

NONPRESCRIPTION DRUGS
ADVISORY COMMITTEE AND
ARTHRITIS ADVISORY
COMMITTEE

JULY 20, 1999

NDA 21070 FLEXERIL OTC
SWITCH

LABEL COMPREHENSION
REVIEW

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DDMAC REVIEW

NDA # 21-070
Drug: Flexeril
Sponsor: Merck
Study: Label Comprehension Study
Study Date: January 22, 1999
Reviewer: Kathryn Aikin, Ph.D.
Reviewing Div.: HFD-40
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Communication Objectives:

The objectives of this label comprehension study centered on several topics: 1) consumer comprehension of label directions, warnings, and uses, 2) accuracy of consumer self-selection for use, and 3) consumer ratings of appropriateness of use for various conditions. The package insert was also evaluated to investigate whether or not it affected comprehension of use and warning information.

Understanding of Uses

- Appropriate uses (i.e., painful muscle tightness and spasm of the back or neck due to recent strain, overuse or minor injury)
- Understanding of the word "temporarily"

Understanding of Warnings

- Ask a doctor before use if you are 65 years of age or older
- Ask a doctor before use if you are taking sedatives, tranquilizers, antidepressants, or other muscle relaxants
- Significant drowsiness may occur when using this product
- Stop using this product if symptoms do not improve within 10 days or get worse
- Stop using this product if new or unusual symptoms appear

Understanding of Directions

- Take 1 tablet every 6-8 hours, do not take more than 3 tablets every 24 hours
- Use the product daily as long as you have symptoms, but do not use for more than 10 days in a row
- Product does not provide immediate pain relief
- Product does not work like other pain relievers
- Product can be used concomitantly with other pain relievers

Methodology

Participants

Four hundred (400) participants were recruited. Participants who had suffered back or neck pain the last 12 months, and who had used prescription medication for back or neck

pain at some time (past or present) were oversampled. Participants may have fallen into one or more groups. In the final sample, 73% (n = 293) indicated they had suffered from back pain at some time, 50% (n = 199) indicated they had suffered from neck pain at some time, and 80% (n = 318) indicated they had suffered from back or neck pain. Fifty-seven percent (n = 228) indicated they had suffered from back pain the last 12 months, 35% (n = 138) indicated they had suffered from neck pain in the last 12 months, and 63% (n = 251) indicated they had suffered from back or neck pain during that time period. Thirty-eight percent (n = 112) had ever taken a prescription medication for back pain.

Participants were distributed into age quotas: 33% aged 18 to 34, 33% aged 35 to 49, and 33% aged 50 and over. The sample included 102 participants aged 65 and over, 48 participants who had not completed a high school education, and was equally divided by gender (200 male, 200 female).

Materials

The main questionnaire was comprised of multiple choice, yes/no, and open-ended questions. A separate, self-administered health questionnaire and demographic questions were included at the end of the questionnaire.

Procedure

Participants were recruited in 14 geographically distributed malls across the U.S. After being screened for eligibility, participants were provided with a picture of the front label of the product. The participant was given the following instructions:

“Here is the front label for a new product you might see when you are shopping for nonprescription products. Please carefully look over the label and tell me when you are finished. Please take as much time as you need.”

After the participant had read the front label, the back product label was provided with the similar introductory instructions: “Here is the back label from the same product. Please carefully look over the label as you would if you were going to consider buying this product for your own use. Please take as much time as you need and tell me when you are finished.” The participant was then informed that questioning would focus on the back label. Both labels were left in front of the respondent during questioning.

The package insert was provided to respondents after they had answered questions 1 through 18. The instructions, “Here’s an insert that would be included in the package. Please read the insert as you would if you were in your home. Please take as much time as you need and tell me when you are finished,” were provided. Questions 19 through 24d were administered with both front and back labels and the insert in view.

Results

The results were analyzed by age (18 to 64 vs. 65 and older) and education level (less than high school graduate vs. high school graduate or more). Significance level was $p < .10$.

Label Only

Q8. For which of the following ailments does the label say it is appropriate for someone to use this product?

Compared to participants over age 65, a greater number of participants under the age of 65 indicated that Flexeril was appropriate for back or neck pain due to recent muscle strain, and back or neck pain due to recent muscle overuse (see Table 1). Similarly, compared to higher educated participants, a greater percentage of lower educated participants indicated that Flexeril was appropriate for back or neck pain due to recent muscle overuse. Older participants were more likely than younger participants to indicate wrongly that Flexeril was appropriate for arthritis in the knees.

**Table 1
For Which Ailments Is Flexeril Appropriate to Use,
by Age and Education Level**

Response	Age			Education Level	
	Total n = 400 A%	18 to 64 n = 354 B%	65+ n = 102 C%	< HS Grad n = 48 D%	HS Grad+ n = 362 E%
Back or neck pain due to recent muscle strain	96	96C	89	94	97
Back or neck pain due to recent muscle overuse	94	94	92	98E	94
Painful muscle tightness and spasm of the back or neck due to recent strain, overuse, or minor injury	94	94C	85	92	94
Leg cramps (incorrect)	34	34	39	33	35
Arthritis in the knees (incorrect)	23	22	31B	25	23
Headaches (incorrect)	19	18	25	23	19
Menstrual cramps (incorrect)	14	14	10	22	13

Significance testing conducted at the .90 level between columns B and C, and D and E.

Q9a. Based on what you know about Flexeril MR from the label and your own medical situation, do you think you, yourself could use this product without first talking to a doctor if you suffered back or neck pain?

Table 2
Can You Use This Product Without First Talking to a Doctor,
by Age and Education Level

Response	Age			Education Level	
	Total n = 400	18 to 64 n = 354	65 + n = 102	< HS Grad n = 48	HS Grad + n = 362
	A%	B%	C%	D%	E%
Can	66	70C	42	77E	65
Cannot	34	31	58B	23	35D

Significance testing conducted at the .90 level between columns B and C, and D and E.

Forty-two percent (42%) of respondents aged 65 and over incorrectly indicated they could use Flexeril without first speaking to a doctor.

Respondents who indicated they could use Flexeril on Q9a were further stratified into appropriate to use and inappropriate to use categories based on self-reported medical conditions or age (e.g., aged 65 or over, taking other muscle relaxants, taking antidepressants, taking sedatives, taking tranquilizers, have heart disease, have thyroid disease, have difficulty urinating, have glaucoma, have liver disease, are pregnant or nursing).

Table 3
Percent Appropriate or Inappropriate to use by Age and Education Level
(among respondents incorrectly indicating they could use the product
without first speaking to a doctor)

Response	Age			Education Level	
	Total n = 265	18 to 64 n = 246	65 + n = 43	< HS Grad n = 37	HS Grad + n = 235
	A%	B%	C%	D%	E%
Appropriate to use	74	80C	0	78	74
Inappropriate to use	26	20	100B	22	26
Not appropriate because:*					
Taking muscle relaxants	10		12		
Age 65+	7		100		
Taking antidepressants	6		9		
Have heart disease	5		7		
Taking sedatives	5		2		
Taking tranquilizers	4		7		
Have thyroid disease	3		9		
Pregnant or nursing	2		0		
Have difficulty urinating	2		2		
Have glaucoma	2		5		
Have liver disease	1		0		

Significance testing conducted at the .90 level between columns B and C, and D and E.

*Inappropriate use was based on self-reporting of age and/or medical condition. Respondents may fall into one or more self-selected categories.

Among respondents who indicated they could use Flexeril without first speaking to a doctor, 26% should not have used the product based on a preexisting medical condition or age. All of the 43 respondents (100%) aged 65 and over who indicated they could use the product without first speaking to a doctor fell in to the inappropriate to use category based on label directions. Approximately 20% of each other subgroup (age 18 to 64, 20%; less than a high school graduate, 22%; high school graduate or more, 26%) incorrectly self-selected for use. These results should be viewed with caution due to the low sample sizes in each cell.

Of the 26% who should not use Flexeril based on a preexisting medical condition, concomitant use of muscle relaxants was the most common reason for ineligibility. Among participants aged 65 and over, age was the most common reason for ineligibility, followed by use of muscle relaxants. Exact percentages are presented in Table 3 (see above).

Q10a. You said you have suffered from [ailment]. Based on what you read on the label, would you, yourself treat your [ailment] with Flexeril or not?, Q10b. Would you use Flexeril MR for back pain caused by (straining your muscles, overuse of muscles, a minor injury, arthritis)?, and Q10c. Would you use Flexeril MR for neck pain caused by (straining your muscles, overuse of muscles, a minor injury, arthritis)? [asked only of participants who answered YES to neck pain in Q10a]

Table 4
Conditions for Which Respondents Who Feel They Can Use Flexeril Would Use It, by Age and Education Level

Response	Total n = 265	Age		Education Level	
		18 to 64 n = 246	65+ n = 43	< HS Grad n = 37	HS Grad+ n = 235
	A%	B%	C%	D%	E%
Back pain (incorrect)	72	72	72	84E	71
Neck pain (incorrect)	49	50	37	43	49
Back or neck pain (incorrect)	79	79	79	89E	78
Back or neck pain caused by muscle strain, overuse or minor injury (correct)	78	78	79	89E	77
Back or neck pain caused by arthritis (incorrect)	23	22	40B	24	23
Headaches (incorrect)	18	18	23	27	18
Leg cramps (incorrect)	28	26	49B	32	28
Arthritis in the knees (incorrect)	12	11	28B	16	11

Significance testing conducted at the .90 level between columns B and C, and D and E.

Among participants who feel they can use Flexeril, significantly more participants aged 65 and over than those aged 18 to 64 said they would use Flexeril for back or neck pain caused by arthritis (40% vs. 22%), leg cramps (49% vs. 26%), and arthritis in the knees (8% vs. 11%). Compared to participants had graduated from high school or more, those who had not graduated high school were more likely to indicate they would use Flexeril for back pain (84% vs. 71%), back or neck pain (89% vs. 78%), and back or neck pain caused by muscle strain, overuse or minor injury (89% vs. 77%).

Participants who said they could use the product were stratified by prior experience with the indicated condition(s). The percentage of respondents who said they would use Flexeril for a condition they had experienced in the past were:

Back pain (n = 199)	96%
Neck pain (n = 136)	96%
Headaches (n = 212)	23%
Leg cramps (n = 137)	55%
Arthritis in the knees (n = 65)	48%

Q12a. Now think about how Flexeril MR works on the first day that it is used. Based on what you read on the label, which of the following statements on this card describes your understanding of how Flexeril MR works on the first day that it is used?

When asked about the way Flexeril works on the first day of use, 57% of respondents agreed with the choice, "It may not provide much relief for back or neck pain during the first day, but relief usually begins after 1 or 2 days of taking the product." (see Table 5). Thirty-five percent (35%) of respondents incorrectly indicated that Flexeril relieves pain in about an hour, but may wear off. Respondents aged 18 to 64 were more likely than those aged 65 and over to indicate that Flexeril may take 1 to 2 days to show an effect (58% vs. 46%).

Table 5
Which Statement Best Describes Your Understanding of How Flexeril Works,
by Age and Education Level

Response	Age			Education Level	
	Total n = 400	18 to 64 n = 354	65+ n = 102	< HS Grad n = 48	HS Grad+ n = 362
	A%	B%	C%	D%	E%
It may not provide much relief for back or neck pain during the first day, but relief usually begins after 1 or 2 days of taking the product	57	58C	46	52	57
It relieves back or neck pain within an hour or so after the product is taken, but then the relief wears off and the pain could come back.	35	34	41	42	35
Neither one describes how Flexeril MR works on the first day it is used.	8	8	13	6	8

Significance testing conducted at the .90 level between columns B and C, and D and E.

Comment: The rate of correct responses is rather low, considering that participants had the label in front of them. It is possible that a large proportion of consumers will expect this product to work in the same manner as other pain relievers (i.e., immediate pain relief) and, as a result, may take the product incorrectly.

Q13a. Based on what you read on the label, what number of tablets should someone take at one time?

Ninety-one percent (91%) of respondents indicated that the maximum dose was 1 tablet. There were no significant differences between groups on this question.

Q13b. Based on what you read on this label, what is the most number of tablets that someone should take in a 24-hour period?

Eighty-eight percent (88%) of respondents indicated that no more than 3 tablets should be taken in a 24-hour period (see Table 6). Respondents aged 18 to 64 were more likely to indicate 2 tablets per 24 hour period as the maximum dose (5%) than were respondents aged 65 and over (2%).

Table 6
What is the Most Number of Tablets Someone Should Take in a 24-Hour Period,
by Age and Education Level

Response (Max tablets per day)	Total n = 400 A%	Age		Education Level	
		18 to 64 n = 354 B%	65+ n = 102 C%	< HS Grad n = 48 D%	HS Grad+ n = 362 E%
1 (incorrect)	0	0	1	0	0
2 (incorrect)	5	5C	2	4	5
3 (correct)	88	88	84	92	88
4 or more (incorrect)	7	7	11	4	7
Unspecified	1	<1	2	0	1

Significance testing conducted at the .90 level between columns B and C, and D and E.

Q13c. Based on what you read on this label, for how many days in a row can someone use this product?

Eighty-eight percent (88%) of respondents indicated that the product could be used for a maximum of 10 days in a row. There were no significant differences between groups on this question.

Q14. In which of the following situations does the label say that a doctor should be consulted before someone starts using this product?

Overall, correct responses for this question ranged from 80% (difficulty urinating) to 95% (heart, liver or thyroid disease- see Table 7). Respondents aged 18 to 64 were less likely than respondents aged 65 and over to indicate that people who had difficulty urinating should consult a doctor before using the product. There were no differences between education levels.

Table 7
In Which of the Following Situations Should A Doctor Be Consulted Before Using This Product, by Age and Education Level

Response (If someone has/is...)	Total n = 400	Age		Education Level	
		18 to 64 n = 354	65+ n = 102	< HS Grad n = 48	HS Grad+ n = 362
	A%	B%	C%	D%	E%
Heart, liver, or thyroid disease	95	94	95	92	96
Pain shooting down their legs or back pain that gets worse when they lie down	93	92	91	96	93
Weakness in an arm or a leg	88	88	87	92	87
Fever	81	80	79	81	81
Difficulty urinating	80	79	89B	73	81
Taking sedatives, tranquilizers, antidepressants, or other muscle relaxants	95	94	92	94	95
65 years of age or older	92	92	90	94	92

Significance testing conducted at the .90 level between columns B and C, and D and E.

Comment: No false positives were included in this list; that is, questions for which a response of "yes" is incorrect. It is not possible to distinguish between respondents who were simply answering "yes" to every question and respondents who were actually reading and understanding the label.

Q15a. Which of the following does the label say about using this product?

Overall, correct responses to this question were 96% and above (see Table 8). More respondents aged 18 to 64 (98%) than those aged 65 and over (92%) indicated that significant drowsiness might occur when using the product. There were no differences between education groups.

Table 8
Which of the Following Does the Label Say About Using This Product,
by Age and Education Level

Response	Age			Education Level	
	Total n = 400	18 to 64 n = 354	65+ n = 102	< HS Grad n = 48	HS Grad+ n = 362
	A%	B%	C%	D%	E%
Significant drowsiness may occur	98	98C	92	96	98
Avoid alcoholic beverages	97	96	95	92	97
Use caution when driving a motor vehicle or operating machinery	96	96	96	96	96
Alcohol, sedatives, and tranquilizers increase the drowsiness effect	96	96	92	92	97

Significance testing conducted at the .90 level between columns B and C, and D and E.

Comment: As with Question 14, no false positives were included in this list, making the results less than conclusive.

Q15c. According to the label, does this product work the same as or differently than pain relievers?

Consistent with the results from question 12a, approximately 30% of the sample indicated that Flexeril either worked the same as pain relievers, or that they did not know how Flexeril worked (see Table 9). Participants aged 65 and over were more likely than those aged 18 to 64 to say they did not know how Flexeril worked (23% vs. 14%). There were no differences between education levels.

Table 9
Does This Product Work the Same as or Differently Than Pain Relievers,
by Age and Education Level

Response	Age			Education Level	
	Total n = 400	18 to 64 n = 354	65+ n = 102	< HS Grad n = 48	HS Grad+ n = 362
	A%	B%	C%	D%	E%
Flexeril MR works the same as pain relievers (incorrect)	17	16	12	15	17
Flexeril MR works differently than pain relievers (correct)	70	70	66	77	69
Don't know	13	14	23B	8	14

Significance testing conducted at the .90 level between columns B and C, and D and E.

Q15d. According to the label, can someone take this product at the same time as recommended doses of pain relievers?

Table 10
Can Someone Take This Product at the Same Time as Recommended Doses of Pain Relievers, by Age and Education Level

Response	Total n = 400	Age		Education Level	
		18 to 64 n = 354	65 + n = 102	< HS Grad n = 48	HS Grad + n = 362
	A%	B%	C%	D%	E%
Can take Flexeril MR with recommended doses of pain relievers (correct)	33	34C	23	17	34D
Cannot take Flexeril MR with recommended doses of pain relievers (incorrect)	60	60	60	77E	58
Don't know	8	6	18B	6	8

Significance testing conducted at the .90 level between columns B and C, and D and E.

Thirty-three percent (33%) of the total sample correctly indicated that Flexeril could be used with recommended doses of pain relievers. Compared to respondents aged 65 and over, significantly more respondents aged 18 to 64 indicated correctly that Flexeril could be used with pain relievers (23% vs. 34%). Older respondents were more likely than younger respondents to say they did not know if Flexeril could be used with pain relievers or not (18% vs. 6%). Similarly, compared to respondents who had not completed a high school education, significantly more respondents who had completed a high school education or more indicated correctly that Flexeril could be used with pain relievers (17% vs. 34%). Respondents who had not completed a high school education were more likely than those who had completed a high school education or more to indicate incorrectly that Flexeril could not be used with pain relievers (77% vs. 58%).

Comment: Over half of the respondents answered this question incorrectly. This may indicate that consumers do not understand how the product works, it may indicate that consumers believe this product acts like a pain reliever, or it may indicate that consumers are overly cautious about the possibility of a drug-drug interaction between Flexeril and pain relievers.

Q16. In which of the following situations does the label say that someone should stop using this product and ask a doctor?

The majority of respondents correctly indicated that someone should stop using the product and ask a doctor 1) if their symptoms do not improve within 10 days (99%), 2) if their symptoms get worse (98%), or 3) if they have new or unusual symptoms (96%). There were no differences between the age or education groups.

Comment: Again, no false positives were included in this list. It is not possible to tell whether respondents understood the question or were simply "yea-saying."

Q17a. It says on the label that Flexeril MR "temporarily relieves pain muscle tightness and spasm of the back or neck due to recent strain, overuse, or minor injury." Based on what you read on the label, which one statement on this card best describes what you think the makers of Flexeril MR mean when they say "temporarily"?

Table 11
What Do You Think the Makers of Flexeril Mean When They Say "Temporarily,"
by Age and Education Level

Response	Age			Education Level	
	Total n = 400	18 to 64 n = 354	65 + n = 102	< HS Grad n = 48	HS Grad + n = 362
	A%	B%	C%	D%	E%
The pain is relieved for a few hours and then could come back (incorrect)	47	48C	38	63E	45
The product is meant for muscle problems that have been present for just a short time (correct)	46	45	50	33	47D
The pain is relieved quickly (incorrect)	5	5	10	4	6
The pain is relieved for a few hours and then could come back <u>OR</u> The pain is relieved quickly (incorrect)	52				
None of these	2	3	2	0	2D

Significance testing conducted at the .90 level between columns B and C, and D and E.

Forty-six percent (46%) of the sample correctly indicated that "temporarily" meant "the product is meant for muscle problems that have been present for just a short time" in relation to Flexeril. However, (52%) incorrectly indicated that "temporarily" meant "the pain is relieved for a few hours and then could come back," or "the pain is relieved quickly."

Respondents aged 18 to 64 were more likely than those aged 65 and over to incorrectly define temporarily as "the pain is relieved for a few hours and then could come back" (48% vs. 38%). Approximately equal percentages chose the correct response (age 18 to 64, 45%; 65 and over, 50%). Similarly, respondents who had not completed a high school education were more likely to incorrectly define temporarily than those who had completed a high school education or more (63% vs. 45%). Those with more education chose the correct response in greater numbers than those with less education (47% vs. 33%).

Comment: The wording of this question asks participants to guess the manufacturer's intentions, not what temporarily means to the participant. This question would have been better presented as an open-ended question to capture a range of responses. The percentage of respondents indicating that temporarily meant "pain relieved for a few hours and then could come back" might be an indication that respondents do not understand how Flexeril works. This answer would seem to indicate about one half (52%) of the surveyed consumers believe Flexeril works like other pain relievers, giving immediate pain relief.

Label Plus Package Insert

At this point, participants were provided with the package insert. They were asked to read the insert as they would if they were in their home. After the participant had read the insert, both the insert and package label were available for reference. The results were analyzed using only participants who had previously answered the questions incorrectly using the label.

Q19. For which of the following ailments does the label and insert say should someone use this product?

As can be seen in Table 12, the majority of participants who previously incorrectly indicated that Flexeril was appropriate for use with leg cramps, headaches, arthritis in the knees, and menstrual cramps after viewing the label continued to be incorrect after viewing the package insert (52% to 80%).

Table 12
For Which of the Following Ailments Does The Label and Insert Say Should
Someone Use This Product, by Age and Education Level
(among participants who had previously answered
this question incorrectly using the label)

Response	Total	Age		Education Level		
		A%	18 to 64 B%	65 + C%	< HS Grad D%	HS Grad + E%
Back or neck pain due to recent muscle strain	n = 15		n = 14	n = 11	n = 3	n = 12
Appropriate (correct)	87		86	73	67	92
Inappropriate (incorrect)	13		14	18	33	8
Back or neck pain due to recent muscle overuse	n = 23		n = 22	n = 8	n = 1	n = 22
Appropriate (correct)	91		91	75	100	91
Inappropriate (incorrect)	9		9	13	0	9
Painful muscle tightness and spasm of the back or neck due to recent minor injury	n = 24		n = 21	n = 15	n = 4	n = 21
Appropriate (correct)	71		71	80	100E	67
Inappropriate (incorrect)	25		24	13	0	29D
Headaches	n = 86		n = 72	n = 35	n = 13	n = 76
Appropriate (incorrect)	64		64	57	69	65
Inappropriate (correct)	33		32	29	31	32
Leg cramps	n = 138		n = 120	n = 49	n = 18	n = 127
Appropriate (incorrect)	68		70	63	72	68
Inappropriate (correct)	31		30	29	28	32
Arthritis in the knees	n = 99		n = 83	n = 41	n = 13	n = 89
Appropriate (incorrect)	61		58	63	69	60
Inappropriate (correct)	36		39	27	31	37
Menstrual cramps*	n = 33		n = 29	n = 8	n = 5	n = 29
Appropriate (incorrect)	58		59	63	80	52
Inappropriate (correct)	42		41	25	20	48

* Asked only of female participants.

Significance testing conducted at the .90 level between columns B and C, and D and E.

Comment: These results should be viewed with caution, given the small numbers of individuals in each cell.

Q20. You said you have suffered from [ailment]. Based on what you read on the label and insert would you, yourself treat your [ailment] with Flexeril MR or not?, and Q21. Would you use Flexeril MR for back pain caused by [straining your muscles, overuse of muscles, a minor injury, arthritis], and Q22. Would you use Flexeril MR for neck pain caused by [straining your muscles, overuse of muscles, a

minor injury, arthritis]. (Questions 21 and 22 were asked only of participants who said "yes" to back pain and/or neck pain in Q20.)

Table 13
Conditions for Which Respondents would use Flexeril, by Age and Education Level,
(among participants who had previously answered
this question incorrectly using the label)

Response	Total	Age		Education Level	
		18 to 64	65 +	< HS Grad	HS Grad +
	A%	B%	C%	D%	E%
Back or neck pain	N = 7	N = 7	N = 1	N = 0	N = 7
Would use	0	0	100B		0
Would not use	100	100C	0		100
Back or neck pain caused by muscle strain, overuse or minor injury	N = 2	N = 2	N = 0	N = 0	N = 2
Would use	100	100			100
Would not use	0	0			0
Back or neck pain caused by arthritis	N = 63	N = 57	N = 16	N = 9	N = 56
Would use	71	68	63	100E	68
Would not use	29	32	38	0	32D
Headaches	N = 50	N = 45	N = 10	N = 10	N = 43
Would use	84	82	80	70	86
Would not use	14	16	10	30	12
Leg cramps	N = 78	N = 68	N = 21	N = 12	N = 68
Would use	77	77	57	92D	75
Would not use	19	19	43B	8	21
Arthritis in the knees	N = 34	N = 30	N = 12	N = 6	N = 28
Would use	71	70	58	83	68
Would not use	21	20	33	17	21

Significance testing conducted at the .90 level between columns B and C, and D and E.

Although the cell sizes in this test are too small to draw any definite conclusions, respondents who had not completed a high school education were more likely than those who had completed a high school education or more to say they would use Flexeril for back or neck pain caused by arthritis (100% vs. 68%), and leg cramps (92% vs. 75%). Respondents aged 65 and over were more likely than those aged 18 to 64 to say they would use Flexeril for back or neck pain (100% vs. 0%), and would not use Flexeril for leg cramps (43% vs. 19%).

Q23a. Now think about how Flexeril MR works on the first day that it is used. Based on what you read on the label and the insert, which of the following statements on this card describes your understanding of how Flexeril MR works on the first day that it is used?

Table 14
Which of the Following Statements Best Describes Your Understanding of How Flexeril Works, by Age and Education Level
(among participants who had previously answered this question incorrectly using the label)

Response	Total n = 174 A%	Age		Education Level	
		18 to 64 n = 149 B%	65 + n = 55 C%	< HS Grad n = 23 D%	HS Grad + n = 157 E%
It may not provide much relief for back or neck pain during the first day, but relief usually begins after 1 or 2 days of taking the product	43	42	44	26	44D
It relieves back or neck pain within an hour or so after the product is taken, but then the relief wears off and the pain could come back	54	55	49	74E	53
Neither one describes how Flexeril MR works on the first day it is used	3	3	7	0	3D

Significance testing conducted at the .90 level between columns B and C, and D and E.

After reading the label and the package insert, respondents with less than a full high school education were still less likely to correctly understand that Flexeril does not work on the first day it is used (26%), compared to respondents who had completed a high school education or more (44%).

Q24a. In which of the following situations does the label and the insert say that a doctor be consulted before someone starts using this product?

Compared to respondents who had completed a high school education or more, respondents who had not completed a high school education answered incorrectly that persons over age 65 (67% compared to 11%) and those taking sedatives, tranquilizers, antidepressants, and other muscle relaxants (67% compared to 17%) do not have to consult a doctor before using the product (see Table 15).

Table 15
Conditions for Which a Doctor Should be Consulted
Before Using the Product, by Age and Education Level
(among participants who had previously answered
this question incorrectly using the label)

Response	Age			Education Level	
	Total A%	18 to 64 B%	65 + C%	< HS Grad D%	HS Grad + E%
Age 65 or over	n = 31	n = 27	n = 10	n = 3	n = 28
Correct	84	85	90	33	89D
Incorrect	16	15	10	67E	11
Taking sedatives, tranquilizers, antidepressants or other muscle relaxants	n = 21	n = 20	n = 8	n = 3	n = 18
Correct	76	75	88	33	83D
Incorrect	24	25	12	67E	17

Significance testing conducted at the .90 level between columns B and C, and D and E.

Comment: There may be a test-retest effect at work here, in that the only response choices provided were those that were the correct choices from the question participants had previously answered. It's possible that the increase in correct answers may be partly due to respondents' recognition of the response categories from the previous question.

Q24b. Which of the following does the label and the insert say about using this product?, and Q24d. According to the label and insert, does this product work the same as or differently than pain relievers?

Table 16
What Does the Label and Insert Say About Using the Product,
by Age and Education Level
(among participants who had previously answered
this question incorrectly using the label)

Response	Age					Education Level	
	Total	18 to 64	65 +	< HS Grad	HS Grad +		
	A%	B%	C%	D%	E%		
Significant drowsiness may occur	n = 8	n = 8	n = 8	n = 2	n = 6		
Correct	88	88	75	100	83		
Incorrect	12	12	0	0	17		
Avoid alcoholic beverages	n = 14	n = 14	n = 5	n = 4	n = 10		
Correct	57	57	60	75	50		
Incorrect	29	29	20	25	30		
Use caution when driving a motor vehicle or operating machinery	n = 15	n = 15	n = 4	n = 2	n = 13		
Correct	93	93	50	100	92		
Incorrect	0	0	25	0	0		
Alcohol, sedatives and tranquilizers may increase the drowsiness effect	n = 16	n = 16	n = 8	n = 4	n = 12		
Correct	81	81	75	100E	75		
Incorrect	13	13	15	0	17		
Flexeril MR works the same as pain relievers (correct)	n = 119	n = 106	n = 35	n = 11	n = 111		
Correct	29	31	17	36	28		
Flexeril MR works differently than pain relievers (incorrect)	n = 119	n = 106	n = 35	n = 11	n = 111		
Incorrect	59	57	69	55	60		
Don't know	n = 119	n = 106	n = 35	n = 11	n = 111		
Don't know	12	12	14	9	12		

Significance testing conducted at the .90 level between columns B and C, and D and E.

Among participants who had previously answered this question incorrectly, viewing both the label and insert increased the number of correct responses for certain conditions: significant drowsiness may occur, use caution when driving a motor vehicle or operating machinery, and alcohol, sedatives and tranquilizers may increase the drowsiness effect. However, approximately 20% to 30% of this subsample still incorrectly indicated that it was not necessary to avoid alcoholic beverages while taking the product. In addition, between 55% and 69% of these participants incorrectly indicated that Flexeril works the same as other pain relievers.

Comment: These results should be viewed with caution because of the small cell sizes.

Q24c. Should Flexeril MR be taken for pain that has already lasted for more than two weeks?

The number of incorrect responses on this question decreased significantly among participants over age 65 after reading the label and the insert (11% label only, 4% label + insert).

Conclusions

There were some methodological problems with the study and analyses. 1) The questions were worded using "would you use," rather than "could you use." There are a variety of reasons why a consumer would or would not use the product, including, but not limited to, instructions on the label, price, color, taste, etc. Questions with the wording "Could you use" are a better indication of comprehension. 2) The sponsor established comprehension criteria prior to the conduct of the study. While this is not unusual, the results of this type of study are typically examined by the agency in toto, rather than whether they meet pre-assigned criteria. 3) A significance test level of $p < .05$ should have been employed. The use of a $p < .10$ significance level may indicate differences that would not appear at the $p < .05$ level. 4) The education categories were presented as "not completed a high school education" vs. "completed a high school education." It would have been more instructive to see the education results broken down into categories of "8th grade education or less," vs. "more than an 8th grade education."

Based on the pattern of results, there is concern that respondents do not understand that Flexeril works differently than pain relievers (30% incorrect), can be taken with pain relievers (68% incorrect), does not provide relief the first day of use (52% incorrect), and should be used only for back and/or neck pain (see Table 17). The percentage of respondents who said they would use Flexeril for conditions they had previously experienced (but not indicated by label instructions) ranged from 49% (neck pain) to 79% (back or neck pain). Forty-two percent (42%) of respondents aged 65 and over incorrectly indicated they could use Flexeril without first speaking to a doctor. Between 28% and 49% of respondents aged 65 and over indicated they would use Flexeril for inappropriate conditions (e.g., back or neck pain caused by arthritis, leg cramps, arthritis in the knees).

Table 17
Concepts Not Well Understood by Participants

Incorrect Concept	Response %
Flexeril can be used for leg cramps	34
Flexeril can be used for arthritis in the knees	23 (31*)
Flexeril can be used for headaches	19
Would use Flexeril (age 65 and over)	42*
Would use Flexeril for back pain (previously experienced condition)	72
Would use Flexeril for neck pain (previously experienced condition)	49
Would use Flexeril for back or neck pain (previously experienced condition)	79
Would use Flexeril for back or neck pain caused by arthritis (previously experienced condition)	23 (40*)
Would use Flexeril for headaches (previously experienced condition)	18
Would use Flexeril for leg cramps (previously experienced condition)	28 (49*)
Would use Flexeril for arthritis in the knees (previously experienced condition)	12 (28*)
It relieves back or neck pain within an hour or so after the product is taken, but then the relief wears off and the pain could come back	35
Flexeril works the same as other pain relievers, and/or don't know how Flexeril works	30
Cannot take Flexeril with recommended doses of pain relievers, and/or don't know	68 (78*)
The pain is relieved for a few hours and then could come back and/or the pain is relieved quickly	52

* age 65 and over.

The combination of these results may indicate that individuals expect Flexeril to act like an analgesic and take it in accordance with their expectations for that type of product. There is great concern that this expectation may lead to situations in which consumers who do not receive immediate relief either overdose or stop using the product because they believe it does not work. There is also concern that elderly consumers would be likely to misuse the product for inappropriate indications such as arthritis in the knees and leg cramps.

There were some concepts on which respondents showed good comprehension (see Table 18). In general, respondents understood that Flexeril should be used for back or neck pain due to recent muscle strain (96%), overuse (94%), or spasm of back or neck due to strain, overuse or injury (94%), several conditions under which to consult a doctor before use (80% to 95%), and side effects related to drowsiness (96% to 98%). Respondents also indicated good comprehension of the maximum daily dose and maximum consecutive dosing (88% to 91%). In some cases the insert increased comprehension above that shown with the label alone (e.g., age 65 and over should consult a doctor before use).

Table 18
Concepts Well Understood by Participants

Correct Concept	Response %
Flexeril can be used for back or neck pain due to recent muscle strain	96
Flexeril can be used for back or neck pain due to recent muscle overuse	94
Flexeril can be used for muscle tightness and spasm of the back or neck due to recent strain, overuse or injury	94
Take 1 tablet at a time	91
Take no more than 3 tablets in a 24-hour period	88
Use for a maximum of 10 days in a row	88
Consult a doctor before using if you have:	
Heart, thyroid or liver disease	95
Pain shooting down the legs or back pain that gets worse when you lie down	93
Weakness in an arm or a leg	88
Fever	81
Difficulty urinating	80
Taking sedatives, tranquilizers, antidepressants, or other muscle relaxants	95
65 years of age or older	92
Significant drowsiness may occur	98
Avoid alcoholic beverages	97
Use caution when driving a motor vehicle or operating machinery	96
Alcohol, sedatives, and tranquilizers increase the drowsiness effect	96

In summary, the results showing that consumers may expect this product to act like an analgesic raise the concern that consumers will not be able to safely and effectively use the product as intended.

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