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

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	• 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 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
10860 NW 27th St. Doral, FL 33172 ©2013

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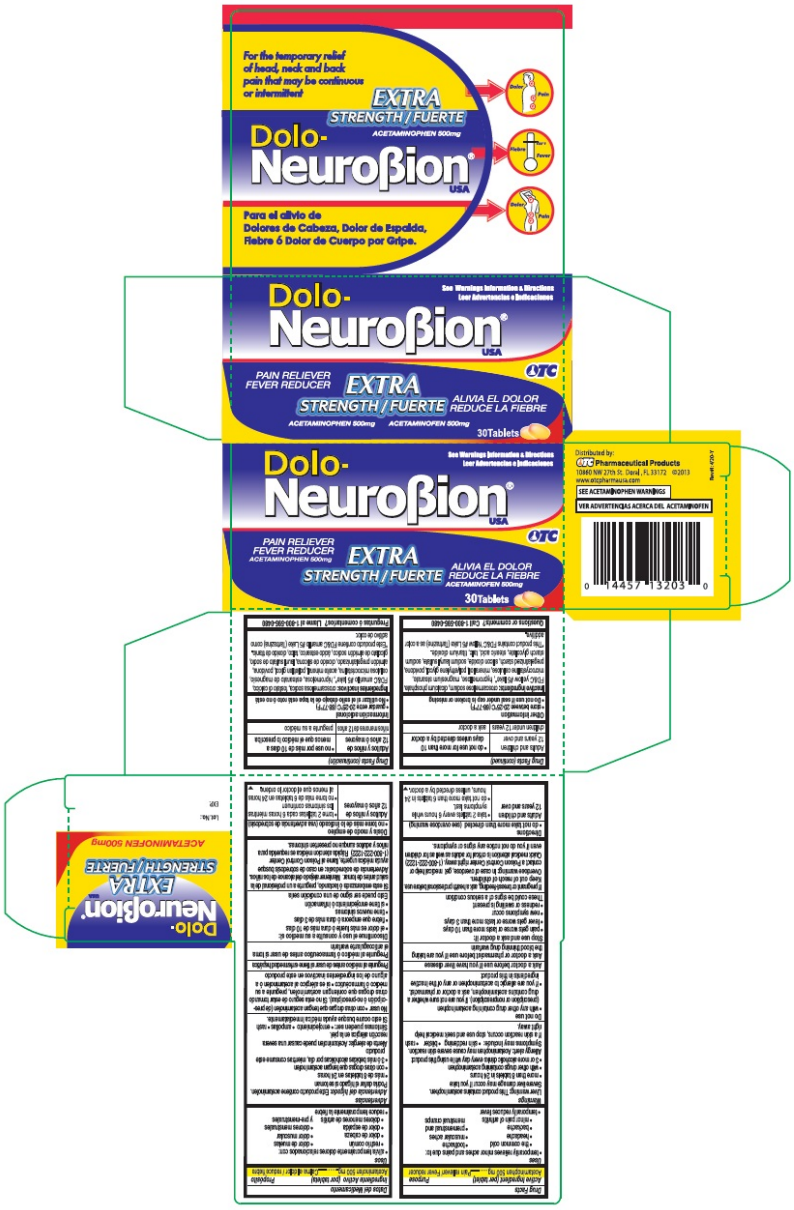
SEE ACETAMINOPHEN WARNINGS

Packaging



DRUG FACTS LABEL

Drug Facts

Active Ingredient (per tablet) — **Purpose**
Acetaminophen 500 mg ..... Pain reliever/ Fever reducer

Uses
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  - 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	• take 2 tablets every 6 hours while symptoms last. • do not take more than 6 tablets in 24 hours, unless directed by a doctor.

Datos del Medicamento

Ingrediente Activo (por tableta) — **Propósito**
Acetaminofen 500 mg ..... Calma el dolor / reduce fiebre

Usos
- alivia temporalmente dolores relacionados con:
  - resfrío común
  - dolor de cabeza
  - dolor de espalda
  - dolores menores de artritis
  - dolor de muelas
  - dolor muscular
  - dolores menstruales y pre-menstruales
- reduce temporalmente la fiebre

Advertencias
Advertencia del hígado: Este producto contiene acetaminofen. Podría dañar el hígado si se toman
- más de 8 tabletas en 24 horas
- con otras drogas que tengan acetaminofen
- 3 ó más bebidas alcohólicas por día, mientras consume este producto

Alerta de alergia: Acetaminofen puede causar una severa reacción alérgica en la piel.
Síntomas pueden ser: • enrojecimiento • ampollas • rash
Si esto ocurre busque ayuda médica inmediatamente.

No usar • con otras drogas que tengan acetaminofen (de prescripción o no-prescriptas). Si no esta seguro de estar tomando otras drogas que contengan acetaminofen, pregunte a su médico ó farmacéutico • si es alérgico al acetaminofen ó a alguno de los ingredientes inactivos en este producto

Pregunte al médico antes de usar si tiene enfermedad hepática

Pregunte al médico ó farmaceutico antes de usar si toma el anticoagulante warfarin

Discontinue el uso y consulte a su medico si:
- el dolor es más fuerte ó dura más de 10 días
- fiebre que empeora ó dura más de 3 días
- tiene nuevos síntomas
- si tiene enrojecimiento ó inflamación

Esto puede ser signo de una condición seria

Si esta embarazada ó lactando, pregunte a un profesional de la salud antes de tomar. **Mantener alejado del alcance de los niños.**
Advertencia de sobredosis: en caso de sobredosis busque ayuda médica urgente, llame al Poison Control Center (1-800-222-1222) Rápida atencion médica es requerida para niños y adultos aunque no presenten síntomas.

Dósis y modo de empleo
- no tome más de lo indicado (vea advertencia de sobredosis)

Adultos y niños de 12 años ó mayores	• tome 2 tabletas cada 6 horas mientras los síntomas continuen • no tome más de 6 tabletas en 24 horas al menos que el doctor lo ordene

Drug Facts (continued)

Adults and children 12 years and over	• do not use for more than 10 days unless directed by a doctor
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

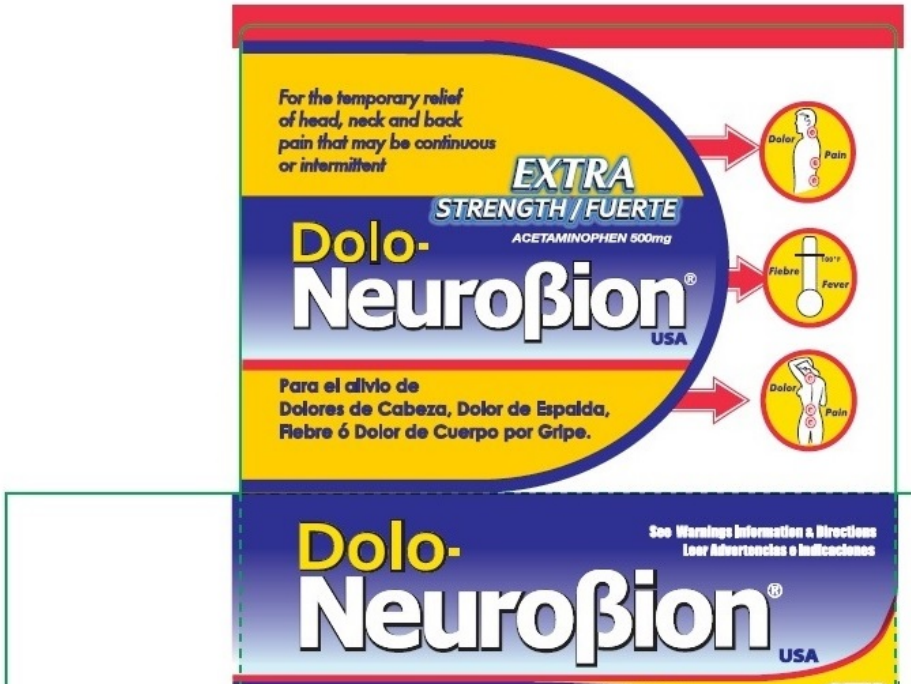
Drug Facts (continuación)

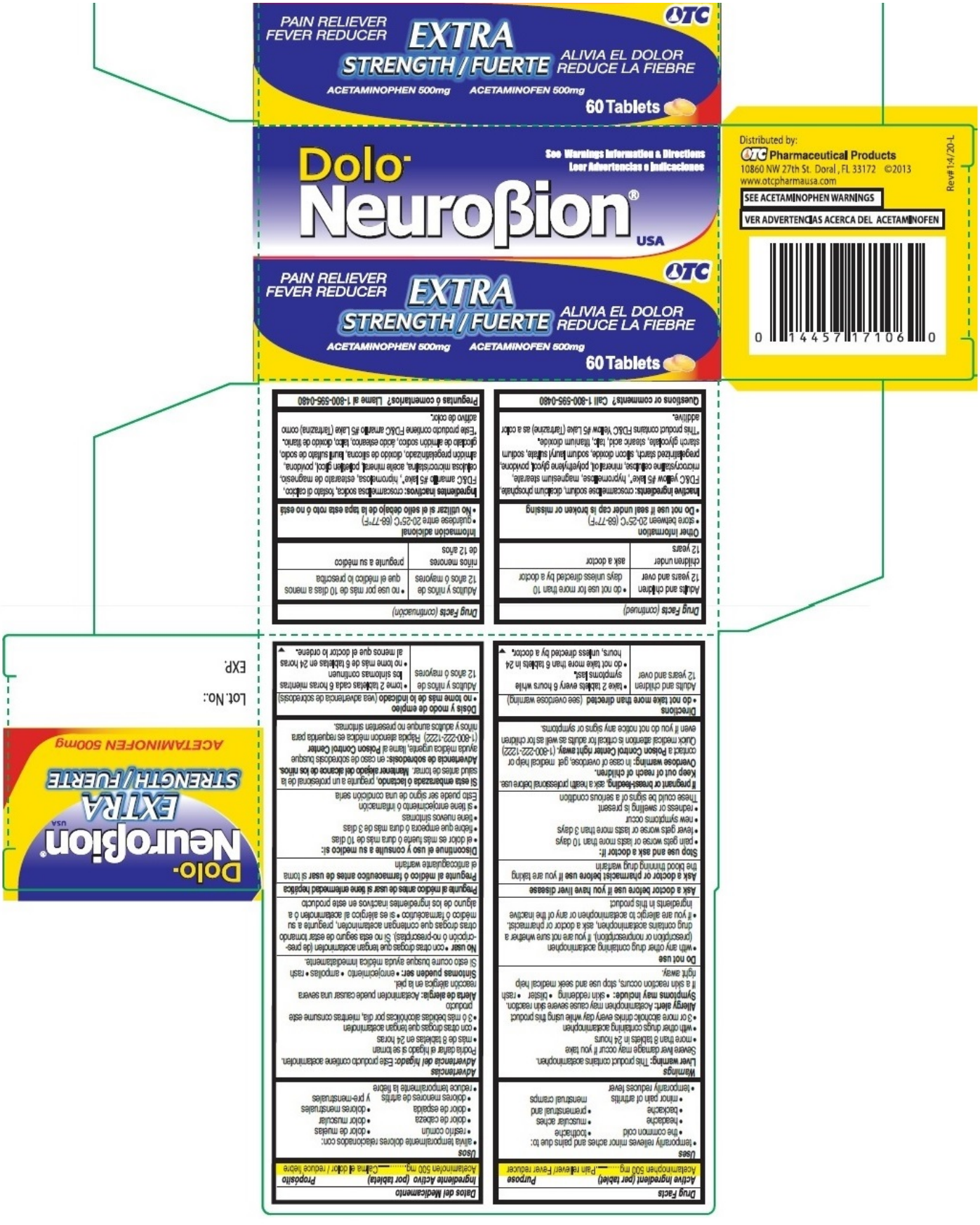
Adultos y niños de 12 años ó mayores	• no use por más de 10 días a menos que el médico lo prescriba
niños menores de12 años	pregunte a su médico

Información adicional
- guardar entre 20-25°C (68-77°F)
- **No utilizar si el sello debajo de la tapa está roto ó no está**

Ingredientes inactivos: croscarmellosa sodica, fosfato di calcico, FD&C amarillo #5 lake*, hipromelosa, estearato de magnesio, celulosa microcristalina, aceite mineral, polietilen glicol, povidona, almidón pregelatinizado, dioxido de silicona, lauril sulfato de sodio, glicolato de almidón sodico, ácido estearico, talco, dioxido de titanio.
*Este producto contiene FD&C amarillo #5 Lake (Tartrazina) como aditivo de color.

Preguntas ó comentarios? Llame al 1-800-595-0480





DOLO- NEUROBION ACETAMINOPHEN 500MG

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55959-171
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	DOLO;N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 Drug	M013	05/04/2016	

Labeler - BENARD INDUSTRIES INC (106700321)

Revised: 11/2024 BENARD INDUSTRIES INC