## MIGRALEX DR. MAUSKOP- aspirin buffered with magnesium oxide tablet, coated Migralex 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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#### **Migralex Labeling**

Active Ingredients (in each tablet)

Aspirin 500 mg (Purpose: Pain Reliever)

Buffered with Magnesium Oxide 75 mg

#### Uses

for the temporary relief of minor aches and pain associated with:

- Tension Headaches
- Sinus Headaches
- Stress Headaches
- Chronic Headaches
- Menstrual Headaches

#### Warnings

**Reye's syndrome**: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert**: Aspirin may cause a severe allergic reaction which may include hives, asthma (wheezing), facial swelling, shock, rash, skin reddening, and blisters.

**Alcohol warning**: If you consume 3 or more alcoholic drinks everyday, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

#### Do not use

if you are allergic to aspirin or any other pain reliever/fever reducer

#### Ask a doctor before use if you have

- kidney disease
- asthma
- a magnesium-restricted diet
- bleeding problems
- stomach problems that last or come back (such as heartburn, upset stomach or stomach pain), or if you have ulcers.

#### Ask a doctor or pharmacist before use if you are taking a prescription drug for

- anticoagulation (thinning the blood)
- gout
- diabetes
- arthritis

#### Stop use and ask a doctor if

- allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts for more than 10 days
- new symptoms occur
- fever gets worse or lasts for more than 3 days
- ringing in the ears or a loss of hearing occurs
- redness or swelling is present

If pregnant or breast feeding, ask a health professional before use. It is especially important not to use aspirin 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.

#### Directions

- Drink a full glass of water with each dose
- Adults and children 12 years and over: take 2 tablets every 6 hours while symptoms persist, but not more than 8 tablets in 24 hours, or as directed by a doctor
- Children under 12 years: ask a doctor

#### **Other Information**

- store at room temperature
- read all product information before using
- save carton for full directions and warnings

#### **Inactive Ingredients**

Fractionated coconut oil, Hypromellose, Maltodextrin, Microcrystalline cellulose, Polydextrose, Sodium starch glycolate, Stearic acid, Talc, Titanium dioxide.

#### Questions or comments: 1877 - 466 - 0294.

**Distributed by Migralex Inc. Larchmont, New York 10538** Made in Canada U.S. Patent #5538959, 5914129

#### TAMPER EVIDENT BOTTLE.

# DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING



### 1.5625" x 1.5625" x 3.75"

### **CMY**K

8262-73000-20 (493)(D6260)



CMYK + PMS 485

MIGRALEX DR. MAUSKOP aspirin buffered with magnesium oxide tablet, coated								
Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49886-001					
Route of Administration	ORAL							

Active Ingredient/A	ctive Moiety						
Ingredient Name				Bas	<b>Basis of Strength</b>		Strength
aspirin (UNII: R16CO5Y76E) (aspirin - UNII:R16CO5Y76E)			aspirir	aspirin			
magnesium oxide (UNII: 3A3U0GI71G) (magnesium oxide - UNII:3A3U0GI71G)			magne	magnesium oxide			
Product Characteris	stics						
Color	white	Score			no	score	
Shape	OVAL	Size			19 n	nm	
Flavor		Imprint (	Imprint Code		М		
Contains							
Packaging							
# Item Code	Package Description		Marketing Start Date		Marketing End Date		
<b>1</b> NDC:49886-001-01	20 in 1 BOTTLE, PLASTIC						
Marketing Inform	mation						
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date		
OTC monograph not final	part343		11/15/2009				

Labeler - Migralex Inc. (009883785)

Revised: 10/2009

Migralex Inc.