

**MYGRIN NIGHTTIME- acetaminophen, aspirin (nsaid), and diphenhydramine
citrate tablet, film coated
Sunascen Therapeutics LLC**

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.

**MYGRIN[®] Nighttime (Acetaminophen, Aspirin (NSAID), and Diphenhydramine
Citrate), Caplets**

ACTIVE INGREDIENTS (In each caplet)

Acetaminophen 250 mg
Aspirin 250 mg (NSAID)*
Diphenhydramine citrate 38 mg
*NonSteroidal Anti-Inflammatory Drug

PURPOSE

Pain reliever
Pain reliever
Nighttime sleep-aid

INDICATIONS AND USAGE

For the temporary relief of occasional headaches, and minor aches and pains, with accompanying sleeplessness

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)

Aspirin may cause a severe allergic reaction, which may include the following,

- Hives
- Facial swelling
- Shock
- Asthma (Wheezing)

Allergy Alert (Acetaminophen)

Acetaminophen may cause severe skin reactions. Symptoms may include the following,

- Blisters
- Rash
- Skin reddening

If a skin reaction does occur, stop use and seek medical help right away.

Liver Warning

This product contains acetaminophen. Severe liver damage may occur if you take the following,

- More than 4,000 mg of acetaminophen in 24 hours, which is the maximum daily amount
- With other drugs containing acetaminophen
- Three or more alcoholic drinks every day while using this product

Stomach Bleeding Warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance of severe stomach bleeding is higher if you

- Are age 60 or older
- Have 3 or more alcoholic drinks every day while using this product
- Take more than directed, or for a longer time than directed
- Take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen or others]
- Have had stomach ulcers or bleeding problems
- Take a blood thinning (anticoagulant) or steroid drug

Do Not Use

Do not use this product in the following scenarios,

- If you ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- With any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- With other products containing diphenhydramine, including any used externally
- In children under 12 years of age

Ask a Doctor

Ask a doctor before using this product if,

- The stomach bleeding warning applies to you
- You have a history of stomach problems, such as heartburn
- You have difficulty in urination due to enlargement of the prostate gland
- You have liver disease
- You have high blood pressure, heart disease, liver cirrhosis or kidney disease
- You have glaucoma
- You are taking a diuretic
- You have asthma
- You have a breathing problem such as emphysema or chronic bronchitis

Ask a Doctor or a Pharmacist

Ask a doctor or pharmacist before using this product if you are taking the following,

- A prescription drug for:
 - + Arthritis
 - + Diabetes
 - + Gout
- Sedatives or Tranquilizers
- Any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer
- Any other drug, or are under a doctor's care for any serious condition

When using this product,

- Do not drive a motor vehicle or operate machinery
- Drowsiness may occur
- Avoid alcoholic beverages

Stop Use and ask a Doctor

Stop use of this product and ask a Doctor in the event of the following,

- If an allergic reaction occurs. Seek medical help right away.
- You experience any of signs of stomach bleeding, such as
 - + Feeling faint
 - + Vomit blood
 - + Have bloody or black stools
 - + Have stomach pain that does not get better
- New symptoms occur
- Redness or swelling is present
- Ringing in the ears or loss of hearing occurs
- Your pain gets worse or lasts for more than 10 days
- Sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

These could be signs of a serious condition

Pregnancy and Nursing Mothers

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 an overdose, seek medical help right away or contact a Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

DOSAGE AND ADMINISTRATION (Directions)

Adults and children 12 years of age and over: take up to 2 caplets at bedtime, with a full glass of water.

- **Do not take more than directed**
- Do not take more than 2 caplets in 24 hours, unless directed by a doctor
- Do not use in children under 12 years of age

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. In case of an overdose, seek medical help right away or contact a Poison Control Center immediately.

Call Poison Control at 1-800-222-1222. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

STORAGE AND HANDLING

- Store at 25°C (77°F); Excursions permitted between 15°C-30°C (59°F-86°F)
- See end flap for expiration date and lot number

INACTIVE INGREDIENTS

Corn Starch, Croscopovidone, FD&C Blue #1 Aluminum Lake, Hypromellose, Maltodextrin, Medium Chain Triglycerides, Microcrystalline Cellulose, Polydextrose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Sodium Sulfate, Stearic Acid, Talc, Titanium Dioxide, Yellow Iron Oxide, Zinc Stearate.

QUESTIONS OR COMMENTS?

Sunascen Therapeutics LLC

Call us toll free at 1-833-SUNASCN (786-2726) Mon-Fri 9am-5pm EST.

Email us at ConsumerCare@Sunascen.com

More information is available on our website at www.sunascen.com

PRINCIPAL DISPLAY PANEL

Sunascen Therapeutics LLC

NDC 49467-230-10

MYGRIN NIGHTTIME

ACETAMINOPHEN, 250 mg

ASPIRIN (NSAID), 250 mg

DIPHENHYDRAMINE CITRATE, 38 mg

Pain Reliever and Sleep-Aid

Non-habit forming

"Helping you turn the face of pain into a grin"™

100 CAPLETS

TAMPER EVIDENT: DO NOT USE IF THE SAFETY SEAL UNDER CAP IS BROKEN

OR MISSING

Distributed by: Sunascen Therapeutics LLC, Rockville MD 20850

© 2018 Sunascen Therapeutics LLC, All rights reserved.

Trademarks are owned by or licensed to Sunascen Therapeutics LLC

Sunascen Therapeutics LLC

Quality Guaranteed

Please Recycle



© 2018 Sunascen Therapeutics LLC. All rights reserved.
 Distributed by: Sunascen Therapeutics LLC
 Rockville MD 20850-6252 USA
 Trademarks are owned by or licensed to
 Sunascen Therapeutics LLC.

"Helping you turn the face of pain into a grin"™ NDC 49467-230-10



**ACETAMINOPHEN 250 mg, ASPIRIN 250 mg (NSAID),
 AND DIPHENHYDRAMINE CITRATE 38 mg**

PAIN RELIEVER AND SLEEP-AID

Actual Size **100 CAPLETS**

3 49467 23010 1

Lot No. / Exp. Date

Drug Facts (continued)

- sleepiness persists continuously for more than 2 weeks. • Irritama may be a symptom of a serious underlying medical illness. These could be signs of a serious condition.
- If pregnant or breast-feeding.** • 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
- Directions:** • Adults and children 12 years of age and over: take up to 2 caplets at bedtime, with a full glass of water. • Children under 12 years of age: do not use. • Do not take more than 2 caplets in 24 hours, unless directed by a doctor.
- Other information:** • Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F). • See end flap for expiration date and lot number.
- Inactive ingredients:** • Corn starch, croscopolone, FD&C blue #1 aluminum lake, hydroxypropyl methylcellulose, medium chain triglycerides, microcrystalline cellulose, polydextrose, povidone, sodium lauryl sulfate, sodium starch glycolate, sodium sulfate, stearic acid, talc, titanium dioxide, yellow iron oxide, zinc stearate.
- Questions or comments?** • 1-833-SUNASCEN
 ConsumerCare@sunascen.com Mon-Fri 9am-5pm EST

Drug Facts (continued)

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- Do not use** • if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with other products containing diphenhydramine, including any used externally. • in children under 12 years of age
- Ask a doctor before use if** • the stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have difficulty in urination due to enlargement of the prostate gland • you have liver disease • you have high blood pressure, heart disease, liver cirrhosis, or kidney disease • you have glaucoma • you are taking a diuretic • you have asthma • you have a breathing problem such as emphysema or chronic bronchitis.
- Ask a doctor or pharmacist before use if you are** taking • sedatives or tranquilizers • any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer • any other drug, or are under a doctor's care for any serious condition • a prescription drug for: • arthritis • diabetes • gout
- When using this product** • do not drive a motor vehicle or operate machinery • drowsiness may occur • avoid alcoholic beverages
- Stop use and ask a doctor if** • an allergic reaction occurs. Seek medical help right away. • you experience any of signs of stomach bleeding, such as: • feeling faint • vomit blood • have bloody or black stools • have stomach pain that does not get better • new symptoms occur • redness or swelling is present • ringing in the ears or a loss of hearing occurs • your pain gets worse or lasts for more than 10 days

Drug Facts

Active ingredients (in each caplet):
 Acetaminophen 250 mg
 Aspirin 250 mg (NSAID)
 Diphenhydramine Citrate 38 mg

Uses For the temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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 • facial swelling • shock • asthma (wheezing).

Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • blisters • rash • skin redness. If a skin reaction occurs, stop use and seek medical help right away.

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 4,000 mg of acetaminophen in 24 hours • with other drugs containing acetaminophen • Three or more alcoholic drinks every day while using this product.

Stomach Bleeding Warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you • are age 60 or older • have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed • take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others).

MYGRIN NIGHTTIME

acetaminophen, aspirin (nsaid), and diphenhydramine citrate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49467-230
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM SULFATE (UNII: OYPR65R21J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Product Characteristics

Color	turquoise	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	ST230
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 49467-230			

1	NDC:49467-230-10	1 in 1 CARTON	02/05/2018	
1		100 in 1 BOTTLE; 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		02/05/2018	

Labeler - Sunascen Therapeutics LLC (078272834)

Registrant - Sunascen Therapeutics LLC (078272834)

Establishment

Name	Address	ID/FEI	Business Operations
Sunascen Therapeutics LLC		078272834	label(49467-230)

Revised: 2/2023

Sunascen Therapeutics LLC