HEADACHE RELIEF PM- acetaminophen, aspirin, and diphenhydramine citrate tablet, film coated
Walgreens

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.

HEADACHE RELIEF PM

Drug Facts

Active ingredients (in each caplet)	*Purposes*
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID) *	Pain reliever
Diphenhydramine citrate 38mg	Nighttime sleep-aid

* nonsteroidal anti-inflammatory drug

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

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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

Allergy alert

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver Warning

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

- more than 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 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 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 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 any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if

- you have liver disease
- 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 are taking a diuretic
- you have asthma
- you have glaucoma
- you have a breathing problem such as emphysema or chronic bronchitis
- you have trouble urinating due to an enlarged prostate gland

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

- diabetes
- gout
- arthritis
- any other drug, or are under a doctor's care for any serious condition
- any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer
- sedatives or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- pain gets worse or last for more than 10 days
- painful area is red or swollen
- ringing in the ears or a loss of hearing occurs
- any new symptoms occur

These could be signs of a serious condition

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last three 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. 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 use more than directed
- do not use in children under 12 years of age
- adults and children 12 years of age and over: take 2 caplets at bedtime, with a full glass of water
- do not take more than 2 caplets in 24 hours, unless directed by a doctor

Other information
- store at 20°-25°C (68°-77°F).
- close cap tightly after use.
- read all product information before using. Keep this box for important information.

Inactive ingredients

Benzoic acid , calcium carbonate, colloidal silicon dioxide, hydroxypropyl cellulose, iron oxide yellow, maltodextrin, magnesium stearate, microcrystalline cellulose Type 101, microcrystalline cellulose Type 112, medium chain triglycerides, Opadry Blue, pregelatinized corn starch, polysorbate 80, povidone K30, stearic acid, talc, zinc stearate

Questions or comments

1-888-333-9792

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

PRINCIPAL DISPLAY PANEL - 100 Caplet Bottle Carton

Well at
Walgreens

NDC 0363-9894-12

WALGREENS PHARMACIST RECOMMENDED ‡

Headache
Relief PM

Acetaminophen / Pain Reliever

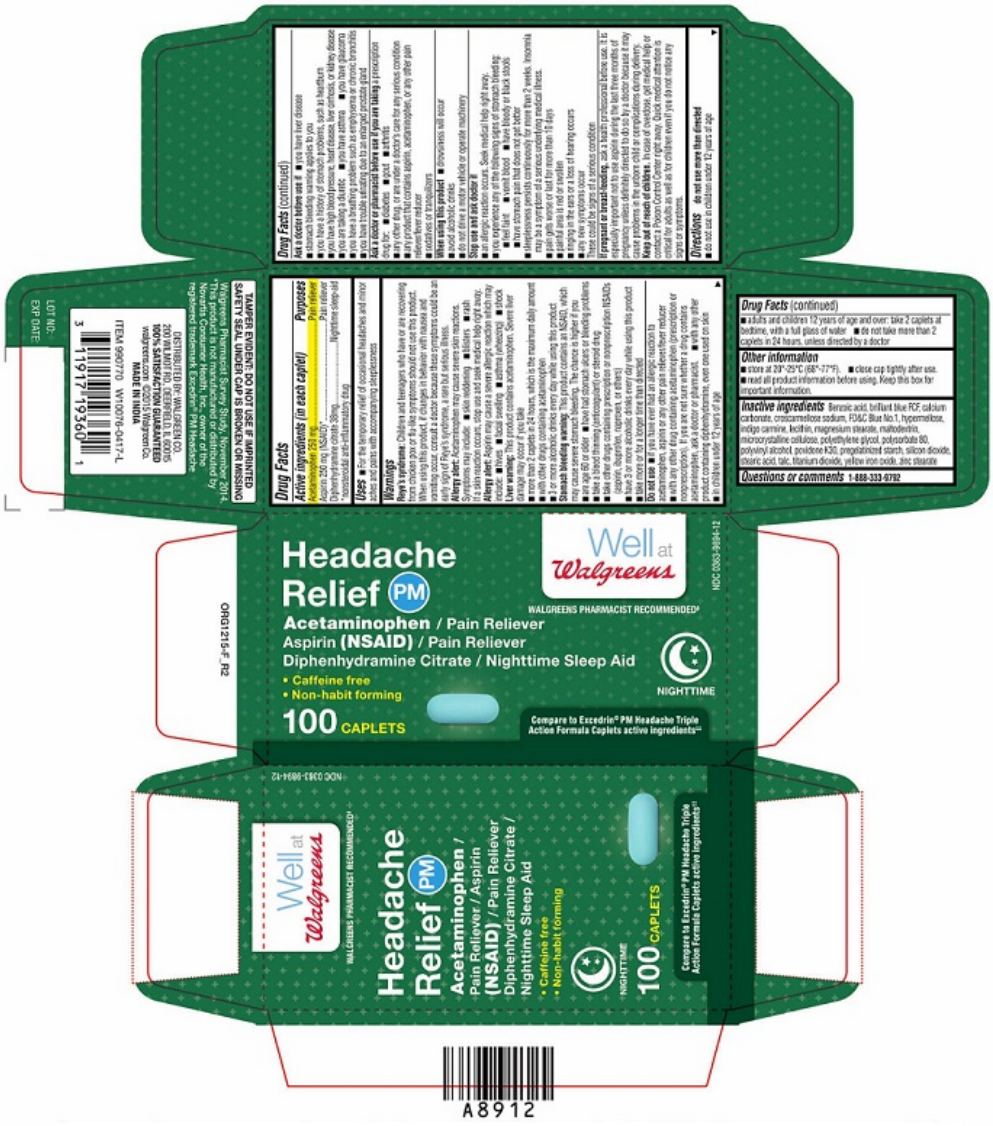
Aspirin **(NSAID)** / Pain Reliever
Diphenhydramine Citrate / Nighttime Sleep Aid

- Caffeine free
- Non-habit forming

NIGHTTIME

100 CAPLETS

Compare to Excedrin ® PM Headache Triple Action Formula Caplets active ingredients ‡‡



HEADACHE RELIEF PM

acetaminophen, aspirin, and diphenhydramine citrate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-9894
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**
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	OVAL (CAPSULE SHAPED)	**Size**	18mm
Flavor		**Imprint Code**	S521
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0363-9894-12	1 in 1 CARTON	12/15/2017	

1		100 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	02/15/2016	

Labeler - Walgreens (008965063)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MOLECULES DRUGS & RESEARCH LABORATORY PVT. LTD.		860240133	manufacture(0363-9894)

Revised: 12/2017 Walgreens