

20. OTHER

20.A. HABITS AND PRACTICES OF CIU SUFFERERS STUDY REPORT



SCHERING-PLOUGH RESEARCH INSTITUTE

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CONFIDENTIAL

**CHRONIC IDIOPATHIC
URTICARIA
CONSUMER HABITS AND
PRACTICES STUDY**

December, 2001



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CHRONIC IDIOPATHIC URTICARIS
CONSUMER HABITS AND PRACTICES
STUDY

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BACKGROUND AND OBJECTIVES

Urticaria is a common disorder that affects between 15 and 20% of the population. Urticaria has many etiologies and different pathophysiologies, having acute and chronic forms. Chronic Urticaria can be idiopathic or of unknown origin. The incidence of chronic idiopathic urticaria is estimated at between 2-3% of the population.

In order to better understand this condition and the consumer habits and practices among those patients who suffer it, Schering-Plough commissioned a research study.

Specifically, the objectives of this research were:

- To understand, from a patient perspective, fundamental dynamics such as frequency of suffering, symptoms suffered and duration, severity and bothersomeness of the condition.
- Patient interaction with their physician initially, when diagnosed as idiopathic and when their condition worsens or does not respond to traditional treatment.
- Treatment modalities and preparations used to manage the disorder.
- Ease of recognizing the condition once a diagnosis of chronic idiopathic urticaria has been rendered by a physician.

STUDY DESIGN AND PROCEDURES

A survey was conducted using the National Family Opinion Interactive Panel of 1.2 million U.S. households. Given the low incidence of chronic idiopathic urticaria (CIU) in the population, an omnibus research tool was used to identify a sufferer population. Over two consecutive weeks (10/30/01 and 11/6/01) surveys were e-mailed to over 500,000 households each week. Each omnibus survey resulted in



STUDY DESIGN AND PROCEDURES (continued)

approximately 15,000 qualified adult subjects. The reported incidence of CIU ranged from 2.7% in Week One to 3.3% in the Week Two. To qualify as a sufferer, respondents were required to answer the following question in the affirmative:

"Have you ever been diagnosed by a medical doctor as having chronic or recurrent hives that have no known discernible cause (also known as chronic urticaria)?"

Upon completion of the omnibus surveys, a more detailed interactive survey was fielded among a sub-sample of 845 subjects randomly drawn from the larger pool of 15,000. The size of the sub-sample was derived with the goal of achieving an ending sample size of 300 chronic idiopathic urticaria sufferers and a projected response rate among the panel of 35%. The desired sample size was determined using the standard method which substitutes the relevant values in the appropriate standard-error formula to solve for N. Assuming a worst case estimated proportion in the population of 50%, a large population and a desired error of +/- 6% at the 95% confidence level, the requisite sample size would be 300. The actual response rate attained was 46% or 388 respondents. Using the same statistical parameters as outlined above, the standard error is +/- 4.9% at the 95% confidence level.



STUDY DESIGN AND PROCEDURES (continued)

The distribution of responses was as follows.

	<u>N=</u>
Outgo (subjects notified to log onto research company web site to complete survey)	845
Did not log in	192
Not 18 years of age or older	1
Work in sensitive occupation ¹	81
Do not suffer CIU at requalification ²	81
Did not want to take survey	7
Logged on after survey closed	95
Completed surveys/ending sample	388

¹Do not work in marketing research, advertising, public relations, a pharmaceutical company, the medical professions or a pharmacy.

²Rescreened to verify they were sufferers of CIU via a question nearly identical to the initial omnibus survey screening question. This is a standard process to ensure that respondents fully understand the initial screening question and criterion condition (chronic or recurrent hives).

The more detailed survey was fielded on 11/9/2001 and completed on 11/14/2001. A total of 388 panelists completed the survey. The only remuneration that panelists who completed the survey received was a nominal number of points to thank them for participating. These points can be accumulated and redeemed by panelists for gifts.

Survey questions were a combination of closed-and open-ended questions. Closed-ended questions were answered via buttons or click boxes. Many of the closed-ended questions had an "Other – Specify" response which permitted study subjects to type a response other than those in the pre-set lists into their browser. Responses to open-ended questions were typed directly into a response area on the study participant's screen. For a number of the "list" questions (e.g., symptoms, descriptors) the list elements were programmed to be rotated randomly.

Due to their experience in consumer panel behavior and demographics, the research company has a variety of tools to employ when a representative sample is



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STUDY DESIGN AND PROCEDURES (continued)

required. Either a representative census population or representative Internet population can be created through quotas and weighting. In the case of this study, the universe of sufferers was primarily a self-defined group due to the low single-digit incidence and therefore extensive weighting was not appropriate.

In order to best represent the population of CIU sufferers, the final survey data were weighted to reflect the gender and age quotas identified from information collected from the omnibus tool. The weights applied were quite small and ranged from a low of .6339 to a high of 1.4990.

DATA PROCESSING AND ANALYSIS

All questionnaires were electronically downloaded by National Family Opinion Interactive. Each questionnaire was checked for completeness and accuracy. Where necessary, verbatim responses were reviewed and classified into appropriate codes. All codes and component responses were reviewed and confirmed by National Family Opinion Interactive. Statistical testing was conducted and noted on the data tables. Significance testing was undertaken at the 95% confidence level using a two-tailed test.

STUDY SUMMARY

The results of this survey conducted in November, 2001 among a population of chronic idiopathic urticaria (CIU) sufferers provides a significant amount of fundamental information about the condition and its treatment.

These results show that CIU is a bothersome condition among those who experience it with nearly seven in ten subjects rating it extremely or very



STUDY SUMMARY (continued)

bothersome. Interestingly, these same subjects do not see the condition as severe with only 4% of sufferers viewing the condition as extremely serious.

- Those who have recurrent episodes of CIU are experienced sufferers. The ailment is frequently suffered with over 40% of subjects experiencing five or more outbreaks each year and one in six experiencing constant episodes.
- There is significant consistency in the symptoms described by CIU sufferers with nine in ten naming itching as the dominant symptom. Hives, wheals, redness and rash also receive high levels of mentions as key symptoms. Conversely, the reported incidence of symptoms that could connote or be confused with anaphylaxis or angioedema is very low (swelling = 4%; breathing problems = 1%).
- One third of sufferers claim to have not seen a physician in the past year for their chronic hives and nearly 20% of study subjects have not seen a physician since initial diagnosis.
- The behavior of not contacting the physician at every outbreak appears to be due, in part, to the use of prescribed medications already on hand and the use of over-the-counter medications. Over half of study subjects indicate that they normally use a prescribed medicine already on hand when their chronic hives occur and 43% report use of OTC medications. In addition, seven in ten of those receiving prescriptions generally receive refills with their prescription and the average number of refills provided is three.
- CIU sufferers who do contact their physician when their hives recur appear to do so principally when symptoms do not respond to current treatment/medication or when more serious symptoms occur. These patients do not wait long before contacting their physician with over half making contact within one day.
- Once diagnosed by a physician as having chronic idiopathic urticaria, 80% of study subjects perceive that it is very easy to identify the condition when it



STUDY SUMMARY (continued)

reappears. A total of 94% of subjects indicated that it was either very or somewhat easy.

- When respondents were asked regarding what actions they would take if they experienced symptoms associated with anaphylaxis along with their hives (i.e., difficulty breathing, fever or trouble swallowing), 95% of subjects indicated they would seek emergency care or call/visit their physician.
- Prior to seeing a physician for their initial outbreak, about two-thirds of study subjects indicated that they took an over-the-counter antihistamine for their hives. Continued itching/discomfort, hives that would not go away and the desire to find a cause of the hives were all key motivators for the initial physician visit.
- Just under one quarter of study subjects indicate that the physician who diagnosed them with CIU recommended an over-the-counter medication, despite lack of indication approval and appropriate labeling guidelines and precautions. Benedryl® was the most frequently mentioned OTC product.

CONCLUSIONS

Once diagnosed by a physician as having chronic idiopathic urticaria (CIU), sufferers appear confident in their ability to recognize a recurrent episode of the condition.

This ability traces to a number of important characteristics. First, symptoms of CIU appear to be consistent and discrete and changes in symptoms or the addition of other more troubling symptoms would seem to send signals to the consumer to seek immediate medical attention/physician contact. Also, the frequency of occurrence provides an experience base with the condition for most diagnosed sufferers that leads them to understand the natural patterns of the ailment. Finally, although they see the condition as quite bothersome, a majority of sufferers do not perceive the condition as serious or severe.



CONCLUSIONS (continued)

Behavior already appears to exist among consumers for self-treatment of the condition with antihistamines. A sizeable proportion of sufferers have not seen a physician for CIU since diagnosis. Additionally, consumers often use over-the-counter antihistamines prior to seeking a diagnosis, and after diagnosis, many consumers use OTC medications on the recommendation of their physician. Based on the proportion of CIU patients reporting they receive refills and the number of refills, many physicians appear to encourage self-management, prescribing medications in advance of outbreaks.

DETAILED FINDINGS

Length of Suffering

- Over two-thirds of the study subjects claim to have suffered from chronic idiopathic urticaria (CIU) for three or more years. Over half claim to have suffered for five years or more.

	Total Sample
Base: Total	(388)
	%
<u>Net-Less Than 2 Years</u>	<u>32</u>
Less than 1 year	13
1 – 2 years	19
<u>Net – 3 or More Years</u>	<u>68</u>
3 – 4 years	13
5 or more years	55
Mean	3.62

- How long have you suffered from episodes of recurring or chronic hives?



Length of Time Since Diagnosis

2. A majority of respondents indicated that they were diagnosed by a physician as having CIU three or more years ago. Over four in ten claimed they were diagnosed five years ago or longer.

	Total
	<u>Sample</u>
	(388)
	%
Base: Total	
<u>Net-Less Than 2 Years Ago</u>	41
Less than 1 year	21
1 – 2 years	20
<u>Net – 3 or More Years Ago</u>	59
3 – 4 years	15
5 or more years	44
Mean	3.23

- Q. How long ago were you diagnosed by a physician as having chronic hives?

Frequency of Suffering Episodes/Number Per Year

3. Frequency of experiencing episodes of CIU is widely distributed from constant suffering to relatively infrequent episodes.

	Total
	<u>Sample</u>
	(388)
	%
Base: Total	
All the time	17
Once a month or more	22
Every 2-3 months	17
Every 4-5 months	12
Every 6 months or less often	32

- Q. How frequently do you suffer episodes of chronic hives?



Frequency of Suffering Episodes/Number Per Year (continued)

- 3a. When placed in the context of a typical one-year period, over four in ten respondents suffer five or more episodes per year. If five episodes per year is ascribed to the 42% who claim to suffer five or more episodes, the average number of episodes for the total sample could be conservatively estimated at 3.4 per year.

Base: Total	<u>Total Sample</u> (388)
	%
1 – 2 episodes/year	34
3 – 4 episodes/year	24
5 or more episodes/year	42
Mean	3.4

- Q. In a typical year, how many episodes of chronic hives do you experience?

Length of Episodes

4. Two-thirds of study subjects indicate that each episode or flare-up of chronic hives lasts up to a week. Another one-sixth claim episodes generally last 2-3 weeks. This finding is not consistent with medical literature which defines CIU as typically lasting six weeks or longer. One explanation for this discrepancy may lie in the consumer interpretation of an episode. Since many subjects are medicating during episodes these subjects may be asymptomatic creating a perception that the “episode” is over and urticaria is under control.



Length of Episodes (continued)

Episode Duration

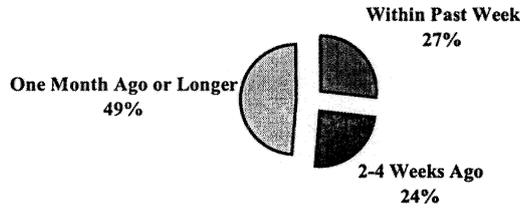
Base: Total	<u>Total Sample</u> (388)
	%
Up to a week	66
2 – 3 weeks	17
4 – 6 weeks	7
7 – 9 weeks	1
10 weeks or more	10

Note: Responses do not add to 100% due to rounding

Q. On average, how long does each episode of chronic hives tend to last?

Most Recent Episode

5. About one-half of study subjects indicate that they experienced an episode of CIU within the past month.



Q. When was the last time you had an episode of your chronic hives?

Symptoms Experienced

6. Over nine in ten CIU sufferers claim to experience itching when their chronic hives recur. Other dominant symptoms are: hives/wheals, redness and rash. Relatively infrequently mentioned symptoms are joint pain and swelling.

Base: Total	Total Sample (388)
<u>Symptoms Experienced</u>	%
Itching	91
Hives or wheals	77
Redness	68
Rash	50
Joint pain	14
Swelling/swelling feet/ tongue or hands	4
Breathing problems	1
All other mentions	5

**NOTE: Responses do not add to 100% due to rounding.
Multiple responses possible.**

- Q. Please indicate the symptoms you experience when your hives recur.
- 6a. Focusing on the subjects who list joint pain or swelling as symptoms experienced suggests that these respondents are more likely to be under a physician's care than the balance of the sample.



Symptoms Experienced (continued)

	<u>Total Sample</u>	<u>Suffer Joint Pain/Swelling</u>
Base:	(388)	(68)
	%	%
Number of times seen Physician for CIU (past year)	(a)	(b)
Never	33	29
1-2 times	[46]	(35)
3 or more times	(21)	[36]

() is statistically different from [] as the 95% confidence level

Q. In the past year, how often have you see a physician for this condition?

6b. Itching, hives or wheals, rash and redness are symptoms of CIU with significant levels of concomitant suffering. Based on this reported concomitant suffering it appears the terms used to describe symptoms may be used interchangeably by subjects.

	<u>Suffer From:</u>			
	<u>Itching</u>	<u>Hives/Wheals</u>	<u>Rash</u>	<u>Redness</u>
Base: Total Suffering				
Symptom	(353)	(300)	(195)	(265)
	%	%	%	%
Suffer From:				
Itching	100	91	95	95
Hives/Wheals	77	100	71	80
Rash	(53)	(46)	100	[61]
Redness	(71)	(71)	[82]	100

() is statistically different from [] at the 95% confidence level

Q. Please indicate the symptoms you experience when your hives recur

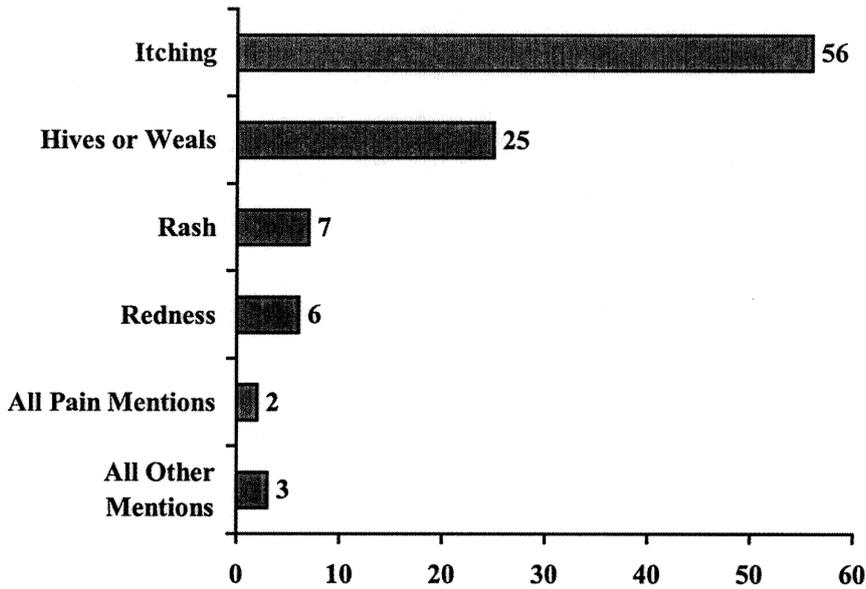


Symptoms Experienced (continued)

6c. Itching is overwhelmingly mentioned by study subjects as one most defining or telltale symptom to identify that a recurring episode is commencing. Hives or wheals are noted by one-quarter of study subjects as the telltale symptom.

Defining Symptom of CIU

Base: Total Sample (N=388) %

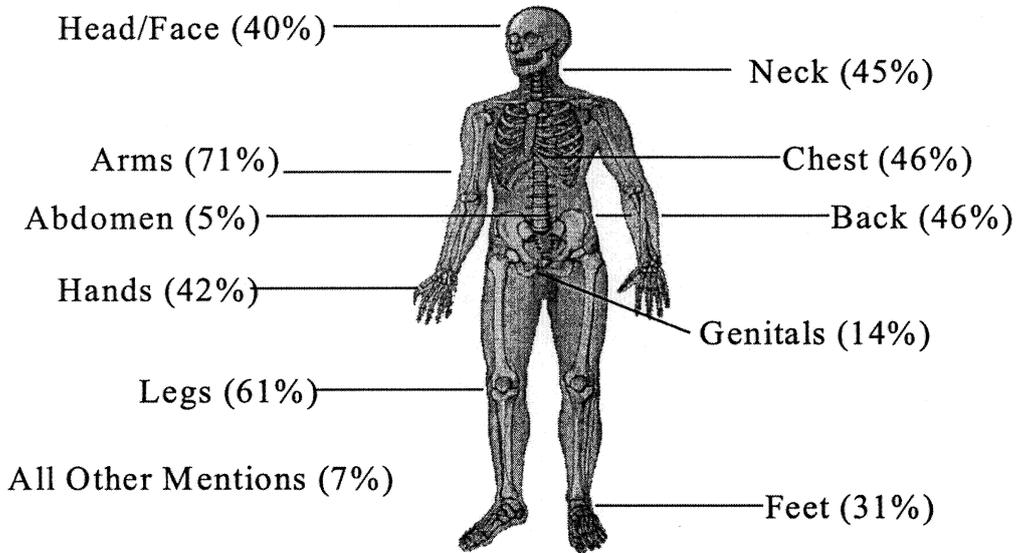


Q. Which symptom, if any, is the most defining or tell-tale symptom to identify to you that a recurring episode is beginning to happen?

- Q. Which symptom, if any, is the most defining or tell-tale symptom to identify to you that a recurring episode is beginning to happen?
- 7. Among those experiencing hives or wheals, the location of urticarial lesions is widely distributed. The arms and legs are the most prevalent locations with the head/face, neck, chest and back all mentioned at comparable levels.

Note: Responses do not equal 100 due to multiple responses

Location of Hives or Wheals
 (Base: Those Experiencing Hives N=300)



Q. When you suffer, where on your body do you usually develop hives or wheals?

NOTE: Multiple responses possible

8. Subjects experiencing hives or wheals claim to usually have an average of 6.6 urticarial lesions per episode. Nearly two-thirds of those experiencing hives/wheals have eight or more hives or wheals per episode.

Number of Hives/Wheals

Base: Those Experiencing Hives/Wheals	Total Sample
	(300)
	%
1 – 2	11
3 – 5	15
6 – 8	12
8 or More	62
Mean	6.6

Q. About how many hives or wheals do you usually get when you experience an episode of chronic hives?

Severity/Bothersomeness of CIU Condition

9. Just over one quarter of study subjects view their condition as serious. Only four percent indicate their chronic hives are extremely serious.

	Total Sample (388)
Base: Total	%
Extremely Serious	4
Very Serious	23
<u>Extremely/Very Serious</u>	<u>27</u>
Neither Serious nor Not Serious	38
Not Very Serious	25
Not Serious At All	10

- Q. Please indicate how severe you think your condition is.

10. CIU is perceived by sufferers to be a bothersome condition. Nearly three in four sufferers rated the condition as extremely or very bothersome. Just over one-quarter of subjects classify CIU as extremely bothersome.

Bothersomeness

	Total Sample (388)
Base: Total	%
Extremely bothersome	28
Very bothersome	45
<u>Extremely/very bothersome</u>	<u>73</u>
Neither bothersome nor Not bothersome	14
Not very bothersome	10
Not bothersome at all	3

- Q. Please indicate how bothersome you think your condition is.



Current Treatment Behavior

11. One-third of sufferers have not seen a physician in the past year for CIU. Another 46% saw their physician either one or two times. The average number of physician visits for study subjects was 1.6 times.

Base: Total	Total Sample (388) %
Have not seen doctor for CIU in past year	33
Saw doctor 1-2 times	46
Saw doctor 3-4 times	12
Saw doctor 5+ times	9
Mean # times	1.57

- Q. In the past year, how often have you seen a physician for this condition.
12. When asked what they normally do when their hives recur, over half indicated that they used prescribed medications already on hand and 43% claimed to use an over-the-counter medication. One in five mentioned contacting their physician.



Action Taken Upon Recurrence

Base: Total	Total Sample (388) %
Use prescribed medication already on hand	52
Use OTC medication	43
Call/visit physician (Net)	20
Take bath/soothing bath/ soak/wash areas	3
Nothing/wait it out/no longer have problem	8
Apply ice	1
Go to emergency room	1
All other mentions	5

NOTE: Multiple responses possible

Q. When your chronic hives recur, please indicate what you normally do.

13. Among those who call or visit their physician when their hives recur (N=78 or 20% of the total sample), over four in ten initiate contact only when symptoms do not respond to treatment or when more serious symptoms occur.

Base: Total	Subjects Who Call/Visit Physician (78) %
<u>When Contact Physician</u>	
Every time	22
Some times	21
Only when symptoms don't respond to current treatments/ medication(s)	35
Only when a more serious symptom such as swelling of face/mouth occurs	8
No answer	16

NOTE: Multiple responses possible

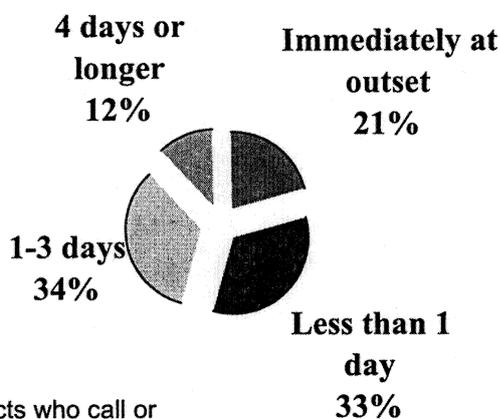
Q. When your chronic hives recur, please indicate what do you normally do.



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Action Taken Upon Recurrence

14. In cases where study subjects contact a physician, most wait an average of 1.75 days before making contact. A majority contact their physician within the first day.



Base: Subjects who call or visit their physician (N=78)

- Q. In cases where you typically contact a physician, how long do you wait before contacting the physician?

Ability To Self-Recognize CIU

15. Once diagnosed by a physician as having chronic idiopathic urticaria, 80% of study subjects perceive that it is "very easy" to identify the condition when it reappears. No respondents reported difficulty in recognizing recurrent episodes of CIU.

	<u>Total Sample</u>
Base: Total	(388)
<u>Ease of Recognition</u>	%
Very easy	80
Somewhat easy	14
<u>Very/Somewhat Easy</u>	94
Neither easy nor difficult	6
Somewhat difficult	--
Very difficult	--

- Q. Now that your condition has been diagnosed by a physician, how easy is it for you to identify this condition when it reappears?



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Ability To Self-Recognize CIU (continued)

16. Respondents were asked what actions they would take if they experienced symptoms associated with anaphylaxis (i.e., difficulty breathing, fever or trouble swallowing) along with their hives. 95% of patients reported that they would seek medical attention with responses of “go to the emergency room”, “call your physician” and “visit your physician” receiving the highest levels of agreement. Only a small minority of respondents indicated they would use a medication they had on hand. One study subject indicated he or she would use an over-the-counter medication if they experienced these symptoms.

Base: Total	Total Sample (388) %
Go to the emergency room	55
Call your physician	29
Visit your physician	11
Use prescribed medication you already have	5
Use over the counter medications	*

*= <1% of respondents

Q. What would you do if you experienced other symptoms such as difficulty breathing, fever or trouble swallowing with your hives?

17. Most subjects who have visited a physician since diagnosis of chronic hives indicate that the doctor usually takes the opportunity to examine them for general health issues. Nearly one in five subjects claim to have not seen a physician since diagnosis.



Ability To Self-Recognize CIU (continued)

Base:	Total Sample (388) %
Yes, examined for general health issues	48
No, not examined	33
Have not seen a physician since initial diagnosis	19

- Q. Other than the initial visit when you were first diagnosed, when you visit a physician for this condition, does your physician take the opportunity to examine you for other non-related conditions?
18. Those who have not seen a physician since initial diagnosis are somewhat lighter sufferers who are less bothered by their chronic hives and are more likely to use either OTCs or prescription products they have on hand.

Base:	Not Seen Physician Since Diagnosis (73) %
Suffer every 6 months or less often	44 (vs. 32% for total sample)
Hives are extremely bothersome	20 (vs. 28% for total sample)
Use Rx already have	34 (vs. 52% for total sample)
Use OTC medication	56 (vs. 43% for total sample)



Historical Habits and Practices

19. Itching and discomfort, hives that would not go away and the desire to find the cause of the hives were all key motivators for the initial physician visit. About one third of subjects went to the physician because their OTC medication did not work.

Base: Total	Total Sample (388) %
<u>Prompted Initial MD Visit</u>	
Itching/discomfort	62
Wanted to find out what caused the hives	57
Hives didn't go away	46
Thought it might be something serious	34
Over-the-counter medicine did not work	32
Redness	24
Family/friend recommended see a physician	23
Noticed during routine visit	2
Hives started breaking out	2
Swelling/facial/throat/eye swelling	1
All other mentions	2

NOTE: Multiple responses possible

Q. What prompted you to see a physician the first time you visited one for hives?

20. Prior to seeing a physician, the first time they suffered, two thirds of study subjects took an over the counter antihistamine for their hives. Use of topical anti-itch lotions, topical antihistamines and Aveeno®/soothing baths were secondary treatment modalities.



Historical Habits and Practices (continued)

Base: Total	Total Sample (388) %
Took an over-the-counter antihistamine such as Benadryl® or Chlor-Trimeton®	62
Used topical anti-itch lotion such as calamine lotion	46
Used topical anti-itch lotion such as Benadryl®	36
Took Aveeno®/soothing baths	24
Used cortisone cream/hydrocortisone ointment	2
Used prescription antihistamine	1
All other mentions	5

NOTE: Multiple responses possible

- Q. Thinking about when the hives appeared prior to seeing a physician, what if anything did you do to treat and/or relieve the condition? (Question context is prior to diagnosis of CIU)
21. Study subjects were asked which of a select list of terms best describes how they described the condition to the physician when they initially saw a doctor for hives. Subjects were prompted to write in the appropriate term if they did not see it on the list. Next they were asked to select or write in the terminology that best represents the words the physician used to describe their chronic hive condition upon initial diagnosis.

“Hives of unknown cause”, “itchy hives” and “recurrent hives” are the descriptors named by subjects as the most common ways they described their condition to the physician upon initial contact. Physicians are also likely to use the terminology “hives of unknown origin or cause” and “recurrent hives” to describe the condition. However, chronic urticaria and chronic hives are also key descriptors claimed to be used by physicians upon diagnosis.



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Historical Habits and Practices (continued)

	Consumer Described <u>Initial Contact</u>	Physician Described <u>Upon Diagnosis</u>
Base: Total Sample	(388)	(388)
	%	%
None/no answer	1	1
Don't know or remember	1	2
Base: Total Answering	(381)	(378)
	%	%
Hives of unknown origin or cause	32	44
Itchy hives	26	4
Recurrent hives	16	13
Repeat hives	6	2
Serious hives	7	2
Chronic idiopathic urticaria	1	6
Chronic hives	4	10
Chronic urticaria	--	10
All other mentions	7	10

Q. When you first went to see a physician which of the following terms best describes how you described your condition to the physician? If you do not see the appropriate term in the list below, please write it in the space below marked "Other".

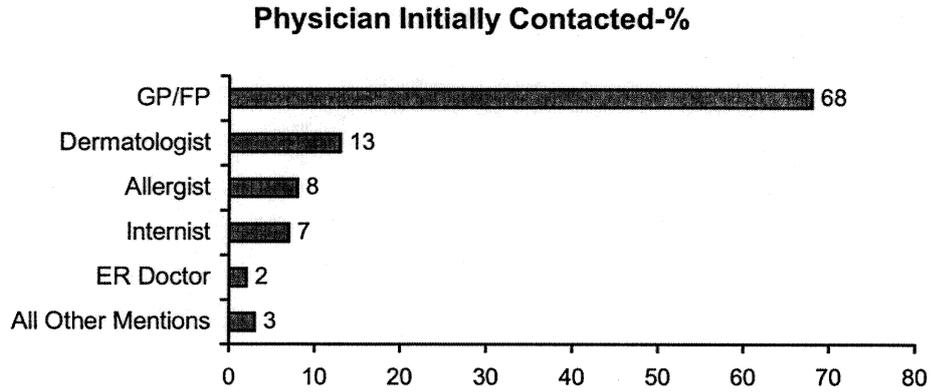
Q. When you first learned about your diagnosis of chronic hives, what words best represents how your physician described the condition to you? If you do not see the appropriate term in the list below, please write it in the space below marked "Other".

22. General and Family practitioners are the type of physicians most subjects initially contacted for their hives. Dermatologists, Allergists and Internists are also contacted.



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Historical Habits and Practices (continued)



Q. Please indicate the type of physician you initially contacted for your condition.

23. For about half of patients, the physician initially contacted is same as the physician treating them currently for their chronic hives.

	Total Sample
Base: Total	(388)
	%
Yes, the same	49
No, not the same	51

Q. Is that the same physician who is treating you for chronic hives?

24a. Among the 51% of patients who are not using the same physician they initially contacted about their hives, most are seeing a GP/FP for their chronic condition.

Historical Habits and Practices (continued)

Base:	Those Not Using Initial Physician
	(198)
	%
<u>Physician Currently Treating</u>	
None/No longer have condition/ cannot afford doctor	22
General/family practitioner	33
Dermatologist	21
Allergist	15
Internist	7
Other	4

Q. Please indicate the type of physician who is treating them for their chronic hives.

24b. Among those subjects who are not using the same physician they initially contacted for hives, only about one-fifth were diagnosed with chronic hives by their current physician.

Base:	Those Not Using Initial Physician
	(198)
	%
<u>Who Diagnosed CIU</u>	
Physician currently treating	20
Physician initially contacted	57
Neither	23

Q. Which physician diagnosed your chronic hives condition?

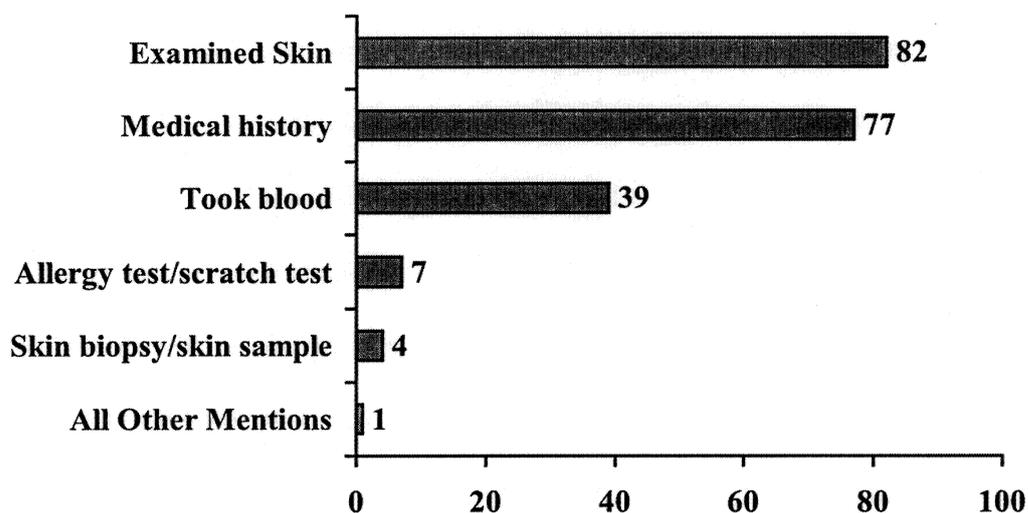


Historical Habits and Practices (continued)

25. Skin examination and medical history were the most frequently mentioned methods or tests that consumers perceived their diagnosing doctor performed to help determine their condition.

Base: Total Sample (N=388)

Perceived Methods or Tests



NOTE: Multiple responses possible

Q. To the best of your knowledge, what methods or tests did your physician perform to help determine you had chronic hives?



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Historical Habits and Practices (continued)

26. Prescription medications or topical ointments were the leading treatments prescribed or recommended by the physician diagnosing chronic idiopathic urticaria. Over one fifth of study subjects received a recommendation for an over-the-counter medication or Aveeno®/soothing baths.

Base: Total	<u>Total Sample</u> (388) %
<u>Treatment Prescribed/Recommended</u>	
Prescription medication	63
Prescription topical ointment	39
Over-the-counter medication	23
Aveeno®/soothing bath	21
Over-the-counter ointment/treatment	17
Calamine lotion	11
Apply ice	11
Wears socks/gloves	3
Shots/Injections	3
All other	7
None/nothing	1

NOTE: Multiple responses possible

Q. What treatment did your diagnosing physician prescribe?

27. Among those subjects who received a prescription, about one in seven also received a recommendation for an over-the-counter medication.

	Treatment Prescribed by Diagnosing Physician	
	<u>Prescription Medication</u>	<u>Prescription Topical</u>
Base: Total Receiving	(242) %	(150) %
Over-the Counter Medication	14	13



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Historical Habits and Practices (continued)

28. Systemic steroids, and the non-sedating antihistamines are the medications most likely to have ever been prescribed and the medications prescribed most often. Beta-adrenergics, H₂ blockers and hydroxyzine are also frequently mentioned.

	Medications	
	Ever Prescribed	One Prescribed Most Often
Base: Total Receiving Prescriptions	(242)	(242)
	%	%
Systemic steroids such as		
Prednisone	41	21
Claritin®	34	18
Allegra®	26	12
Zyrtec®	25	10
Beta-adrenergics such as		
Proventil®/Albuterol®	11	4
H₂ blockers such as		
Pepcid®/Tagamet®	11	3
Benadryl®	5	5
Hydroxyzine	4	4
Thyroid supplements	3	1
Atarax®	3	3
Other mentions	14	12
Don't know	5	6

Q. Please indicate which medications were ever prescribed.

Q. Please indicate which one medication has been prescribed most often.

29. Seven of ten study subjects indicate they receive refills of the drug prescribed most often for their chronic hives. An average of three refills were provided with the initial prescription.



Historical Habits and Practices (continued)

	<u>Total Receiving Prescriptions</u>
Base:	(242)
	%
Received refill	70
Did not receive refill	30
Base: Received refill	(168)
<u>Number of refills</u>	
1	16
2	22
3	22
4 or more	40
Mean	2.85

Q. For this one medication that has been prescribed most often, did the prescription come with a refill? Q. How many refills?

30. Among those subjects for whom any systemic or topical OTC preparation was recommended by the diagnosing physician (33% of total sample), Benadryl® was the most recommended product.

	<u>Total Receiving Any OTC Recommendation</u>
Base:	(128)
	%
Benadryl®	74
Benadryl® or other topical cream	39
Store brand antihistamine	14
Chlor-Trimeton®	10
Tylenol®Allergy Sinus	4
All others	4
Don't know/no answer	2

NOTE: Multiple responses possible

Q. Please indicate which over-the-counter medication was recommended.



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Historical Habits and Practices (continued)

31. Consumers perceive that prescription medications are most effective in relieving chronic urticaria. However, interestingly, those receiving recommendations for an internal OTC medication appear relatively satisfied with the efficacy.

Which Medication Most Effective

	<u>Total Sample</u>	<u>Received Recommendation For OTC Medication</u>
Base: Total	(388)	(88)
	%	%
Prescription medication	44	20
Prescription topical	18	3
OTC medication	12	54
OTC topical	6	9
All other mentions¹	19	22

¹Includes Aveeno® baths, calamine lotion, ice, injections, etc.

- Q. In your opinion, which medication or treatment was the most effective in relieving the condition?

Classification

32. Consistent with published medical literature the sample skewed female.

	<u>Total Sample</u>
Base: Total	(388)
	%
Male	34
Female	66

- Q. Please indicate your gender below.



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Classification (continued)

33. Subject age averaged 45.4 years and consistent with medical literature the largest portions of subjects were in their fourth and fifth decades.

Base: Total	<u>Total Sample</u> (388)
<u>Age Groups</u>	%
18 – 24	4
25 – 29	7
30 – 39	21
40 – 49	29
50 – 59	27
60 – 69	9
70+	3
Mean	45.4

Q. Please indicate your age below.



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Other Demographics

34. The sample was regionally dispersed and represented a mix of metropolitan statistical areas.

	Total Sample
Base: Total	(388)
	%
<u>Region</u>	
Northeast	18
Midwest	20
South	35
West	27
<u>Market Size</u>	
Rural and C/MSA<100K	20
C/MSA 100 - 499K	18
C/MSA 500 – 1,999K	21
C/MSA 2MM +	41

¹Combined/Metropolitan Statistical Area

35. Chronic hive sufferers skewed to one and two person households.

	Total Sample
Base: Total	(388)
	%
1 Member	18
2 Members	39
3 Members	18
4 Members	15
5+ Members	10

36. Study subjects were predominantly white. This is true of panel demographics which tend to understate ethnic groups.



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Other Demographics (continued)

	Total Sample
Base: Total	(388)
	%
<u>Race</u>	
White	84
Black/African American	2
Asian/Pacific Islander	2
Native American	1
Other	3
No Answer	8

37. Education of the female head of household skewed toward high school graduate or higher.

	Total Sample
Base: Total	(388)
	%
<u>Female Education</u>	
Some high school or less	3
Graduated high school	19
Some college	31
Graduated college with Associates Degree	9
Graduated college with Bachelors Degree	16
Post graduate	9
No answer/No female	15



Other Demographics (continued)

38. The greatest proportion of study subjects are in the \$35 – 55,000 bracket.

Base: Total	Total Sample (388)
	%
Under \$20,000	16
\$20,000 – 34,999	22
\$35,000 – 54,999	27
\$55,000 – 84,999	20
\$85,000 +	16



APPENDIX
(STUDY QUESTIONNAIRE)



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SCHERING PLOUGH**Hives A&U****Project #49341****November, 2001**

1. Do you or anyone else in your household, work in...? **(SELECT ALL THAT APPLY)**

Marketing Research	(TERMINATE)
Advertising	(TERMINATE)
Public Relations	(TERMINATE)
Pharmaceutical Company	(TERMINATE)
Medical Profession/Pharmacy	(TERMINATE)
None of the above	(CONTINUE)

2. Please indicate your current age below **(SELECT ONE RESPONSE)**

Under 18	(TERMINATE)
18-24	(CONTINUE)
25-29	(CONTINUE)
30-39	(CONTINUE)
40-49	(CONTINUE)
50-59	(CONTINUE)
60-69	(CONTINUE)
70+	(CONTINUE)
Refused	(TERMINATE)



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3. Recently you told us that you have been diagnosed by a physician as having chronic or recurrent hives that have no known/discernable cause (also known as Chronic Urticaria). Is this correct?

Yes

(CONTINUE)

No

(TERMINATE)

4. Based on your previous answers you qualify for a survey about hives. This survey will take you about 10 minutes to complete. For your cooperation, you will receive 35 additional NFO Reward Points that will be added to your account in about 2-3 weeks. Do you wish to continue with this survey?

Yes

(CONTINUE)

No

(TERMINATE)

5. How long have you suffered from episodes of recurring or chronic hives?
(SELECT ONE RESPONSE)

Less than 1 year

1-2 years

3-4 years

5+ years



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6. Thinking about when the hives appeared prior to seeing a physician, what if anything, did you do to treat and/or relieve the condition? (**SELECT ALL THAT APPLY**)

Used topical anti-itch lotion such as calamine lotion

Took over-the-counter antihistamine such as Benadryl or Chlor-Trimeton

Used topical antihistamine ointments such as Benadryl

Took Aveeno or soothing baths

Other (SPECIFY)

Nothing

7. What prompted you to see a physician the first time you visited one for hives?
SELECT ALL THAT APPLY

ROTATE RANDOMLY

Redness

Hives didn't go away

Over-the-counter medications didn't work

Itching/discomfort

Family/friends recommended I go see a physician

Wanted to find out what caused the hives

Thought it might be something serious

Other (SPECIFY)



8. How long ago were you diagnosed by a physician as having chronic hives?
(SELECT ONE RESPONSE)

Less than one year ago

1-2 years ago

3-4 years ago

5 years ago or more

9. When you first went to see a physician, which of the following terms best describes how **you** described your condition to the physician? If you do not see the appropriate term in the list below, please write it in the space below marked "Other." **(SELECT ONE RESPONSE)**

ROTATE RANDOMLY

Itchy Hives

Chronic Hives

Recurrent Hives

Hives of unknown origin/cause

Serious Hives

Repeat Hives

Chronic Urticaria

Chronic Idiopathic Urticaria

Other (SPECIFY)



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10. When you first learned about your diagnosis of chronic hives, what words best represents how your physician described the condition to you? If you do not see the appropriate term in the list below, please write it in the space below marked "Other." (SELECT ONE RESPONSE)

ROTATE RANDOMLY

Itchy Hives

Chronic Hives

Recurrent Hives

Hives of unknown origin/cause

Serious Hives

Repeat Hives

Chronic Urticaria

Chronic Idiopathic Urticaria

Other (SPECIFY)

11. Please indicate the type of physician you initially contacted for your condition?
(SELECT ONE RESPONSE)

General/Family Practitioner

Allergist

Dermatologist

Internist

Gynecologist

Pediatrician

Other (SPECIFY)



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11a. Is that the same physician who is currently treating you for chronic hives?

Yes

(SKIP TO Q.12)

No

11b. Were you referred to your current physician by the physician you initially contacted?

Yes

No

11c. Please indicate the type of physician who is currently treating you for your condition. **(SELECT ONE RESPONSE)**

General/Family Practitioner

Allergist

Dermatologist

Internist

Gynecologist

Pediatrician

Other (SPECIFY)



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11d. Which physician diagnosed your chronic hives condition? **(SELECT ONE RESPONSE)**

Physician currently treating

Physician initially contacted

Neither

12. To the best of your knowledge, what methods or tests did your physician perform to help determine you had chronic hives? **(SELECT ALL THAT APPLY)**

Took blood

Examined skin

Took medical history/Asked for symptoms

Other (SPECIFY)



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13. What treatment did your diagnosing physician prescribe? **(SELECT ALL THAT APPLY)**

- | | |
|---|----------------|
| Take prescription medication | (CONTINUE) |
| Take over-the-counter medication | (SKIP TO Q.16) |
| Apply prescription topical ointment/treatment | (SKIP TO Q.16) |
| Apply over-the-counter topical ointment/treatment | (SKIP TO Q.16) |
| Take Aveeno®, or soothing bath | (SKIP TO Q.16) |
| Apply ice | (SKIP TO Q.16) |
| Wear socks or gloves on your hands | (SKIP TO Q.16) |
| Use calamine lotion | (SKIP TO Q.16) |
| Other (SPECIFY) | |

14a. Please indicate which medication(s) were ever prescribed. **(SELECT ALL THAT APPLY)**

- Allegra®
- Claritin®
- Zyrtec®
- H2 Blockers such as Pepcid® or Tagamet®
- Systemic steroids such as Prednisone
- Thyroid supplements
- Beta-adrenergics such as Proventil®/Albuterol
- Calcium channel blockers
- Other (SPECIFY)



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14b. Please indicate which one medication has been prescribed most often.
(SELECT ONE RESPONSE)

Allegra®

Claritin®

Zyrtec®

H2 Blockers such as Pepcid® or Tagamet®

Systemic steroids such as Prednisone

Thyroid supplements

Beta-adrenergics such as Proventil®/Albuterol

Calcium channel blockers

Other (SPECIFY)

14c. For this one medication that has been prescribed most often, did the prescription come with a refill? **(SELECT ONE RESPONSE)**

Yes

(CONTINUE)

No

(SKIP TO Q.16)

15. How many refills? **(SELECT ONE RESPONSE)**

1

2

3

4 or more



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16. Please indicate which over-the-counter medication was recommended.
(SELECT ALL THAT APPLY)

Benadryl®

Chlor-Trimeton®

Tylenol® Allergy Sinus

Store brand antihistamine

Benadryl® or other topical cream

Other (SPECIFY)

17. In your opinion, which medication or treatment was the most effective in relieving the condition **(SELECT ONE RESPONSE)**

Prescription medication

Over-the-counter medication

Prescription topical ointment/treatment

Over-the-counter topical ointment/treatment

Taking Aveeno®, or soothing baths

Applying ice

Wearing socks or gloves on your hands

Use calamine lotion

Other (SPECIFY)



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18. How frequently do you suffer episodes of chronic hives? **(SELECT ONE RESPONSE)**

- All the time
- Once a month or more
- Every 2-3 months
- Every 4-5 months
- Every 6 months or less

19. In a typical year, how many episodes of chronic hives do you experience? **(SELECT ONE RESPONSE)**

- 1-2 episodes
- 3-4 episodes
- 5 episodes or more

20. On average, how long does each episode of chronic hives tend to last? **(SELECT ONE RESPONSE)**

- Up to a week
- 2-3 weeks
- 4-6 weeks
- 7-9 weeks
- More than 10 weeks



21. When was the last time you had an episode of your chronic hives? **(SELECT ONE RESPONSE)**

Within the last week

2-4 weeks ago

1 month ago or longer

22. Please indicate the symptoms you experience when your hives recur. **(SELECT ALL THAT APPLY)**

ROTATE RANDOMLY

Itching

Hives or wheals

Rash

Redness

Joint pain

Other (SPECIFY)



23. When you suffer, where on your body do you usually develop hives or wheals.

(SELECT ALL THAT APPLY)

ROTATE RANDOMLY

Head/face

Neck

Hands

Feet

Arms

Legs

Genitals

Chest

Back

Other (SPECIFY)

24. About how many hive welts or wheals do you usually get when you experience an episode of chronic hives? **(SELECT ONE RESPONSE)**

1-2

3-5

6-8

8 or more



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25. Which symptom, if any is the **most** defining or tell-tale symptom to identify to you that a recurring episode is beginning to happen? **(SELECT ONE RESPONSE)**

ROTATE RANDOMLY

Itching

Hives or wheals

Rash

Redness

Joint pain

Other (SPECIFY)

26. Please indicate how severe you think your condition is. **(SELECT ONE RESPONSE)**

Extremely serious

Very serious

Neither serious nor not serious

Not very serious

Not serious at all



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27. Please indicate how bothersome you think your condition is. **(SELECT ONE RESPONSE)**

Extremely bothersome

Very bothersome

Neither bothersome nor not bothersome

Not very bothersome

Not bothersome at all

28. When your chronic hives recur, please indicate what you normally do. **(SELECT ONE RESPONSE)**

Call your physician (CONTINUE)

Visit your physician (CONTINUE)

Use prescribed medication you already have (SKIP TO Q.30)

Use over-the-counter medications (SKIP TO Q.30)

Other (SPECIFY) (SKIP TO Q.30)



29. Please indicate below when you usually contact your physician for your recurring chronic hives. **(SELECT ONE RESPONSE)**

Every time

Sometimes

Only when symptoms don't respond to current treatment/medication(s)

Only when a more serious symptom such as swelling of the face or mouth occurs

Never

Other (SPECIFY)

30. In cases where you contact a physician, how long do you typically wait before contacting a physician? **(SELECT ONE RESPONSE)**

Immediately at onset

Less than 1 day

1-3 days

4-5 days

1 week or longer

31. In the past year, how often have you seen a physician for this condition? **(SELECT ONE RESPONSE)**

Never

1-2 times

3-4 times

5 times or more



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32. Now that your condition has been diagnosed by a physician, how easy is it for you to identify this condition when it reappears? **(SELECT ONE RESPONSE)**

Very easy

Somewhat easy

Neither easy nor difficult

Somewhat difficult

Very difficult

33. Other than the initial visit when you were first diagnosed, when you visit a physician for this condition, does your physician take the opportunity to examine you for other non-related conditions? **(SELECT ONE RESPONSE)**

Yes

No

Haven't visited a physician since first diagnosed



34. What would you do if you experienced other symptoms such as difficulty breathing, fever, or trouble swallowing along with your hives? **(SELECT ONE RESPONSE)**

Call your physician

Visit your physician

Go to an emergency room

Use prescribed medication you already have

Use over-the-counter medications

Other (SPECIFY)

The following questions are for classification only.

35. Please indicate your gender below. **(SELECT ONE RESPONSE)**

Male

Female

(ASK OF FEMALES ONLY)

36. Are you currently... ?**(SELECT ALL THAT APPLY)**

Lactating/breastfeeding

Pregnant



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37. Do you currently have...?(SELECT ALL THAT APPLY)

Kidney disease

Liver disease

None of the above

Thank you. These are all the questions we have for you!



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