• Taste summer without getting burned.

Relax. Just one and heartburn's done.

When heartburn keeps coming back...

© ohnsonjay & ohnsonjay Erckmey 2005 www.amcidcomplete.com
BRIEF SUMMARY OF PRESCRIBING INFORMATION
AMCOTIN ® (AMODITINE) TABLETS
AMCOTIN ® (AMODITINE) FOR ORAL SUSPENSION

CONTRAINDICATIONS

Hypersensitivity to any component of these products.

PRECAUTIONS

General
Symptomatic response to therapy with AMCOTIN does not preclude the presence of gastric malignancy.

Patients with Severe Renal Insufficiency
Larger intervals between doses or lower doses may need to be used in patients with severe renal insufficiency (creatinine clearance < 10 mL/min) to adjust for the longer elimination half-life of amoditine. However, currently, no drug-related toxicity has been found with high plasma concentrations of amoditine.

Information for Patients
The patient should be instructed to shake the oral suspension vigorously for 5 to 10 seconds prior to each use. Unused constituted oral suspension should be discarded after 30 days.

Drug Interactions
No drug interactions have been identified. Studies with amoditine in man, in animal models, and in vitro have shown no significant interference with the disposition of compounds metabolized by the hepatic microsomal enzymes, e.g., cytochrome P450 system. Compounds tested in man include warfarin, theophylline, phenytoin, diazepam, amitriptyline, and antipyrine. Indocyanine green as an index of hepatic drug extraction has been tested and no significant effects have been found.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104 week study in rats and a 52 week study in mice given oral doses of up to 2000 mg/kg/day approximating 250 times the recommended human dose for active duodenal ulcer, there was no evidence of carcinogenic potential for AMCOTIN. Amoditine was negative in the microbial mutagen test (Ames test) using Salmonella typhimurium and Escherichia coli with or without rat liver enzyme activation at concentrations up to 10,000 mcg/mL. In in vivo studies in mice, with a micronutrient test and a chromosome aberration test, no evidence of a mutagenic effect was observed.

In studies with rats given oral doses of up to 2000 mg/kg/day or intravenous doses of up to 200 mg/kg/day, fertility and reproductive performance were not affected.

Pregnancy
Pregnancy Category B

Reproductive studies have been performed in rats and rabbits at oral doses of up to 2000 and 500 mg/kg/day, respectively, and in both species at IV doses of up to 200 mg/kg/day, and have revealed no significant evidence of impaired fertility or harm to the fetus due to AMCOTIN (amoditine). While no direct teratotoxic effects have been observed, sporadic abortions occurring only in mothers displaying marked decreased food intake were seen in some rabbits at oral doses of 200 mg/kg/day (250 times the usual human dose) or higher. There are, however, no adequate or well controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Studies performed in lactating rats have shown that amoditine is secreted into breast milk. Transient growth depression was observed in weanling rats suckling from mothers treated with amoxicillin at doses of at least 600 times the usual human dose. Amoditine is detectable in human milk. Because of the potential for serious adverse reactions in nursing infants from AMCOTIN, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in children have not been established.

Use in Elderly Patients

No dosage adjustment is required based on age. Dosage adjustment in the case of severe renal impairment may be necessary.

ADVERSE REACTIONS

The adverse reactions listed below have been reported during domestic and international clinical trials in approximately 2500 patients. In these controlled clinical trials in which AMCOTIN Tablets were compared to placebo, the incidence of adverse experiences in the group which received AMCOTIN Tablets, 40 mg at bedtime, was similar to that in the placebo group. The following adverse reactions have been reported to occur in more than 1% of patients on therapy with AMCOTIN in controlled clinical trials, and may be causally related to the drug: headache (4.7%), diarrhea (3.3%), constipation (1.7%), nausea (1.7%), vomiting (1.7%), and dry mouth (1.7%). The following other adverse reactions have been reported infrequently in clinical trials or since the drug was marketed. The relationship to therapy with AMCOTIN has been unclear in many cases. Within each category, the adverse reactions are listed in order of decreasing severity:

Body as a Whole: fatigue
Cardiovascular: chest pain, palpitation
Gastrointestinal: cholestatic jaundice, liver enzyme abnormalities, vomiting, nausea, abdominal discomfort, anorexia, dry mouth
Hematologic: rare cases of agranulocytosis, pancytopenia, leukopenia, thrombocytopenia
Hyperkalemia: hyperkalemia, edema, abdominal pain, tachycardia, rash, conjunctivitis
Musculoskeletal: muscle spasm including muscle cramps, arthralgia
Nervous System/Psychiatric: grand mal seizure, psychic disturbances, which were reversible in cases for which follow-up data was obtained, including hallucinations, confusion, agitation, depression, anxiety, decreased libido, paresthesia, insomnia, somnolence
Respiratory: bronchospasm
Skin: toxic epidermal necrolysis (very rare), alopecia, acne, pruritus, dry skin, flushing
Special Senses: taste disorder
Other: rare cases of impotence and rare cases of gynecomastia have been reported; however, in controlled clinical trials, the incidences were not greater than those seen with placebo.

The adverse reactions reported for AMCOTIN (amoditine) Tablets may also occur with AMCOTIN for Oral Suspension.

OVERDOSAGE

There is no experience to date with deliberate overdosage. Oral doses of up to 40 mg/day have been given to patients with pathological hypersecreatory conditions without serious adverse effects. In the event of overdosage, treatment should be symptomatic and supportive. Undeburred material should be removed from the gastrointestinal tract, the patient should be monitored, and supportive therapy should be employed.

For more detailed information, please read the Prescribing Information.

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973837(028R)-04-PEP
**Prescription Drug Facts: AMCID (amodicaine)**

**What is this drug for?** To relieve heartburn

**Who might consider taking it?** Men and women bothered by heartburn or acid reflux disease

**Who should NOT take it?** Women who are pregnant or breastfeeding

**Recommended testing** None

**Other things to consider doing** Eat frequent small meals; avoid fatty foods (and others which trigger your symptoms); excessive alcohol and eating close to bedtime; don’t smoke; look into other medications.

**AMCID Study Findings Box**

500 people with bothersome heartburn were given AMCID or a sugar pill for 2 weeks. Here’s what happened:

<table>
<thead>
<tr>
<th>What difference did AMCID make?</th>
<th>People given a sugar pill</th>
<th>People given AMCID (20 mg a day)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Did AMCID help?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fewer people taking AMCID had heartburn (17% fewer)</td>
<td>81% 810 in 1000</td>
<td>64% 640 in 1000</td>
</tr>
<tr>
<td><strong>Did AMCID have side effects?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Life threatening side effects</em></td>
<td>None observed</td>
<td></td>
</tr>
<tr>
<td>No difference between AMCID and a sugar pill</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Symptom side effects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No difference in headache</td>
<td>About 5% in both groups</td>
<td>About 2% in both groups</td>
</tr>
<tr>
<td>No difference in diarrhea</td>
<td>50 in 1000</td>
<td>20 in 1000</td>
</tr>
<tr>
<td>No difference in dizziness</td>
<td>About 1% in both groups</td>
<td>About 1% in both groups</td>
</tr>
<tr>
<td></td>
<td>10 in 1000</td>
<td>10 in 1000</td>
</tr>
</tbody>
</table>

**How long has the drug been in use?**

*Amcid was approved by FDA in 1991 - Studies show that most serious side effects or recalls of new drugs happen during their first 5 years of approval.*
It’s time for a Maxtor summer.

You already know that the makers of prescription Maxtor are the experts in acid reflux disease. And that Maxtor can help keep you heartburn free. Now you can tell your friends who may suffer from frequent and persistent heartburn about Maxtor.

Remember to take your Maxtor as directed for 24 hours of complete heartburn relief that’s possible with Maxtor.

Get your acid relief now!
1-888-636-9963

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AstraEnecazay

Please read the important Product Information on the following page and discuss it with your doctor.

Maxtor
(Moprasozole) 20-MG CAPSULES
MAXTOR® (moprasozole) Delayed-Release Capsules

BRIEF SUMMARY.

CLINICAL PHARMACOLOGY Pharmacokinetics and Metabolism. Moprasozole is a pharmacokinetic study of an in vivo drug release in humans. It is indicated for the treatment of patients with severe, moderate, or mild thrombocytopenia. Moprasozole is indicated for the treatment of patients with severe, moderate, or mild thrombocytopenia. Moprasozole is indicated for the treatment of patients with severe, moderate, or mild thrombocytopenia. Moprasozole is indicated for the treatment of patients with severe, moderate, or mild thrombocytopenia. Moprasozole is indicated for the treatment of patients with severe, moderate, or mild thrombocytopenia. Moprasozole is indicated for the treatment of patients with severe, moderate, or mild thrombocytopenia. Moprasozole is indicated for the treatment of patients with severe, moderate, or mild thrombocytopenia.

INDICATIONS AND USAGE.

Idiopathic Thrombocytopenic Purpura (ITP): Moprasozole is indicated for the treatment of patients with ITP. Moprasozole is indicated for the treatment of patients with ITP. Moprasozole is indicated for the treatment of patients with ITP. Moprasozole is indicated for the treatment of patients with ITP. Moprasozole is indicated for the treatment of patients with ITP. Moprasozole is indicated for the treatment of patients with ITP. Moprasozole is indicated for the treatment of patients with ITP.

Irritable Bowel Syndrome (IBS): Moprasozole is indicated for the treatment of patients with IBS. Moprasozole is indicated for the treatment of patients with IBS. Moprasozole is indicated for the treatment of patients with IBS. Moprasozole is indicated for the treatment of patients with IBS. Moprasozole is indicated for the treatment of patients with IBS. Moprasozole is indicated for the treatment of patients with IBS. Moprasozole is indicated for the treatment of patients with IBS.

Methylmalonic Acidemia: Moprasozole is indicated for the treatment of patients with methylmalonic acidemia. Moprasozole is indicated for the treatment of patients with methylmalonic acidemia. Moprasozole is indicated for the treatment of patients with methylmalonic acidemia. Moprasozole is indicated for the treatment of patients with methylmalonic acidemia. Moprasozole is indicated for the treatment of patients with methylmalonic acidemia. Moprasozole is indicated for the treatment of patients with methylmalonic acidemia. Moprasozole is indicated for the treatment of patients with methylmalonic acidemia.

Gastroesophageal Reflux Disease (GERD): Moprasozole is indicated for the treatment of GERD. Moprasozole is indicated for the treatment of GERD. Moprasozole is indicated for the treatment of GERD. Moprasozole is indicated for the treatment of GERD. Moprasozole is indicated for the treatment of GERD. Moprasozole is indicated for the treatment of GERD. Moprasozole is indicated for the treatment of GERD.

CONTRAINDICATIONS.

Moprasozole Delayed-Release Capsules are contraindicated in patients with known or suspected hypersensitivity to any component of the product. Moprasozole is contraindicated in patients with known or suspected hypersensitivity to any component of the product. Moprasozole is contraindicated in patients with known or suspected hypersensitivity to any component of the product. Moprasozole is contraindicated in patients with known or suspected hypersensitivity to any component of the product. Moprasozole is contraindicated in patients with known or suspected hypersensitivity to any component of the product. Moprasozole is contraindicated in patients with known or suspected hypersensitivity to any component of the product. Moprasozole is contraindicated in patients with known or suspected hypersensitivity to any component of the product.

WARNINGS:

Thrombocytopenia: Thrombocytopenia should be considered in patients with a history of significant reactions to any component of the product. Thrombocytopenia should be considered in patients with a history of significant reactions to any component of the product. Thrombocytopenia should be considered in patients with a history of significant reactions to any component of the product. Thrombocytopenia should be considered in patients with a history of significant reactions to any component of the product. Thrombocytopenia should be considered in patients with a history of significant reactions to any component of the product. Thrombocytopenia should be considered in patients with a history of significant reactions to any component of the product. Thrombocytopenia should be considered in patients with a history of significant reactions to any component of the product.

Thrombus formation: Thrombus formation should be considered in patients with a history of significant reactions to any component of the product. Thrombus formation should be considered in patients with a history of significant reactions to any component of the product. Thrombus formation should be considered in patients with a history of significant reactions to any component of the product. Thrombus formation should be considered in patients with a history of significant reactions to any component of the product. Thrombus formation should be considered in patients with a history of significant reactions to any component of the product. Thrombus formation should be considered in patients with a history of significant reactions to any component of the product. Thrombus formation should be considered in patients with a history of significant reactions to any component of the product.

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PRECAUTIONS:

Thromboses: Thromboses may be associated with the use of this product. Thromboses may be associated with the use of this product. Thromboses may be associated with the use of this product. Thromboses may be associated with the use of this product. Thromboses may be associated with the use of this product. Thromboses may be associated with the use of this product. Thromboses may be associated with the use of this product.

Renal Impairment: Patients with renal impairment should be monitored closely during therapy. Patients with renal impairment should be monitored closely during therapy. Patients with renal impairment should be monitored closely during therapy. Patients with renal impairment should be monitored closely during therapy. Patients with renal impairment should be monitored closely during therapy. Patients with renal impairment should be monitored closely during therapy. Patients with renal impairment should be monitored closely during therapy.
Prescription Drug Facts: MAXTOR (moprasozole)

**What is this drug for?** To relieve heartburn

**Who might consider taking it?** Men and women bothered by heartburn or acid reflux disease

**Who should NOT take it?** Women who are pregnant or breastfeeding

**Recommended testing** None

**Other things to consider doing** Eat frequent small meals; avoid fatty foods (and others which trigger your symptoms); excessive alcohol and eating close to bedtime; don't smoke; look into other medications.

---

**MAXTOR Study Findings Box**

500 people with bothersome heartburn were given MAXTOR or a sugar pill for 2 weeks. Here's what happened:

<table>
<thead>
<tr>
<th>What difference did MAXTOR make?</th>
<th>People given a sugar pill</th>
<th>People given MAXTOR (20 mg a day)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Did MAXTOR help?</strong> Fewer people taking MAXTOR had heartburn (70% fewer)</td>
<td>81% 810 in 1000</td>
<td>11% 110 in 1000</td>
</tr>
<tr>
<td><strong>Did MAXTOR have side effects?</strong> No difference between AMDID and a sugar pill</td>
<td>None observed</td>
<td></td>
</tr>
<tr>
<td><em>Life threatening side effects</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No difference in abdominal pain</td>
<td></td>
<td>About 5% in both groups 50 in 1000</td>
</tr>
<tr>
<td>No difference in diarrhea</td>
<td></td>
<td>About 4% in both groups 40 in 1000</td>
</tr>
<tr>
<td>No difference in headache</td>
<td></td>
<td>About 3% in both groups 30 in 1000</td>
</tr>
</tbody>
</table>

**How long has the drug been in use?**
*Maxtor was approved by FDA in 1997 - Studies show that most serious side effects or recalls of new drugs happen during their first 5 years of approval.*
What People Think about Information in Ads for Prescription Drugs

2006

a study sponsored by: Dartmouth Medical School
and Department of Veterans Affairs

conducted by: Center for Survey Research
University of Massachusetts Boston

Confidential: No information shall be presented or published in any way that would permit identification of any individual
SURVEY INSTRUCTIONS

◆ Your participation in this study is voluntary. If you come across a question you would rather not answer, feel free to skip it and go on to the next question.

◆ Your answers will be treated confidentially. They will be combined with other people’s answers and no individual person’s answers will ever be presented.

◆ Please answer all the questions by checking the box to the left of your answer.

◆ You are sometimes told to skip over some questions in this survey. When this happens you will see an arrow with a note that tells you what question to answer next, like this:

✔ Yes  ➔ If YES, go to Question 1

☐ No

◆ When you have completed the questionnaire, please return it to the Center for Survey Research in the postage-paid envelope provided.

If you have any questions about this survey, please call the Center for Survey Research at 1-800-492-5845
ABOUT THIS STUDY

Researchers at Dartmouth Medical School want to know how consumers like you feel about different ways to provide drug information in advertising. Your answers may help the federal Food and Drug Administration (FDA) develop new advertising standards for pharmaceutical companies.

AMCID

Please take a few minutes to look at the ad we enclosed for the drug named AMCID. This is the ad that has the picture of the hamburger and hot dog on it. It looks like this:

The ad has 2 parts - the first page with the picture and then the 2nd page with more detailed information about the drug. When we say ad, we are referring to both pages. Looking at the ad, please do your best to try to find the answers to the following questions.

1. What does the ad say is the main goal of taking AMCID?
   □ To relieve diarrhea
   □ To relieve heartburn
   □ To prevent stomach cancer
   □ To prevent gallstones
2. The next 3 questions are about people who have all heard of AMCID. They all have bothersome heartburn and are thinking about taking this drug.

   a. According to the 2nd page of the ad, is it OK for a 60-year-old man with a history of acid reflux to take AMCID?
      □ Yes
      □ No
      □ Can't find/Ad doesn't say

   b. According to the 2nd page of the ad, is it OK for a 36-year-old pregnant woman who has had severe heartburn for 4 months to take AMCID?
      □ Yes
      □ No
      □ Can't find/Ad doesn't say

   c. According to the 2nd page of the ad, is it OK for a 50-year-old man with high blood pressure to take AMCID?
      □ Yes
      □ No
      □ Can't find/Ad doesn't say

3. In your opinion, how effective do you think AMCID is in relieving heartburn?
   □ Extremely effective
   □ Very effective
   □ Somewhat effective
   □ A little effective
   □ Not effective

4. According to the ad, about what percent of the people given AMCID developed dizziness?
   ___%
   □ Can't find/Ad doesn't say
5. Overall, how would you describe the **benefits** of AMCID for people with bothersome heartburn?

- [ ] Very Large
- [ ] Large
- [ ] Moderate
- [ ] Small
- [ ] Very small
- [ ] There are no benefits

6. How much did the 2nd page of the ad help you understand the **benefits** of AMCID?

- [ ] Helped a lot
- [ ] Helped a little
- [ ] Didn't help at all

7. Overall, how would you describe the **side effects** of AMCID for people with bothersome heartburn?

- [ ] Very Large
- [ ] Large
- [ ] Moderate
- [ ] Small
- [ ] Very small
- [ ] There are no side effects

8. How much did the 2nd page of the ad help you understand the **side effects** of AMCID?

- [ ] Helped a lot
- [ ] Helped a little
- [ ] Didn't help at all

9. Overall, do you think the possible benefits of AMCID are worth the possible side effects for people with bothersome heartburn?

- [ ] Definitely yes
- [ ] Probably yes
- [ ] Probably no
- [ ] Definitely no
Now look at the other ad we sent. It’s for the drug MAXTOR and has the picture of the woman in front of the clock. It looks like this:

Please take a minute to read through both pages of the ad and answer the following questions.

10. What does the ad say is the main goal of taking MAXTOR?
   - [ ] To relieve diarrhea
   - [ ] To relieve heartburn
   - [ ] To prevent stomach cancer
   - [ ] To prevent gallstones

11. According to the ad, which of the following things should a person with bothersome heartburn also consider doing? (Please check one box on each line.)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Ad doesn’t say</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eat frequent small meals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take vitamins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoid fatty foods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eat a high protein diet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not smoke</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. In your opinion, how effective do you think MAXTOR is in relieving heartburn?
   - [ ] Extremely effective
   - [ ] Very effective
   - [ ] Somewhat effective
   - [ ] A little effective
   - [ ] Not effective
13. According to the ad, about what percent of the people given MAXTOR developed a headache?

[ ] ___%

[ ] Can't find/Ad doesn't say

14. In your opinion, how much does MAXTOR change the chance of developing a headache?

[ ] A great deal
[ ] A lot
[ ] A moderate amount
[ ] A little
[ ] Not at all

15. Overall, how would you describe the benefits of MAXTOR for people with bothersome heartburn?

[ ] Very Large
[ ] Large
[ ] Moderate
[ ] Small
[ ] Very small
[ ] There are no benefits

16. Overall, how would you describe the side effects of MAXTOR for people with bothersome heartburn?

[ ] Very Large
[ ] Large
[ ] Moderate
[ ] Small
[ ] Very small
[ ] There are no side effects

17. Overall, do you think the possible benefits of MAXTOR are worth the possible side effects for people with bothersome heartburn?

[ ] Definitely yes
[ ] Probably yes
[ ] Probably no
[ ] Definitely no
Comparing Ads

Now please compare the 2 drugs ads – AMCID (the hamburger and hot dog) and MAXTOR (the woman in front of the clock).

18. First think about people with bothersome heartburn who **do not take a drug to relieve their heartburn**. Which of the following is your best guess of what percent of these people will still have heartburn in the next 2 weeks?

   - [ ] 100%
   - [ ] 96%
   - [ ] 81%
   - [ ] 74%
   - [ ] 50%
   - [ ] 23%
   - [ ] 0% (No one)

19. Now, think about people with bothersome heartburn who **take AMCID**. What’s your best guess about what percent of these people (who take AMCID) will still have heartburn in the next 2 weeks?

   _________%

20. Now, think about people with bothersome heartburn who **take MAXTOR**. What’s your best guess about what percent of these people (who take MAXTOR) will still have heartburn in the next 2 weeks?

   _________%

21. In your opinion, how does AMCID compare to MAXTOR in relieving heartburn?

   - [ ] AMCID is a lot more effective
   - [ ] AMCID is a little more effective
   - [ ] AMCID is about the same
   - [ ] AMCID is a little less effective
   - [ ] AMCID is a lot less effective

22. Overall, how do the side effects of AMCID compare to the side effects of MAXTOR?

   - [ ] AMCID side effects are more serious
   - [ ] MAXTOR side effects are more serious
   - [ ] The side effects are about the same
23. Imagine you had bothersome heartburn. If you could take either AMCID or MAXTOR for free, which drug would you rather take?

☐ AMCID
☐ MAXTOR
☐ Neither

a. Why did you choose your answer?


24. The next questions are about drug ads in general – not just the ones we've shown you. Think about all the different drug ads you have seen, such as those in magazines and in newspapers.

Which best describes what you think about drugs being advertised directly to consumers?

☐ Great idea
☐ Good idea
☐ Bad idea
☐ Terrible idea

25. In general, how much do you trust the information presented in standard drug ads?

☐ A lot
☐ A little
☐ Not at all

26. How much attention do you pay to the information on the 2nd page of drug ads in magazines and newspapers?

☐ A lot
☐ A little
☐ None at all
27. Imagine two drugs which work equally well for the same problem and cost the same. One drug, which we’ll call “OLDDRUG,” was approved by the FDA 10 years ago. The other drug, “NEWDRUG,” was approved this year.

a. If you had to take one of these drugs, which would you choose?

☐ OLDDRUG
☐ NEWDRUG
☐ Either one is fine

b. Which drug do you think is safer?

☐ OLDDRUG
☐ NEWDRUG
☐ Either one is fine

28. In a drug ad there can be words that describe how a drug works (for example: “some people said their pain was completely better”) and there can be numbers (such as “26% of people said their pain was completely better”).

a. How important is it to you that drug ads show how well a drug works in numbers?

☐ Extremely important
☐ Very important
☐ Somewhat important
☐ A little important
☐ Not important at all

b. How important is it to you that drug ads show the chance of side effects in numbers?

☐ Extremely important
☐ Very important
☐ Somewhat important
☐ A little important
☐ Not important at all

29. The FDA approves drugs based on studies which show how well they work and their side effects. How important do you think it is that basic facts from these studies (like how many people were studied, how long they took the drug, and the results) appear in prescription drug ads?

☐ Extremely important
☐ Very important
☐ Somewhat important
☐ A little important
☐ Not important at all
These next few questions are about you.

30.  Are you male or female?

   □  Male  
   □  Female  

31.  In what year were you born?

   ___________ Write in year

32.  What is the highest grade in school that you completed?

   □  8th grade or less  
   □  Some high school, but did not graduate  
   □  High school graduate or GED  
   □  Some college or 2-year degree  
   □  4-year college graduate  
   □  Some post-college/graduate work  
   □  Post-graduate degree  

33.  Are you of Hispanic or Latino origin or descent?

   □  Yes, Hispanic or Latino  
   □  No, not Hispanic or Latino  

34.  What is your race? Please mark one or more.

   □  White  
   □  Black or African-American  
   □  Asian  
   □  Native Hawaiian or other Pacific Islander  
   □  American Indian or Alaska Native  
   □  Other (Please print: ________________________________ )
35. In general, how would you rate your overall health?

☐ Excellent
☐ Very good
☐ Good
☐ Fair
☐ Poor

36. Have you ever taken medicine to relieve or prevent heartburn?

☐ Yes
☐ No → If No, go to Question 37

a. In the last 4 weeks, have you taken any medicine to relieve or prevent heartburn?

☐ Yes
☐ No → If No, go to Question 37

b. In the last 4 weeks how often have you taken medicine to relieve or prevent heartburn?

☐ Every day
☐ Most days
☐ Occasionally

c. What is the name of the medicine?

__________________________________________

37. Which of the following best describes your total household income in 2005; this means income before taxes from all sources, such as salaries, interest, retirement, or any other source for all family members living in your household.

☐ Less than $25,000
☐ Between $25,000 and $50,000
☐ Between $50,000 and $100,000
☐ More than $100,000
The last few questions are about chance and working with numbers. For each question, please give us your best estimate, even if you think your estimate is only a guess.

The first question asks how many times something would happen in 1000 tries.

Example: Imagine picking a jelly bean from a jar filled with an equal number of 4 different colored jelly beans (red, black, blue and green).

Question: Out of 1000 tries, how many times would you expect to pick a red jelly bean?

Answer: 250 times out of 1000

38. Imagine that we flip a coin 1000 times. What is your best guess about how many times the coin would come up heads in 1000 flips?

_______ time(s) out of 1000

39. Imagine a person taking Drug A has a 1% chance of having an allergic reaction. If 1000 people take Drug A, how many would you expect to have an allergic reaction?

_______ person(s) out of 1000

40. Imagine a person taking Drug B has a 1 in 1,000 chance of an allergic reaction. What percent of people taking Drug B will have an allergic reaction?

_______ %

THANK YOU!

Please return the completed survey in the postage-paid envelope to:

The Center for Survey Research
100 Morrissey Boulevard
Boston, MA 02125
What People Think about Information in Ads for Prescription Drugs

2006

a study sponsored by: Dartmouth Medical School and Department of Veterans Affairs

conducted by: Center for Survey Research University of Massachusetts Boston

Confidential: No information shall be presented or published in any way that would permit identification of any individual
SURVEY INSTRUCTIONS

◆ Your participation in this study is voluntary. If you come across a question you would rather not answer, feel free to skip it and go on to the next question.

◆ Your answers will be treated confidentially. They will be combined with other people’s answers and no individual person’s answers will ever be presented.

◆ Please answer all the questions by checking the box to the left of your answer.

◆ You are sometimes told to skip over some questions in this survey. When this happens you will see an arrow with a note that tells you what question to answer next, like this:

✔ Yes → If YES, go to Question 1

☐ No

◆ When you have completed the questionnaire, please return it to the Center for Survey Research in the postage-paid envelope provided.

If you have any questions about this survey, please call the Center for Survey Research at 1-800-492-5845
ABOUT THIS STUDY

Researchers at Dartmouth Medical School want to know how consumers like you feel about different ways to provide drug information in advertising. Your answers may help the federal Food and Drug Administration (FDA) develop new advertising standards for pharmaceutical companies.

AMCID

Please take a few minutes to look at the ad we enclosed for the drug named AMCID. This is the ad that has the picture of the hamburger and hot dog on it. It looks like this:

The ad has 2 parts - the first page with the picture and then the 2nd page with more detailed information about the drug. When we say ad, we are referring to both pages. Looking at the ad, please do your best to try to find the answers to the following questions.

1. What does the ad say is the main goal of taking AMCID?
   - [ ] To relieve diarrhea
   - [ ] To relieve heartburn
   - [ ] To prevent stomach cancer
   - [ ] To prevent gallstones

2. In what year was AMCID approved by the FDA?
   ______ Write in year
3. The next 3 questions are about people who have all heard of AMCID. They all have bothersome heartburn and are thinking about taking this drug.

a. According to the 2nd page of the ad, is it OK for a 60-year-old man with a history of acid reflux to take AMCID?
   - □ Yes
   - □ No
   - □ Can't find/Ad doesn't say

b. According to the 2nd page of the ad, is it OK for a 36-year-old pregnant woman who has had severe heartburn for 4 months to take AMCID?
   - □ Yes
   - □ No
   - □ Can't find/Ad doesn't say

c. According to the 2nd page of the ad, is it OK for a 50-year-old man with high blood pressure to take AMCID?
   - □ Yes
   - □ No
   - □ Can't find/Ad doesn't say

4. According to the AMCID Study Findings Box on the 2nd page of the ad, what percent of the people given AMCID had heartburn at the end of the 2 week study?

   _______%
   - □ Can't find/Ad doesn't say

5a. According to the AMCID Study Findings Box, which statement is correct about how much AMCID affects heartburn?

   - □ 70% fewer people had heartburn than with a sugar pill
   - □ 17% fewer people had heartburn than with a sugar pill
   - □ Does not change the chance
   - □ 17% more people had heartburn than with a sugar pill
   - □ 70% more people had heartburn than with a sugar pill
   - □ Can't find/Ad doesn't say

5b. Percents (%) show how many times in 100 something happens. Sometimes researchers show results as how many times in 1000 something happens. Please change the number part of the answer you just marked in Question 5a into how many times in 1000.

   _______ in 1000 (Please write in number)
6. In your opinion, how effective do you think AMCID is in relieving heartburn?
   □ Extremely effective
   □ Very effective
   □ Somewhat effective
   □ A little effective
   □ Not effective

7. According to the AMCID Study Findings Box, about what percent of the people given AMCID had dizziness?
   _____%
   □ Can't find/Ad doesn't say

8. According to the AMCID Study Findings Box, which group of people was more likely to have diarrhea?
   □ Those who were given AMCID
   □ Those who were given a sugar pill
   □ Diarrhea was about the same in both groups
   □ Can't find/Ad doesn't say

9. Overall, how would you describe the benefits of AMCID for people with bothersome heartburn?
   □ Very Large
   □ Large
   □ Moderate
   □ Small
   □ Very small
   □ There are no benefits

10. How much did the 2nd page of the ad help you understand the benefits of AMCID?
    □ Helped a lot
    □ Helped a little
    □ Didn't help at all
11. Overall, how would you describe the **side effects** of AMCID for people with bothersome heartburn?

- Very Large
- Large
- Moderate
- Small
- Very small
- There are no side effects

12. How much did the 2nd page of the ad help you understand the **side effects** of AMCID?

- Helped a lot
- Helped a little
- Didn’t help at all

13. Overall, do you think the possible benefits of AMCID are worth the possible side effects for people with bothersome heartburn?

- Definitely yes
- Probably yes
- Probably no
- Definitely no
Now look at the other ad we sent. It's for the drug MAXTOR and has the picture of the woman in front of the clock. It looks like this:

Please take a minute to read through both pages of the ad and answer the following questions.

14. What does the ad say is the main goal of taking MAXTOR?

☐ To relieve diarrhea
☐ To relieve heartburn
☐ To prevent stomach cancer
☐ To prevent gallstones

15. According to the ad, which of the following things should a person with bothersome heartburn also consider doing? (Please check one box on each line.)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Ad doesn't say</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eat frequent small meals</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Take vitamins</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Avoid fatty foods</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Eat a high protein diet</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Not smoke</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
16. According to the *MAXTOR Study Findings Box* on the 2\textsuperscript{nd} page, how many people were followed in the study?

_____ Write in number of people

☐ Can't find/Ad doesn't say

17. According to the *MAXTOR Study Findings Box* on the 2\textsuperscript{nd} page, what percent of the people given MAXTOR had heartburn at the end of the 2 week study?

_____ %

☐ Can't find/Ad doesn't say

18. According to the *MAXTOR Study Findings Box*, which statement is correct about how much MAXTOR changes the chance of someone continuing to have heartburn?

☐ 70\% fewer people had heartburn than with a sugar pill

☐ 17\% fewer people had heartburn than with a sugar pill

☐ Does not change the chance

☐ 17\% more people had heartburn than with a sugar pill

☐ 70\% more people had heartburn than with a sugar pill

☐ Can't find/Ad doesn't say

19. In your opinion, how effective do you think MAXTOR is in relieving heartburn?

☐ Extremely effective

☐ Very effective

☐ Somewhat effective

☐ A little effective

☐ Not effective

20. According to the *MAXTOR Study Findings Box*, about what percent of the people given MAXTOR developed a headache?

_____ %

☐ Can't find/Ad doesn't say
21. In your opinion, how much does MAXTOR change the chance of developing a headache?
   □ A great deal
   □ A lot
   □ A moderate amount
   □ A little
   □ Not at all

22. Overall, how would you describe the benefits of MAXTOR for people with bothersome heartburn?
   □ Very Large
   □ Large
   □ Moderate
   □ Small
   □ Very small
   □ There are no benefits

23. Overall, how would you describe the side effects of MAXTOR for people with bothersome heartburn?
   □ Very Large
   □ Large
   □ Moderate
   □ Small
   □ Very small
   □ There are no benefits

24. Overall, do you think the possible benefits of MAXTOR are worth the possible side effects for people with bothersome heartburn?
   □ Definitely yes
   □ Probably yes
   □ Probably no
   □ Definitely no
COMPARING ADS

Now please compare the 2 drugs ads – AMCID (the hamburger and hot dog) and MAXTOR (the woman in front of the clock).

25. According to the *AMCID Study Findings Box*, what percent of people with bothersome heartburn who **do not take a drug to relieve their heartburn** had heartburn at the end of the 2 week study?

- [ ] 100%
- [ ] 96%
- [ ] 81%
- [ ] 74%
- [ ] 50%
- [ ] 23%
- [ ] 0% (No one)

26. According to the *AMCID Study Findings Box*, what percent of the people given AMCID had heartburn at the end of the 2 week study?

\[ \text{_______ \%} \]

27. According to the *MAXTOR Study Findings Box*, what percent of the people given MAXTOR had heartburn at the end of the 2 week study?

\[ \text{_______ \%} \]

28. In your opinion, how does AMCID compare to MAXTOR in relieving heartburn?

- [ ] AMCID is a lot more effective
- [ ] AMCID is a little more effective
- [ ] AMCID is about the same
- [ ] AMCID is a little less effective
- [ ] AMCID is a lot less effective

29. Overall, how do the side effects of AMCID compare to the side effects of MAXTOR?

- [ ] AMCID side effects are more serious
- [ ] MAXTOR side effects are more serious
- [ ] The side effects are about the same
30. Imagine you had bothersome heartburn. If you could take either AMCID or MAXTOR for free, which drug would you rather take?

☐ AMCID
☐ MAXTOR
☐ Neither

a. Why did you choose your answer?

31. Please think about the 2nd page of the ads. How easy or hard was it for you to find information in the Study Findings Boxes on the 2nd page of the ads?

☐ Very easy
☐ Somewhat easy
☐ A little hard
☐ Very hard

32. How easy or hard was it for you to understand information in the Study Findings Boxes on the 2nd page of the ads?

☐ Very easy
☐ Somewhat easy
☐ A little hard
☐ Very hard

33. Think about the drug ads you just looked at for AMCID and MAXTOR. Overall, how would you rate the 2nd page of these ads in helping you to weigh the pros and cons of these drugs?

☐ Extremely useful
☐ Very useful
☐ A little useful
☐ Useless

34. The next questions are about drug ads in general – not just the ones we've shown you. Think about all the different drug ads you have seen, such as those in magazines and in newspapers.

Which best describes what you think about drugs being advertised directly to consumers?

☐ Great idea
☐ Good idea
☐ Bad idea
☐ Terrible idea
35. In general, how much do you trust the information presented in standard drug ads?

- A lot
- A little
- Not at all

36. How much attention do you pay to the information on the 2nd page of drug ads in magazines and newspapers?

- A lot
- A little
- None at all

37. Imagine two drugs which work equally well for the same problem and cost the same. One drug, which we’ll call “OLDDRUG,” was approved by the FDA 10 years ago. The other drug, “NEWDRUG,” was approved this year.

a. If you had to take one of these drugs, which would you choose?

- OLDDRUG
- NEWDRUG
- Either one is fine

b. Which drug do you think is safer?

- OLDDRUG
- NEWDRUG
- Either one is fine

38. In a drug ad there can be words that describe how a drug works (for example: “some people said their pain was completely better”) and there can be numbers (such as “26% of people said their pain was completely better”).

a. How important is it to you that drug ads show how well a drug works in numbers?

- Extremely important
- Very important
- Somewhat important
- A little important
- Not important at all

b. How important is it to you that drug ads show the chance of side effects in numbers?

- Extremely important
- Very important
- Somewhat important
- A little important
- Not important at all
39. The FDA approves drugs based on studies showing how well the drugs work and their side effects. The AMCID and MAXTOR ads had Study Findings Boxes describing the basic facts from these studies. How important do you think it is that a Study Findings Box appear in prescription drug ads?

☐ Extremely important
☐ Very important
☐ Somewhat important
☐ A little important
☐ Not important at all

About You

These next few questions are about you.

40. Are you male or female?

☐ Male
☐ Female

41. In what year were you born?

_________ Write in year

42. What is the highest grade in school that you completed?

☐ 8th grade or less
☐ Some high school, but did not graduate
☐ High school graduate or GED
☐ Some college or 2-year degree
☐ 4-year college graduate
☐ Some post-college/graduate work
☐ Post-graduate degree

43. Are you of Hispanic or Latino origin or descent?

☐ Yes, Hispanic or Latino
☐ No, not Hispanic or Latino

44. What is your race? Please mark one or more.

☐ White
☐ Black or African-American
☐ Asian
☐ Native Hawaiian or other Pacific Islander
☐ American Indian or Alaska Native
☐ Other (Please print: ___________________________ )
45. In general, how would you rate your overall health?
   □ Excellent
   □ Very good
   □ Good
   □ Fair
   □ Poor

46. Have you ever taken medicine to relieve or prevent heartburn?
   □ Yes
   □ No → If No, go to Question 47

   a. In the last 4 weeks, have you taken any medicine to relieve or prevent heartburn?
      □ Yes
      □ No → If No, go to Question 47

   b. In the last 4 weeks, how often have you taken medicine to relieve or prevent heartburn?
      □ Every day
      □ Most days
      □ Occasionally

   c. What is the name of the medicine?
      ________________________________

47. Which of the following best describes your total household income in 2005; this means income before taxes from all sources, such as salaries, interest, retirement, or any other source for all family members living in your household.
   □ Less than $25,000
   □ Between $25,000 and $50,000
   □ Between $50,000 and $100,000
   □ More than $100,000
The last few questions are about chance and working with numbers. For each question, please give us your best estimate, even if you think your estimate is only a guess.

The first question asks how many times something would happen in 1000 tries.

Example: Imagine picking a jelly bean from a jar filled with an equal number of 4 different colored jelly beans (red, black, blue and green).

Question: Out of 1000 tries, how many times would you expect to pick a red jelly bean?

Answer: 250 times out of 1000

48. Imagine that we flip a coin 1000 times. What is your best guess about how many times the coin would come up heads in 1000 flips?

_____ time(s) out of 1000

49. Imagine a person taking Drug A has a 1% chance of having an allergic reaction. If 1000 people take Drug A, how many would you expect to have an allergic reaction?

_____ person(s) out of 1000

50. Imagine a person taking Drug B has a 1 in 1,000 chance of an allergic reaction. What percent of people taking Drug B will have an allergic reaction?

_____ %

THANK YOU!

Please return the completed survey in the postage-paid envelope to:

The Center for Survey Research
100 Morrissey Boulevard
Boston, MA 02125