

**DOLO- NEUROBION ACETAMINOPHEN 500MG- acetaminophen tablet, film coated**  
**BENARD INDUSTRIES INC**

*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.*

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**Dolo-NeuroBion**

***Drug Facts***

***Active Ingredient (per tablet)***

Acetaminophen 500mg

***Purpose***

Pain reliever/ Fever reducer

***Uses***

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

***Warnings***

**Liver warning:** This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 8 tablets in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reaction.

**Symptoms may include:** • skin reddening • blister • 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 take more than directed** (see overdose warning)

Adults and children 12 years and over	<ul style="list-style-type: none"> <li>• take 2 tablets every 6 hours while symptoms last.</li> <li>• do not take more than 6 tablets in 24 hours, unless directed by a doctor.</li> <li>• do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

**Other information**

- store between 20°-25°C (68°-77°F)
- **Do not use if seal under cap is broken or missing**

**Inactive ingredients:**

croscarmellose sodium, dicalcium phosphate, FD&C yellow #5 lake\*, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, stearic acid, talc, titanium dioxide.

\*This product contains FD&C Yellow #5 Lake (Tartrazine) as a color additive.

**Questions or comments?**

**Call 1-800-595-0480**

***For the temporary relief of head, neck and back pain that may be continuous or intermittent***

***EXTRA STRENGTH***

*PAIN RELIEVER  
FEVER REDUCER*

Distributed by:

**OTC Pharmaceutical Products**

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**SEE ACETAMINOPHEN WARNINGS**

**Packaging**



**DRUG FACTS LABEL**

Drug Facts	
<b>Active Ingredient (per tablet)</b> Acetaminophen 500 mg	<b>Purpose</b> Pain reliever / Fever reducer
<b>Uses</b>	
<ul style="list-style-type: none"> <li>temporarily relieves minor aches and pains due to:               <ul style="list-style-type: none"> <li>the common cold</li> <li>headache</li> <li>backache</li> <li>minor pain of arthritis</li> </ul> </li> <li>toothache</li> <li>muscular aches</li> <li>premenstrual and menstrual cramps</li> </ul>	
<ul style="list-style-type: none"> <li>temporarily reduces fever</li> </ul>	
<b>Warnings</b>	
<p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>more than 8 tablets in 24 hours</li> <li>with other drugs containing acetaminophen</li> <li>3 or more alcoholic drinks every day while using this product.</li> </ul> <p>Acetaminophen may cause severe skin reaction. Symptoms may include: • skin redness • blister • rash If a skin reaction occurs, stop use and seek medical help right away.</p>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are allergic to acetaminophen or any of the inactive ingredients in this product</li> </ul>	
<p><b>Ask a doctor before use if you have liver disease</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</b></p>	
<b>Stop use and ask a doctor if:</b>	
<ul style="list-style-type: none"> <li>pain gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>itchiness or swelling is present</li> </ul> <p>These could be signs of a serious condition</p>	
<p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p><b>Overdose warning:</b> 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.</p>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>do not take more than directed (see overdose warning)</li> </ul>	
Adults and children 12 years and over	<ul style="list-style-type: none"> <li>take 2 tablets every 6 hours while symptoms last.</li> <li>do not take more than 6 tablets in 24 hours, unless directed by a doctor.</li> </ul>

Datos del Medicamento	
<b>Ingresante Activo (por tableta)</b> Acetaminofen 500 mg	<b>Propósito</b> Calma el dolor / reduce fiebre
<b>Usos</b>	
<ul style="list-style-type: none"> <li>alivia temporalmente dolores relacionados con:               <ul style="list-style-type: none"> <li>resfrío común</li> <li>dolor de cabeza</li> <li>dolor de espalda</li> <li>dolores menores de artritis y pre-menstruales</li> </ul> </li> <li>dolor de muelas</li> <li>dolor muscular</li> <li>dolores menstruales</li> </ul>	
<ul style="list-style-type: none"> <li>reduce temporalmente la fiebre</li> </ul>	
<b>Advertencias</b>	
<p><b>Advertencia del hígado:</b> Este producto contiene acetaminofen. Podría dañar el hígado si se toman</p> <ul style="list-style-type: none"> <li>más de 8 tabletas en 24 horas</li> <li>con otras drogas que tengan acetaminofen</li> <li>3 o más bebidas alcohólicas por día, mientras consume este producto</li> </ul> <p>Acetaminofen puede causar una severa reacción alérgica en la piel. Síntomas pueden ser: • enrojecimiento • ampollas • rash Si esto ocurre busque ayuda médica inmediatamente.</p>	
<p>No usar • con otras drogas que tengan acetaminofen (de prescripción o no-prescripción). Si no está seguro de estar tomando otras drogas que contengan acetaminofen, pregunte a su médico o farmacéutico • si es alérgico al acetaminofen o a alguno de los ingredientes inactivos en este producto</p>	
<p>Pregunte al médico antes de usar si tiene enfermedad hepática</p> <p>Pregunte al médico o farmacéutico antes de usar si toma el anticoagulante warfarin</p>	
<p>Discontinúe el uso y consulte a su médico si:</p> <ul style="list-style-type: none"> <li>el dolor es más fuerte o dura más de 10 días</li> <li>fiebre que empeora o dura más de 3 días</li> <li>tiene nuevos síntomas</li> <li>si tiene enrojecimiento o inflamación</li> </ul> <p>Esto puede ser signo de una condición seria</p> <p>Si está embarazada o lactando, pregunte a un profesional de la salud antes de tomar. Mantener alejado del alcance de los niños.</p> <p>Advertencia de sobredosis: en caso de sobredosis busque ayuda médica urgente. Llame al Poison Control Center (1-800-222-1222). Rápida atención médica es requerida para niños y adultos aunque no presenten síntomas.</p>	
<b>Dosis y modo de empleo</b>	
<ul style="list-style-type: none"> <li>no tome más de lo indicado (vea advertencia de sobredosis)</li> </ul>	
Adultos y niños de 12 años o mayores	<ul style="list-style-type: none"> <li>tome 2 tabletas cada 6 horas mientras los síntomas continúan</li> <li>no tome más de 6 tabletas en 24 horas al menos que el doctor lo ordene</li> </ul>

Drug Facts (continued)	
Adults and children 12 years and over	<ul style="list-style-type: none"> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor
<b>Other information</b>	
<ul style="list-style-type: none"> <li>store between 20-25°C (68-77°F)</li> <li>do not use if seal under cap is broken or missing</li> </ul>	
<b>Inactive ingredients:</b> croscarmellose sodium, dicalcium phosphate, FD&C yellow #5 lake <sup>1</sup> , hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, stearic acid, talc, titanium dioxide.	
<sup>1</sup> This product contains FD&C Yellow #5 Lake (Tartrazine) as a color additive.	
Questions or comments? Call 1-800-595-0480	

Drug Facts (continuación)	
Adultos y niños de 12 años o mayores	<ul style="list-style-type: none"> <li>no use por más de 10 días a menos que el médico lo prescriba</li> </ul>
niños menores de 12 años	pregunte a su médico
<b>Información adicional</b>	
<ul style="list-style-type: none"> <li>guarde entre 20-25°C (68-77°F)</li> <li>no utilizar si el sello debajo de la tapa está roto ó no está</li> </ul>	
<b>Ingredientes inactivos:</b> croscarmellose sodica, fosfato de calcio, FD&C amarillo #5 lake <sup>1</sup> , hipromelosa, estearato de magnesio, celulosa microcristalina, aceite mineral, polietileno glicol, povidona, almidón pregelatinizado, dióxido de silicio, lauril sulfato de sodio, glicolato de almidón sodico, ácido esteárico, talco, dióxido de titanio.	
<sup>1</sup> Este producto contiene FD&C amarillo #5 Lake (Tartrazina) como aditivo de color.	
Preguntas o comentarios? Llame al 1-800-595-0480	







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SEE ACETAMINOPHEN WARNINGS

VER ADVERTENCIAS ACERCA DEL ACETAMINOFEN



Rev# 14/20-L

<b>Preguntas o comentarios? Llame al 1-800-595-0480</b> addive. "Este producto contiene FD&C Yellow #5 Lake (tartrazina) como aditivo."	<b>Questions or comments? Call 1-800-595-0480</b> "This product contains FD&C Yellow #5 Lake (tartrazine) as a color additive."
<b>Información adicional</b> • guardar entre 20-25°C (68-77°F) • No utilizar si el sello debajo de la tapa esta roto o no está.	<b>Other information</b> • Store between 20-25°C (68-77°F) • Do not use if seal under cap is broken or missing
<b>Adultos y niños de 12 años o mayores:</b> no use por más de 10 días a menos que el médico lo prescriba. <b>niños menores de 12 años:</b> consulte a su médico.	<b>Adults and children 12 years and over:</b> do not use for more than 10 days unless directed by a doctor. <b>children under 12 years:</b> ask a doctor.
<b>Drug Facts (continued)</b>	<b>Drug Facts (continued)</b>

<b>Preguntas al médico o farmacéutico antes de usar si tiene enfermedad hepática</b> Pregunte al médico o farmacéutico antes de usar si toma algún de los siguientes fármacos: • se alargó al acetaminofen o a otros fármacos que contienen acetaminofen, pregunte a su médico o farmacéutico. • si se alargó al acetaminofen o a otros fármacos que contienen acetaminofen, pregunte a su médico o farmacéutico. • si se alargó al acetaminofen o a otros fármacos que contienen acetaminofen, pregunte a su médico o farmacéutico.	<b>Do not use</b> 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. <b>Ask a doctor or pharmacist before use if you have liver disease</b> Ask a doctor or pharmacist before use if you are taking blood thinning drug warfarin. <b>Stop use and ask a doctor if:</b> • 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.
<b>Advertencias</b> Puede dañar el hígado si se toman más de 8 tabletas en 24 horas. • con otras drogas que tengan acetaminofen • 3 o más bebidas alcohólicas por día, mientras consume este producto. Aleja de la lengua: Acetaminofen puede causar una severa reacción alérgica en la piel. Síntomas pueden ser: • enrojecimiento • ampollas • rash.	<b>Warnings</b> Severe liver damage may occur if you take more than 8 tablets in 24 hours. • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product. Symptoms may include: skin redness • blister • rash. If a skin reaction occurs, stop use and seek medical help right away.
<b>Usos</b> alivia temporalmente dolores relacionados con: • resaca común • dolor muscular • dolor de cabeza • dolor de espalda • dolores menores de artritis y pre-menstruales. • reduce temporalmente la fiebre.	<b>Uses</b> temporarily relieves minor aches and pains due to: • the common cold • toothache • muscular aches • premenstrual and menstrual cramps • headache • toothache • minor pain of arthritis temporarily reduces fever.
<b>Propósito</b> Acetaminofen 500 mg. — Pain reliever/fever reducer. Acetaminofen 500mg. — Calma el dolor / reduce fiebre.	<b>Active ingredient (per tablet)</b> Acetaminophen 500 mg. — Pain reliever/fever reducer.
<b>Dosis y modo de empleo</b> • no tome más de lo indicado (vea advertencias de sobredosis). • tome 2 tabletas cada 6 horas mientras los síntomas continúan. • no tome más de 6 tabletas en 24 horas. • no tome más que el doctor lo ordene.	<b>Directions</b> • do not take more than directed (see overdose warning). • take 2 tablets every 6 hours while symptoms last. • do not take more than 6 tablets in 24 hours, unless directed by a doctor.
<b>Si estas embarazada o lactando,</b> pregunte a un profesional de la salud antes de tomar. Mantener alejado del alcance de los niños. Esto puede ser signo de una condición seria. • si tiene enrojecimiento o inflamación • si tiene nuevos síntomas. • fiebre que empeora o dura más de 3 días. • dolor que empeora o dura más de 10 días. Discontinúe el uso y consulte a su médico si:	<b>Keep out of reach of children.</b> If pregnant or breastfeeding, ask a health professional before use. These could be signs of a serious condition. • redness or swelling is present • new symptoms occur • fever gets worse or lasts more than 10 days • pain gets worse or lasts more than 3 days



Lot No.: EXP

**DOLO- NEUROBION ACETAMINOPHEN 500MG**  
 acetaminophen tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55959-171
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	DOLO;N
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55959-171-03	1 in 1 CARTON	05/04/2016	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55959-171-06	1 in 1 CARTON	05/04/2016	
2		60 in 1 BOTTLE, PLASTIC; 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	05/04/2016	

**Labeler** - BENARD INDUSTRIES INC (106700321)

Revised: 9/2023

BENARD INDUSTRIES INC