DOLO - NEUROBION ACETAMINOPHEN MAX EXTENDED-RELEASE 650 MG- acetaminophen tablet
BENARD INDUSTRIES INC

Benard Industries - Dolo-NeuroBion Acetaminophen Max, Extended-Release Tablets 650 mg (55959-179)

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen 650 mg

Purpose

Pain reliever/ Fever reducer

Uses

temporarily relieves minor aches and pains due to:

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

Warnings

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

- more than 6 caplets 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 drugs 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(1-800-222-1222) right away. 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 take more than directed (see overdose warning)

adults	• take 2 tablets every 8 hours with water • swallow whole; do not crush, chew, split, or dissolve • do not take more than 6 caplets in 24 hours • do not use for more than 10 days unless directed by a doctor
under 18 years of age	• ask a doctor

Other information
- store between 20-25°C (68-77°F)

Inactive ingredients:

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions?

call 305-594-0480


0 14457 13204 7
Dolo-
Neuroβion®
ACETAMINOPHEN
MAX
Extended-Release Tablets 650 mg
Pain Reliever / Fever Reducer
for up to 8 hours Relief of
Minor Muscle Aches & Pain
30 Caplets*
650 mg each
*Capsule shaped tablet

DO NOT USE IF SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredient (in each caplet)	*Purpose*
Acetaminophen 650 mg	Pain reliever/fever reducer

Uses

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PEEL FOR DIRECTIONS

LIFT HERE

G7365-030-100-0

Drug Facts (continued)

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Distributed by:
OTC Pharmaceutical Products
Doral, FL 33172

DOLO - NEUROBION ACETAMINOPHEN MAX EXTENDED-RELEASE 650 MG

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55959-179
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE (Capsule-shaped)	**Size**	20mm
Flavor		**Imprint Code**	G650
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55959-179-03	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	06/19/2023	

Labeler - BENARD INDUSTRIES INC (106700321)