to 5:00p.m. EST

Package Labeling:

FLAXENDOL EXTRA STRENGTH ACETAMINOPHEN

acetaminophen capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69377-002

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)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	**Score**	no score
Shape	OVAL (27)	**Size**	10mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69377-002-01	1 in 1 CARTON	07/01/2022	
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 Drug	M013	07/01/2022	

Labeler - Gelpharma S.A. de C.V. (812773665)

Revised: 11/2023 Gelpharma S.A. de C.V.