

**PAIN AID BRF - acetaminophen magnesium salicylate tablet**  
**Zee Medical 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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**Drug Facts**

Active Ingredient/Tablet Acetaminophen 250mg, Magnesium Salicylate Tetrahydrate 250 mg (NSAID)

Purpose-Pain Reliever

Temporarily relieves minor back pain

Adults: Take 2 tablets every 6 hours, not more than 8 tablets in 24 hours

Children under 12 years, ask a doctor

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy Alert: Magnesium Salicylate 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 8 tablets in 24 hours
- with other drugs containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 3 or more alcoholic drinks every day while using this product

Stomach Bleeding Warning: This product contains nonsteroidal anti-inflammatory drugs (NSAIDs), which may cause stomach bleeding. The chance is higher if you:

- o are age 60 or older
- o have had stomach ulcers or bleeding problems
- o take a blood thinning (anticoagulant) or steroid drug
- o take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others).
- o Take more or for a longer time than directed

Ask a doctor before use if : Stomach bleeding warnings apply to you, you have a history of stomach problems such as heartburn, you have asthma, high blood pressure, heart disease, liver disease or kidney disease\_\_\_\_\_

Do not use:

- with any other product containing acetaminophen this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- When using this product do not exceed recommended dose.

Do not use:

- if you are allergic to aspirin or salicylates
- with any other pain reliever/fever reducer
- if you have ever had an allergic reaction to any other pain reliever/fever reducer

- for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor
  - with any other product containing acetaminophen
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Stop use and ask a doctor if:

- symptoms do not improve
- pain or fever persists or gets worse
- new symptoms occur
- redness or swelling is present

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

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

Stop use and ask a 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 black or bloody stools, have stomach pain that does not get better

- ringing in the ears or loss of hearing occurs
- pain or fever persists or gets worse
- new symptoms occur
- redness or swelling is present

If pregnant or breast-feeding baby, ask a health professional

before use. **IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY 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.

Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Inactive Ingredients: corn starch, DC Yellow 10, FDC Yellow 6, microcrystalline cellulose, polydextrose, povidone, propylene glycol, silicon dioxide, stearic acid, titanium dioxide

MM1



CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	orange (light orange)	Score	no score
Shape	ROUND (FR40)	Size	12mm
Flavor		Imprint Code	FR40
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35418-801-68	50 in 1 CARTON		
1	NDC:35418-801-67	125 in 1 CARTON		
1	NDC:35418-801-02	2 in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/19/2012	

**Labeler** - Zee Medical Inc (009645623)

**Registrant** - Ultra Seal Corporation (085752004)

### Establishment

Name	Address	ID/FEI	Business Operations
Ultratab Laboratories, Inc.		151051757	manufacture(35418-801)

Revised: 7/2012

Zee Medical Inc