

**DRAGON TABS- ibuprofen 200 mg tablet**  
**Genomma Lab USA**

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**Drug Facts**

**Active ingredient**

Ibuprofen USP, 200mg (NSAID)\*\*  
\*\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever/fever reducer

**Uses**

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

**Warnings**

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin reddening ■ rash ■ blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed.

**Do not use**

if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery

**Ask a doctor before use if**

■ you have problems or serious side effects from taking pain relievers or fever reducers ■ the stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you have asthma ■ you are taking a diuretic

**Ask a doctor or pharmacist before use if**

you are taking any other drug containing an NSAID (prescription or nonprescription) taking a blood thinning (anticoagulant) or steroid drug under a doctor's care for any serious condition taking any other drug

**When using this product**

take with food or milk if stomach upset occurs  
long term continuous use may increase the risk of heart attack or stroke

### **Stop use and ask a doctor if**

you faint, vomit blood, have bloody or black stools. These are signs of stomach bleeding. pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days stomach pain or upset gets worse or lasts redness or swelling is present in the painful area any new symptoms appear

### **If pregnant or breast-feeding**

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

### **Keep Out of Reach of Children**

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

### **Directions**

■ **do not take more than directed**

■ **the smallest effective dose should be used**

■ do not take longer than 10 days, unless directed by a doctor (see Warnings)

**Adults and children 12 years and older:** ■ take 1 tablet every 4 to 6 hours while symptoms persist

■ if pain or fever does not respond to 1 tablet, 2 tablets may be used ■ do not exceed 6 tablets in 24 hours unless directed by a doctor

**Children under 12 years:**ask a doctor

### **Other information**

store between 20-25 °C (68-77° F).■ Read all warnings and directions before use**Do not use if seal under bottle cap is broken or missing.**

### **Inactive Ingredients**

colloidal silicon dioxide, corn starch, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide, carnuba wax, lactose, polydextrose, polyethylene glycol

### **Questions or Comments?**

Call 1-888-952-0050 Monday through Friday 9AM – 5PM EST.

### **Package/Label Principal Display Panel**

Dragon Tabs

Ibuprofen 200 mg/Ibuprofeno 200mg

Pain Reliever/Fever Reducer (NSAID)

Alivia el Dolor/Reduce la fiebre (AINE)

Temporarily Relieves:

Backache

Muscular aches

Alivio Temporal de:

Dolor de Espalda

# Dolores Musculares

40 Tablets/Tabletas

**Temporarily Relieves:**  
**Backache**  
**Muscular aches**  
**Alivio Temporal de:**  
**Dolor de Espalda**  
**Dolores Musculares**

**DRAGON TABS**  
**ibuprofen 200mg / ibuprofeno 200mg**  
**40 TABLETS / 40 TABLETAS**

Made in India/Hecho en India  
 Distributed by/Distribuido por:  
 Genomma Lab USA, Inc., Houston, TX 77027

LOT/LOTE  
 EXP/CAD:

6 50066 00064 5 LB1362 R 014

**Drug Facts (cont.)**  
 odor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**  
 Do not take more than directed. The smallest effective dose should be used. Do not take longer than 10 days, unless directed by a doctor.

**Adults and children 12 years and older**  
 Take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, a 2nd tablet may be used. Do not exceed 6 tablets in 24 hours unless directed by a doctor.

**12 years and older**  
 Ask a doctor.

**Other information**  
 Store between 20-25°C (68-77°F). Read all warnings and directions before use. Do not use if seal under bottle cap is broken or missing.

**Inactive ingredients**  
 include docusone dihydrate, corn starch, hydroxyethylcellulose, iron oxide red, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide, xanthan gum, hydroxypropylmethylcellulose.

**Questions or Comments?**  
 Call 1-888-845-2400 Monday through Friday 9AM - 5PM EST.

**Información del medicamento (cont.)**  
 o complicaciones durante el parto. Manténgalo fuera del alcance de los niños. En caso de sobredosis, solicite asistencia médica o acuda al Centro de Intoxicaciones.

**Instrucciones**  
 No tome más de lo indicado. Se debe usar la dosis mínima efectiva. No tome más de 10 días, a menos que lo indique un médico.

**Adultos y niños de 12 años en adelante**  
 Tome 1 tabletas cada 4 a 6 horas mientras los síntomas persistan. Si el dolor o la fiebre no responden a 1 tableta, tome 2 tabletas. No exceda 6 tabletas en 24 horas, a menos que lo indique el médico.

**Menores de 12 años**  
 Consulte con su médico.

**Información adicional**  
 Almacene a temperatura entre 20-25 °C (68-77 °F). Lea todas las advertencias e instrucciones antes de usar. No use si el sello de la tapa de la botella está roto o faltante.

**Ingredientes inactivos**  
 Incluyen docusone dihidrato, almidón de maíz, hidroxietilcelulosa, óxido de hierro rojo, estearato de magnesio, celulosa microcristalina, glicolato de sodio de almidón, dióxido de titanio, goma de xantano, hidroxipropilmetilcelulosa, polidimetilsiloxano.

**¿Preguntas o comentarios?**  
 Llame al 1-888-845-2400 Lunes a Viernes 9 am - 5 pm hora del Este (EST).

**Drug Facts**  
 Active ingredient (in each tablet) Purposes  
 Ibuprofen USP 200mg (NSAID) Pain reliever  
 Nonsteroidal anti-inflammatory drug fever reducer

**Uses**  
 Temporarily relieves minor aches and pains due to:  
 • headache • muscular aches • minor pain of arthritis  
 • toothache • backache • the common cold  
 • menstrual cramps • temporarily reduces fever

**Warnings**  
 Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  
 • hives • facial swelling • asthma (wheezing) • shock • skin redness • rash • dizziness. If an allergic reaction occurs, stop use and seek medical help right away!  
 Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you:  
 • are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or blood drug • take other drugs containing NSAID (aspirin, ibuprofen, indomethacin, or others) • have 2 or more stomach ulcers every day while using this product • take more or for a longer time than directed.

**Información del medicamento**  
 Ingredientes activos (en cada tableta) Propósitos  
 Ibuprofen USP 200 mg (AINE) Analgésico antiinflamatorio  
 Medicamento no esteroideo (AINE)

**USOS**  
 Alivia temporalmente dolores menores causados por:  
 • dolor de cabeza • dolor de músculos • dolores menores de artritis  
 • dolor de muelas • dolor de espalda • dolores de síndrome menstrual común • reduce temporalmente la fiebre.

**Advertencias**  
 Alerta sobre alergia: El ibuprofeno puede causar una reacción alérgica severa, en especial en personas alérgicas a la aspirina. Los síntomas incluyen:  
 • urticaria • hinchazón facial • asma (sibilancias) • edema • dificultad de respiración • shock • erupción de la piel • sarpullido • shock anafiláctico. Si se presenta una reacción alérgica, detenga su uso y busque ayuda médica inmediata.  
 Advertencia de sangrado de estómago: Este producto contiene AINE, que puede causar sangrado severo de estómago. La posibilidad es más alta si:  
 • tiene 60 años o más • tiene úlceras de estómago o problemas de sangrado • toma otros antiinflamatorios o medicamentos esteroideos • toma cualquier otro medicamento que contenga aspirina o un prescripcón AINE (aspirina, ibuprofeno, naproxeno u otros) • bebe 3 o más bebidas alcohólicas desde el inicio de este producto • usa el producto por períodos de tiempo prolongados que el indicado.  
 Advertencia de sangrado: Este medicamento puede causar sangrado o hemorragia. El riesgo es mayor si:  
 • toma medicamentos que interfieren con la coagulación • toma aspirina o otros medicamentos que interfieren con la coagulación • toma cualquier otro medicamento.

**Drug Facts (cont.)**  
 Do not take: • If you have ever had an allergic reaction to any other pain reliever/fever reducer • right before or after heart surgery

**Ask a doctor before use if you have:**  
 • stomach or intestinal ulcers or bleeding • kidney disease • heart disease • high blood pressure • heart or kidney disease

**Ask a doctor or pharmacist before use if:**  
 • you are taking any other drug containing an NSAID (prescription or over-the-counter) • taking a blood thinning (anticoagulant) or blood drug • under a doctor's care for any serious condition • taking any other drug

**When using this product:**  
 • take with food or milk if stomach upset occurs • do not drink alcohol while using this product • do not use if you have had a heart attack or stroke.

**Stop use and ask a doctor if:**  
 • you feel faint, vomit blood or have bloody or black stools. These are signs of stomach bleeding • pain gets worse or lasts more than 10 days • stomach pain or upset gets worse or lasts • redness or swelling is present in painful area • any other symptoms appear

**If pregnant or breast-feeding, ask a health professional before use.**  
 Use especially if instructed to use longer than the last 3 months of pregnancy unless definitely directed to do so by a professional.

**Información del medicamento (cont.)**  
 No tome si:  
 • presenta problemas o efectos secundarios al tomar analgésicos o antiinflamatorios • presenta advertencias de sangrado estomacal • tiene historial de problemas estomacales, tal como úlceras, hemorragias • problemas de sangrado • padeció presión alta, cardiopatía, insuficiencia hepática o enfermedad renal o cardíaca

**Consulte al médico antes de usar si:**  
 • tiene úlceras o problemas de sangrado • toma otros antiinflamatorios o medicamentos esteroideos • toma cualquier otro medicamento que contenga aspirina o un prescripcón AINE (con otros nombres) • toma aspirina o cualquier otro medicamento que interfiera con el tratamiento médico de cualquier tipo • toma cualquier otro medicamento

**Cuando use este producto:**  
 • tómelo con comida o leche si presenta náuseas estomacales • el riesgo de ataques al corazón o accidentes cerebrovasculares puede incrementarse si se utiliza durante un período de tiempo más largo que el indicado

**Suspensión de uso y consulte al médico si:**  
 • se siente débil, vomita sangre, tiene deposiciones con sangre o negras • este es su primer día de sangrado estomacal • sangra el dolor o dura más de 10 días • el dolor empeora la noche o dura más de 3 días • presenta dolor estomacal que no mejora • presenta sangrado o hinchazón en el área con dolor • presenta síntomas nuevos

**Si está embarazada o en lactancia, antes de usarlo consulte a un profesional médico.**  
 Es muy importante no usar ibuprofeno durante los 3 últimos meses de embarazo, a menos que así lo indique el médico, ya que el medicamento puede causar problemas en el feto.

**DRAGON TABS**  
**Pain Reliever/Fever Reducer (NSAID)**  
**Alivia el Dolor/Reduce la Fiebre**

## DRAGON TABS

ibuprofen 200 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-374
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

**Inactive Ingredients**

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LACTOSE (UNII: J2B2A4N98G)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

**Product Characteristics**

Color	BROWN	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44291
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-374-40	40 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	04/17/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075010	04/17/2015	

**Labeler** - Genomma Lab USA (832323534)**Registrant** - Genomma Lab USA (832323534)