

# Improving Prescription Drug Labeling

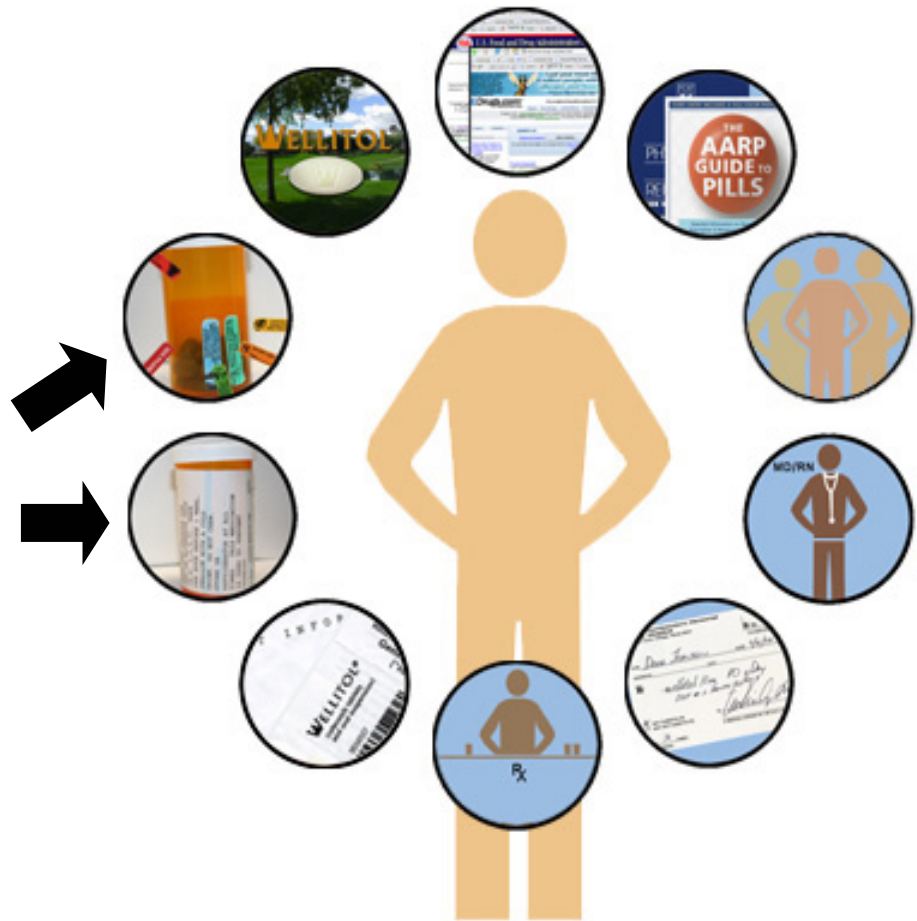
**Michael Wolf, MA MPH PhD**

Health Literacy and Learning Program  
Center for Communication in Healthcare  
Feinberg School of Medicine  
School of Education & Social Policy  
Northwestern University



## Value of Rx Labels

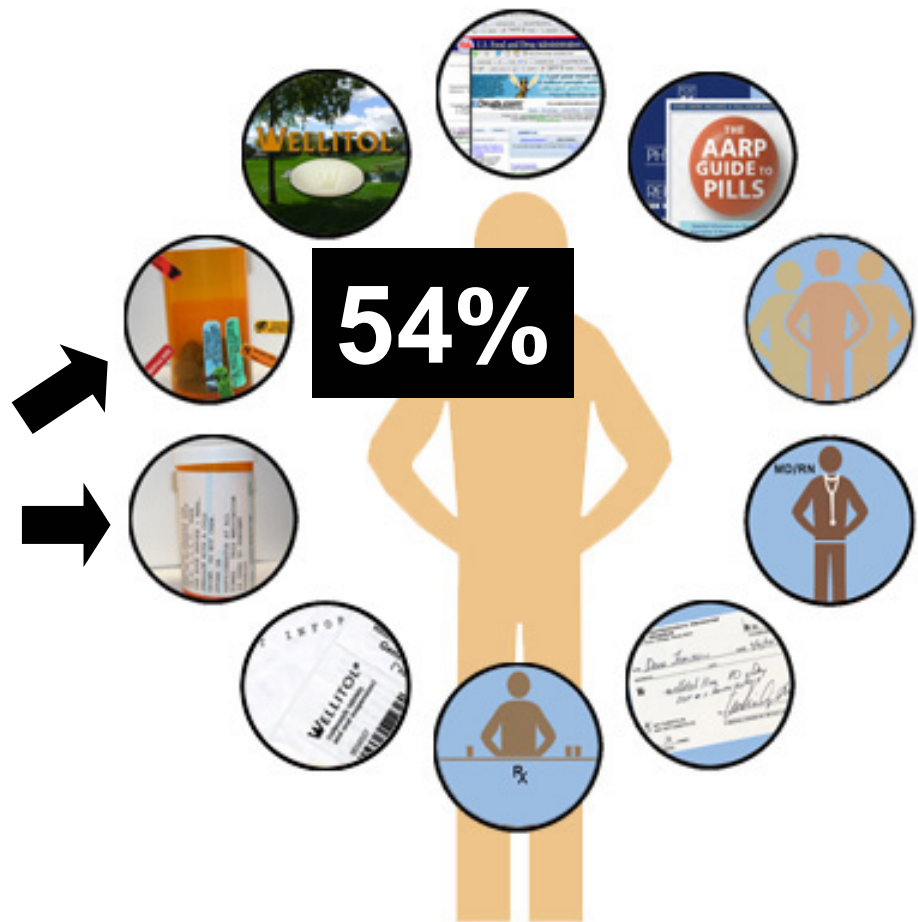
- Tangible
- Brief
- Repeatedly used
- Only source for many





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# New Studies

- AHRQ R01
- Target Corp.
- NCI R21

# Enhanced Rx Label Design

*Enhanced Prescription Drug Label Design to Support Patient Understanding and Use*  
(R01 HS017687-01; PI Wolf)

**Overall Objective** to test the efficacy of an evidence-based, enhanced prescription drug container label design to improve older patients' understanding of instructions for use.

# Methods.

- Actual Use Assessment

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# Methods.

- Actual Use Assessment
- 11 Safety Net Clinics, 1 Central-Fill Pharmacy (Va.)
- Random Assignment to Enhanced vs. Standard Label
- Sample = 960 Diabetic Patients, > 40 years of age
- Assessment: Baseline, 3 months 1 Year
- Outcomes:
  1. Functional Understanding
  2. Adherence
  3. HBA1C

# Enhanced Label Prototype











<p><b>MICHAEL WOLF</b>      04/29/71</p> <p><b>GLYBURIDE 5 mg</b></p> <p>Take for <u>Diabetes</u></p> <p><b>TAKE 2 PILLS AT BREAKFAST</b> <b>2 PILLS AT DINNER</b></p>	<p>Rx #: 1234567      10/30/2008</p> <p>You have 11 refills 180 pills</p> <p><b>Discard after 10/30/2009</b></p> <p>Provider: RUTH PARKER, MD Emory Medical Center (414) 123-4567</p> <p>Pharmacy: NoVA ScriptsCentral 11445 Sunset Blvd. Reston, VA (713) 123-4567</p> <p><b>NDC # 1234567</b></p>	<ul style="list-style-type: none"><li>• Take with food</li><li>• Do not drink alcohol while taking this medicine</li><li>• Limit your time in the sun</li></ul>								
<table border="1"><thead><tr><th>Breakfast</th><th>Lunch</th><th>Dinner</th><th>Bedtime</th></tr></thead><tbody><tr><td>2</td><td></td><td>2</td><td></td></tr></tbody></table>	Breakfast	Lunch	Dinner	Bedtime	2		2			
Breakfast	Lunch	Dinner	Bedtime							
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# Improving Dosage Instructions.

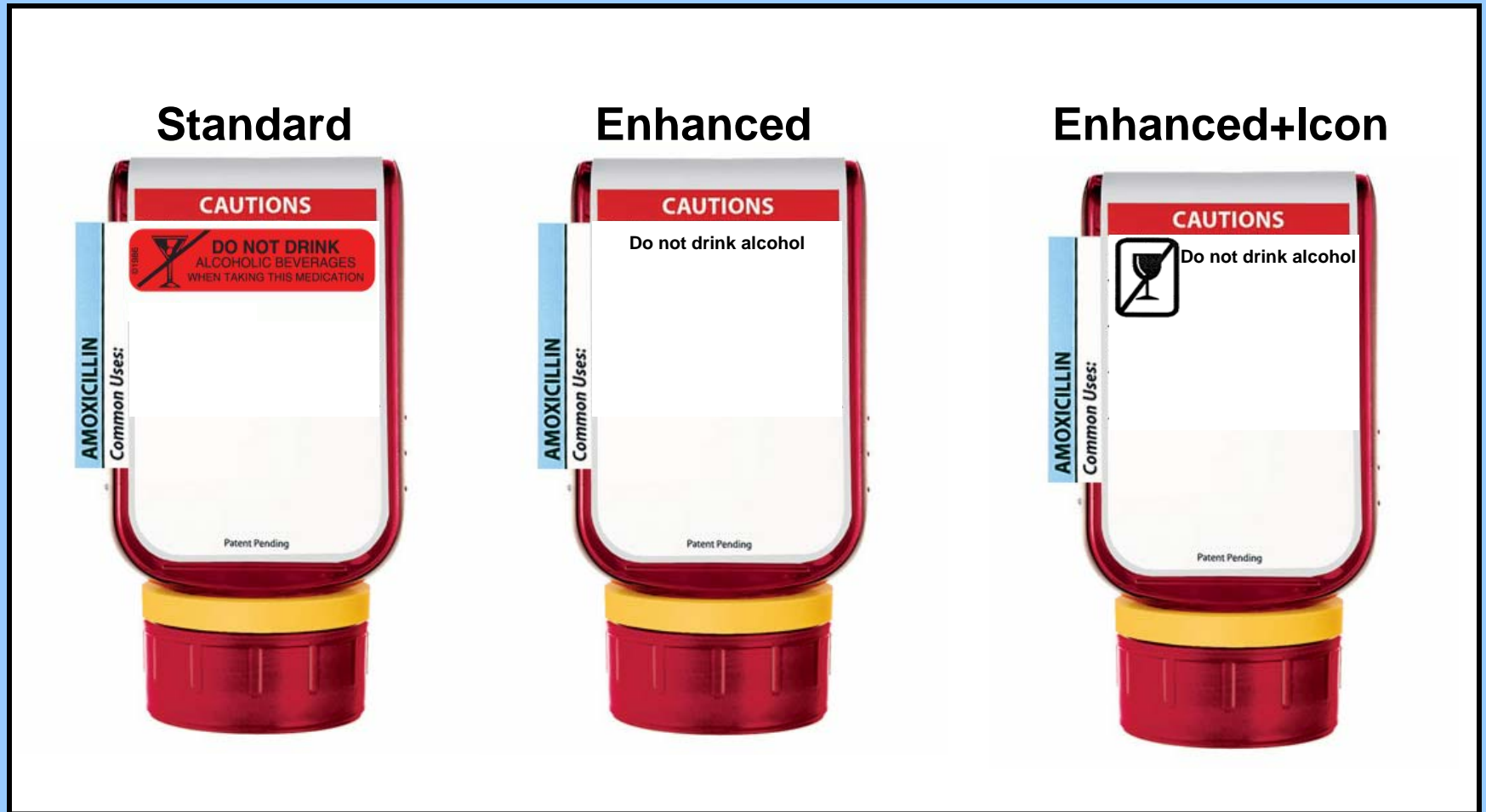
Standard	Enhanced no/UMS	Enhanced w/ UMS								
Take one tablet by mouth daily.	Take 1 tablet at bedtime.	<table border="1"> <thead> <tr> <th data-bbox="1309 492 1425 532">Morning</th> <th data-bbox="1425 492 1541 532">Noon</th> <th data-bbox="1541 492 1657 532">Evening</th> <th data-bbox="1657 492 1763 532">Bedtime</th> </tr> </thead> <tbody> <tr> <td colspan="3" data-bbox="1309 532 1657 646">[Redacted]</td> <td data-bbox="1657 532 1763 646">1</td> </tr> </tbody> </table>	Morning	Noon	Evening	Bedtime	[Redacted]			1
Morning	Noon	Evening	Bedtime							
[Redacted]			1							
Take one tablet by mouth three times daily.	Take 1 tablet in the morning 1 tablet at noon 1 tablet in the evening	<table border="1"> <thead> <tr> <th data-bbox="1315 746 1431 786">Morning</th> <th data-bbox="1431 746 1547 786">Noon</th> <th data-bbox="1547 746 1663 786">Evening</th> <th data-bbox="1663 746 1763 786">Bedtime</th> </tr> </thead> <tbody> <tr> <td data-bbox="1315 786 1431 901">1</td> <td data-bbox="1431 786 1547 901">1</td> <td data-bbox="1547 786 1663 901">1</td> <td data-bbox="1663 786 1763 901">[Redacted]</td> </tr> </tbody> </table>	Morning	Noon	Evening	Bedtime	1	1	1	[Redacted]
Morning	Noon	Evening	Bedtime							
1	1	1	[Redacted]							
Take two tablets by mouth twice daily.	Take 2 tablets in the morning, And 2 tablets at bedtime	<table border="1"> <thead> <tr> <th data-bbox="1315 1015 1431 1055">Morning</th> <th data-bbox="1431 1015 1547 1055">Noon</th> <th data-bbox="1547 1015 1663 1055">Evening</th> <th data-bbox="1663 1015 1763 1055">Bedtime</th> </tr> </thead> <tbody> <tr> <td data-bbox="1315 1055 1431 1169">2</td> <td colspan="2" data-bbox="1431 1055 1663 1169">[Redacted]</td> <td data-bbox="1663 1055 1763 1169">2</td> </tr> </tbody> </table>	Morning	Noon	Evening	Bedtime	2	[Redacted]		2
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# Findings.

- 96% of patients correctly interpreted UMS + explicit instructions
- 3x greater comprehension of UMS instructions vs. standard label instructions  
(ARR 3.01, 95% CI 1.97 – 4.42)
- Explicit instructions only better than standard, not UMS  
(87%; ARR 1.51, 95% CI 1.11 – 2.77)
- Improvement solely on 2 or 3x daily schedules  
(40% of US prescriptions)

Original Message	Revised Message	Icon
SHAKE WELL. Before Using.	Shake well before using.	
Warning: Do not use if you are pregnant, suspect that you are pregnant, or while breast feeding. Consult your doctor or pharmacist.	Do not use if you are pregnant, think you are pregnant, or breast feeding.	
Take with food or milk.	Take with food or milk.	
Do not drink alcoholic beverages when taking this medication.	Do not drink alcohol.	
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.	Limit your time in the sun.	
For external use ONLY.	Use only on your skin.	
May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machinery.	May cause drowsiness. Be careful when driving a car or using machinery.	
Obtain medical advice before taking nonprescription drugs. Some may affect the action of this medicine.	Talk to your doctor before using any over-the-counter drugs.	
It is very important that you take or use this exactly as directed. Do not skip doses or discontinue unless directed by your doctor.	Do not stop taking unless directed by your doctor.	
To control your blood pressure take regularly, do not continue unless directed by your doctor.		

# Improving Rx Warnings.



# Patient-Friendly Prescriptions

- Standardize 'sigs'
- Generate Rx info using EHR
- Structure MD counseling
- Ensure families leave with clear/concise Rx info

*Promoting Health Literacy for Newly Prescribed Medications via the EMR; R21 CA13277; PI Wolf*

*Using IT for Patient-Centered Communication and Decision Making about Medications R18 HS17220; PI: Wolf*


## You Have a New Medication

Date: August 1, 2008

Name: John Doe

Doctor: David Baker, MD

Please read the information below. This tells you how to take your medicine.

Drug Name	Lipitor®
Generic Name	Atorvasatin ( a TORE va sta tin)
Purpose	This medication can lower "bad" cholesterol.
Benefit	It can help prevent a heart attack or stroke.
How to Take	Take 1 tablet by mouth at bedtime.
For How Long	You may need to be on this medication for the rest of your life.
Call Your Doctor	If you have any of these symptoms for more than <u>1 week</u> : <ul style="list-style-type: none"><li>• Headaches</li><li>• Stomach pain</li><li>• Diarrhea</li></ul>
Stop Taking and Call Your Doctor	If you ever have: <ul style="list-style-type: none"><li>• Muscle pain</li><li>• Muscle weakness</li><li>• Joint pain</li></ul>
Important!	<ul style="list-style-type: none"><li>• Take this medicine only the way your doctors tells you.</li></ul>  Tell your doctor or pharmacist if you are pregnant, think you are pregnant, or breastfeeding. You should not take this medicine. <ul style="list-style-type: none"><li>• If you take over-the-counter medicines every day, tell your doctor.</li><li>• Limit how much grapefruit juice you drink every day.</li></ul>

Please call NoVA ScriptsCentral Pharmacy at (123) 456-7890 if you have questions or concerns.

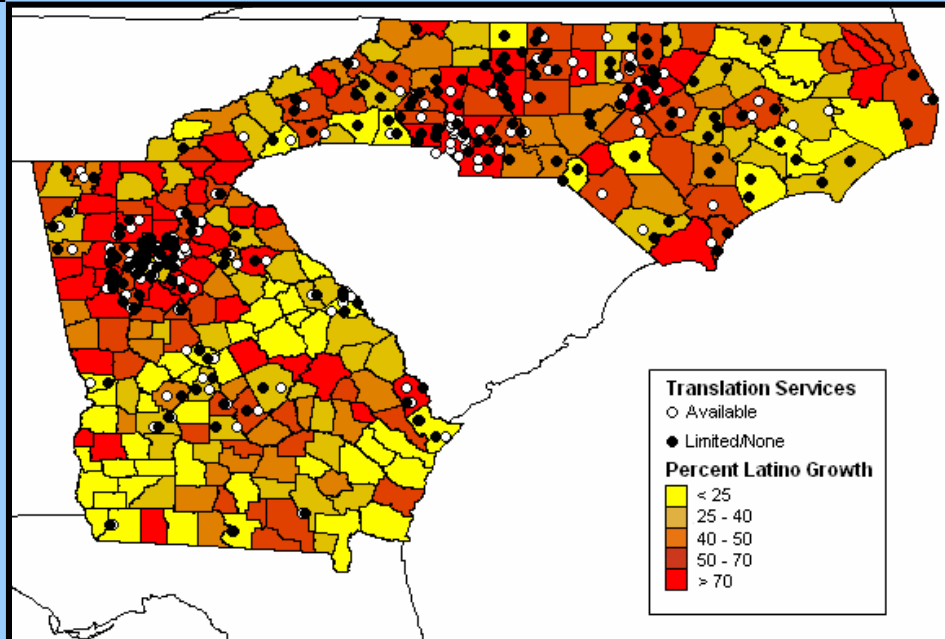
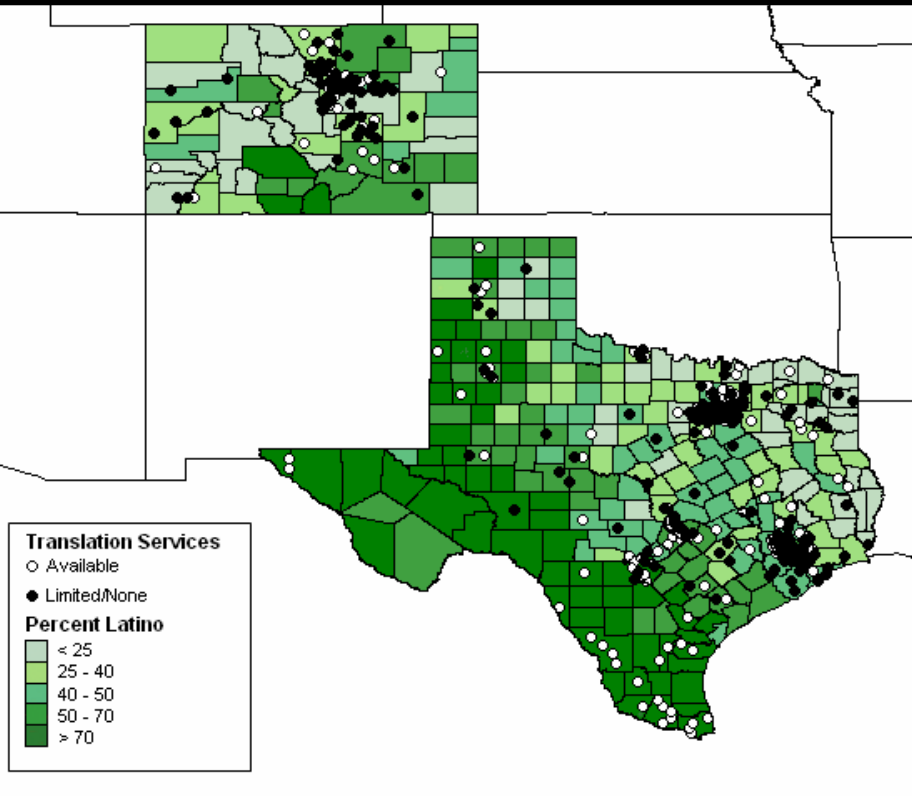
These websites can tell you more about your medicine:

[www.ahrq.gov/consumer](http://www.ahrq.gov/consumer) and [www.nlm.nih.gov/medlineplus](http://www.nlm.nih.gov/medlineplus)

# Language Concordance

# Bailey, et al.

- National Pharmacy Survey (CO, TX/GA, NC)
- **56%** limited/no translation capability
- Problem not limited to rural, fewer Latino areas



Bailey SC, Pandit A, Curtis L, Wolf MS. Availability of Spanish Prescription Drug Labels: A National Survey. Under review, *Medical Care*, 2008.

# **Over-the-Counter Drug Info**

# Drug Facts

## Active ingredient (in each tablet)

Chlorpheniramine maleate 2 mg .....Antihistamine

## Purpose

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- sneezing
- runny nose
- itchy, watery eyes
- itchy throat

## Warnings

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

## When using this product

- You may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

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

## Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

**Other information** store at 20-25° C (68-77° F) ■ protect from excessive moisture

**Inactive ingredients** D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Is this adequate?

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Is this patient-centered?

