

DOLO-NEUROBION- acetaminophen tablet, film coated
BENARD INDUSTRIES INC

EXTRA STRENGTH Dolo-NeuroBion® USA

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

• headache • muscular aches • minor pain of arthritis • backache • the common cold • toothache • premenstrual and menstrual cramps

temporarily reduces fever

Warnings

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

- more than 4,000 mg 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

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 you are allergic to acetaminophen or any 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
- new symptoms occur

- redness or swelling is present

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 use more than directed (see overdose warning)**

Adults and children: (12 years and over)	<ul style="list-style-type: none"> • take 2 tablets every 6 hours while symptoms last • do not take more than 6 tablets 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 at room temperature 59°-86°F (15°-30°C)
- **TAMPER EVIDENT** child resistant packets
- do not use any opened or torn packets

Inactive ingredients

corn starch, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

305.594.0480

EXTRA STRENGTH

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

See Warnings Information & Directions

See acetaminophen warnings

Do not use if pouch is opened

Child-Resistant Packets

Retain carton for complete product information

Distributed by:

OTC Pharmaceutical Products

Doral, FL 33172

www.otcpharmausa.com © 2023

Packaging

Outer Package Label

Dolo-Neurobion[®] USA
EXTRA STRENGTH
Acetaminophen 500 mg
Pain Reliever/Fever Reducer
2 Tablets
500 mg each
50 Packets
(2 Tablets Per Packet)

Dolo-Neurobion[®] USA
EXTRA STRENGTH
Acetaminophen 500 mg
Pain Reliever/Fever Reducer
2 Tablets
500 mg each
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Design CAD File

Dolo-Neurobion[®] USA
EXTRA STRENGTH
Acetaminophen 500 mg
Pain Reliever/Fever Reducer
2 Tablets
500 mg each
50 Packets
(2 Tablets Per Packet)

100 Tablets 50 Packets (2 Tablets Per Packet)

Retain carton for complete product information

100 Tablets 50 Packets (2 Tablets Per Packet)

Retain carton for complete product information

14457 13205

Inner Package Label

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN
See Warnings Information & Directions
EXTRA STRENGTH
Dolo-Neurobion[®] USA
PAIN RELIEVER FEVER REDUCER
ACETAMINOPHEN 500mg
OTC

2 Tablets
500 mg each

► **Drug Facts (continued)**
Stop use and ask a doctor if • pain gets worse or lasts for more than 10 days • fever gets worse or lasts more than 3 days • new symptoms occur • redness or swelling is present. 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 use more than directed (see overdose warning)
Adults and children (12 years and over) • take 2 tablets every 6 hours while symptoms last • do not take more than 6 tablets 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
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Questions or comments? 305.594.0460
See acetaminophen warnings
Do not use if pouch is opened
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DOLO-NEUROBION

acetaminophen tablet, film coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55959-131

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	AZ;235
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55959-131-01	50 in 1 BOX	11/30/2023	
1		2 in 1 POUCH; 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	11/30/2023	

Labeler - BENARD INDUSTRIES INC (106700321)

Revised: 6/2025

BENARD INDUSTRIES INC