

INTRODUCTION

Hello!

Stethos is a market research institute specialising in the pharmaceutical sector. We are currently conducting a **nation-wide survey on Chronic Spontaneous Urticaria**, with the aim of understanding **patients' attitudes** to the disease and **any needs that remain unmet**. More specifically, the purpose of the survey is to identify the needs and opinions of patients affected by CSU, in order to involve them directly in the development of new activities and services to support disease's management and treatment.

Please feel free to express your thoughts and opinions with regard to the topics addressed in this questionnaire. Stethos does not represent any of the Pharmaceutical Companies that may be mentioned, so please have no qualms about expressing any type of opinion or comment.

Also note that in accordance with the Italian laws on privacy (Italian Law no. 196/03 and subsequent amendments), you are free to interrupt the interview whenever you want and to avoid to answer to some questions... Moreover, we guarantee that any information you provide will be handled with strict confidentiality and anonymity, without the use of personal data or other contact details.

The privacy of the answers provided in the course of this interview will clearly be safeguarded; only in the case that you should mention an adverse event encountered while or after drug administration, we will ask for your permission to give your name to the pharmacovigilance department of the pharmaceutical company producing the drug, even if you have already notified it to the company or to your doctor. The content of the rest of the interview will continue to remain anonymous and confidential.

Firstly, thank you for agreeing to collaborate in this survey.

Q. 1. Do you suffer from Chronic Spontaneous Urticaria?

- yes**→ continue with the questionnaire
- no**→ terminate the questionnaire

Q. 2. How long have you been suffering from Chronic Spontaneous Urticaria? To answer, consider the first time in which the symptoms of your Chronic Spontaneous Urticaria appeared.

|_|_| years

Q. 3. When the disease has been diagnosed (year)? |_|_|_|_| year of diagnosis

Q. 4. Which is your current therapy for your Chronic Spontaneous Urticaria?

- no treatment
- only antihistamine
- antihistamine in combination with leukotriene antagonist (e.g., Singulair, Montegen, Lukasm, Montelukast Tev)
- cortisone/steroids (alone or in combination with other therapies)
- omalizumab (Xolair)
- another medicine / combination of medicines

Q. 5. Who did you seek help from when the symptoms of urticaria first appeared?

- emergency department
- my general practitioner (GP)
- the Dermatologist who is currently treating me
- the Allergologist who is currently treating me
- another Dermatologist, different from my current one
- another Allergologist, different from my current one
- another specialist _____ please specify _____

Q. 6. How long after the appearance of the first symptoms did you go to the emergency department or a doctor for the first time?

- immediately, as soon as I saw the first signs of the disease
- a few days later
- a few weeks later
- after 2-3 months
- after 4-6 months
- after about 1 year
- after about 2-3 years
- after more than 4 years
- I don't remember when

Q. 7. What were your first symptoms that prompted you to seek medical help from a doctor or emergency department?

Specify _____

Q. 8. Which doctor first gave you a diagnosis of Chronic Spontaneous Urticaria? To answer, consider the doctor who actually diagnosed the disease, not the doctor you saw when the first symptoms appeared (this might have been a different doctor from the one who actually made the diagnosis).

- the emergency department doctor
- my general practitioner (GP)
- the Dermatologist who is currently treating me
- the Allergologist who is currently treating me
- another Dermatologist, different from my current one
- another Allergologist different from my current one
- another specialist _____ please specify _____

Q. 9. And how long after the appearance of the first symptoms did you receive a diagnosis of Chronic Spontaneous Urticaria? In other words, how long passed between the appearance of your first symptoms and the first time the doctor made the diagnosis?

- immediately, at the time of the first signs of disease
- a few days later
- a few weeks later
- after 2-3 months
- after 4-6 months
- after about 1 year
- after about 2-3 years
- after more than 4 years
- I don't remember when

Q. 10. Now, how often do your urticaria symptoms re-appear?

- every day
- every week
- every 2/3 weeks
- every month
- every 2/3 months
- every 4-5 months
- about once/twice a year
- less frequently

Q. 11. When these symptoms re-appear, how long do they last?

- a few hours
- 1-2 days
- 3-4 days
- 5-6 days / 1 week
- 2-3 weeks
- 1 month / 1 month and a half
- other _____ specify _____

Q. 12. In the past, did you see other specialists before to be in charge of by your current specialist? If so, could you indicate how many other specialists you saw before your current one?

- No, my current specialist is the only one I contacted If NO → Q.16
- Yes, I saw |__|__| specialists before my current one If YES → Q.13

Q. 13. In the past, why did you change several physicians and center before arriving at your current one?

- I was not satisfied with the healthcare staff (physicians and/or nurses) of the previous center
- my current center / specialist is closer to the city where I live
- in the new center I can be treated with innovative therapies that were not available in the other center
- the previous physicians were finding it difficult / were taking too long to diagnose my condition
- the previous physicians were unable to find a suitable treatment for me
- another reason _____

Q. 14. For your Chronic Spontaneous Urticaria you are currently treated by ...

- Allergologist
- Dermatologist
- Another specialist _____

Q. 15. Who indicated or suggested that you should go to your current treating specialist / center?

- general practitioner (GP)
- another Dermatologist
- another Allergologist
- another specialist
- family member / friend / relative
- another person _____

Q.16 only if Q.4≠ no treatment & Q.4≠ omalizumab (Xolair)

Q. 16. Is the treatment you have been taking one that you take "as needed" (PRN) , i.e., only when the symptoms re-appear?

- yes
- no

If Q.16=YES (as-needed treatment)

Q.16.A) How long have you been taking this treatment?

- for less than 1 month
- for 1-2 months
- for 3-4 months
- for 5-6 months
- for 6-12 months (less than 1 year)
- for about 1-2 years
- for about 2-3 years
- for 4 years or longer
- I don't remember for how long

If Q.16=YES (as-needed treatment)

Q.16.B) On average, for how long do you take this treatment whenever the symptoms of the disease re-appear?

- for 1 day only
- for a few days
- for 1-2 weeks
- for 3-4 weeks / about 1 month
- for longer _____ specify _____

Q. 17. In the past, did you take other treatments to try and control the symptoms of urticaria?

- No, no other treatment in the past (neither topical, oral or by injection)
- Yes, other topical treatments in the past _____please specify _____
- Yes, other oral treatments in the past _____please specify _____
- Yes, other treatments by injection in the past _____please specify _____

Q. 18. Every how often do you see the specialist who is treating your urticaria, for check-ups and follow-up appointments?

- more than once a month
- about once a month
- about once every 2/3 months
- about once every 4/5 months (twice a year)
- about once a year
- less often / at less frequent intervals

Q. 19. Do you go to see your specialist only when a need arises (e.g., when symptoms re-appear or for problems with the treatment) or do you schedule your visits in advance?

- only as needed
- scheduled visits

Q. 20. How satisfied are you with the relationship you have with your current treating specialist?

- definitely satisfied
- satisfied
- neither satisfied not dissatisfied
- dissatisfied
- definitely dissatisfied

Q. 21. Would you like to have more time / more interaction with your doctor or, on the contrary, would you prefer these visits, these opportunities for interaction to be more sporadic and less frequent?

- Yes, I would like more time / more interaction with my doctor
- No, I would prefer these opportunities for interaction to be less frequent
- No, I am happy as it is / the time my doctor devotes to me is sufficient

Q. 22. Which information channels do you use to keep up to date / locate information about your condition? Who do you ask for information?

- internet sites devoted to urticaria → **Which ones?** _____ open _____
- internet sites in general → **Which ones?** _____ open _____
- online discussion forums
- meetings / conferences
- paper-based publications (magazines / brochures / flyers)
- patient associations → **Which ones?** _____ open _____
- trusted dermatologist / dermatology center where I am being treated
- nurse at the center where I am being treated
- other
- none / I don't look for information / I don't ask for information

Q. 23. Based on the diagnosis you have received from your doctor, what level of severity is the form of urticaria you are suffering from?

- mild
- moderate
- severe
- the doctor hasn't indicated a level of severity of the disease

Q. 24. How much does urticaria affect your life (personal and working life)? Rate its impact from 1 to 6, where 1 indicates that "the disease has no impact on my life" and 6 that "the disease has a considerable impact on my life".

Impact of the disease on your life 1 2 3 4 5 6

Q. 25. Which of these statements best reflects your thoughts about your Chronic Spontaneous Urticaria?

- it's a disease I am suffering the consequences of
- it's a condition I live with
- it's part of my life like other "things"
- it's a daily challenge

Q. 26. Compared to the past, for example to when you were not being treated yet or when you were taking a treatment that failed to provide the desired effects, how has your relationship and your attitude to the disease changed today?

Compared to the past now it is ...

- definitely worse worse more or less the same better definitely better

Q. 27. Financially, how burdensome / impacting are the costs you incur for your treatments, for the medicines you need to take, and for the assessments and tests you need to undergo periodically? Please answer by taking into consideration all of the expenses you incur to treat your urticaria, and giving a score from 1 to 6 where 1 indicates "no financial impact, as everything is reimbursed" and 6 indicates "very burdensome, the financial impact is high, as nothing is reimbursed and I have to pay for everything myself".

- 1 no financial impact / all expenses are reimbursed by the NHS
- 2

- 3
4
5
6

very burdensome, the financial impact is high, as nothing is reimbursed and I have to pay for everything myself

Q. 28. What does the NHS reimburse (so what don't you pay for) and what do you have to pay for out of your own pocket? For each item you can check both boxes if the item is in part paid for out of your own pocket and in part reimbursed.

| | Reimbursed by the NHS | Paid for out of your own pocket |
|---|--------------------------|---------------------------------|
| - medicines | <input type="checkbox"/> | <input type="checkbox"/> |
| - creams/ointments/lotions | <input type="checkbox"/> | <input type="checkbox"/> |
| - follow-up tests | <input type="checkbox"/> | <input type="checkbox"/> |
| - visits to your treating specialist / center | <input type="checkbox"/> | <input type="checkbox"/> |

Q. 29. If you were asked to indicate what is or has been the element or aspect of your condition that has most affected your life, what would come to mind?

_____ open _____

Q. 30. Now think about the ideal drug for the treatment of your urticaria. What characteristics do you consider important? Put them in order of importance, from the most important characteristic - i.e., the one you consider absolutely fundamental for a drug used for treating urticaria - to the one you consider least important. (choose at least three items)

The drug should have

- long-lasting effectiveness
- a fast action
- bearable / tolerable side effects
- a frequency of administration that does not negatively affect my quality of life
- a route of administration that does not negatively affect my quality of life

Q. 31. How willing would you be to follow a therapy based on once-monthly injections over a period of about 3-6 months? Answer by giving a rating from 1 to 10 where 1 indicates "I would definitely NOT follow an injection therapy" and 10 indicates "I would definitely follow an injection therapy".

1 2 3 4 5 6 7 8 9 10

Q. 32. Does your treating center offer specific services to support patients affected by Chronic Spontaneous Urticaria? If so, which ones?

NO

YES → Q.32.A **What are these services?** _____ open _____

Q. 33. Has your treating center ever given you paper-based material about your condition?

NO

YES → Q.33.A **What kind of material?**

- Patient diaries (e.g., questionnaire on quality of life / severity scale for itching / hives)
- Evolution of the disease and symptoms
- Advice on diet and lifestyle
- Therapies
- Route of administration
- Information brochures

Q. 34. What tests and assessments do you need to have regularly? To answer, think about all the tests you have to undergo in connection with your Chronic Spontaneous Urticaria.

_____ open _____

Q. 35. Now we ask you to rate the following aspects, on a scale from 1 to 10 where 1 indicates a "definitely negative rating reflecting total dissatisfaction" and 10 indicates a "a definitely positive rating reflecting total satisfaction".

| | |
|---|--|
| • Waiting times to book an appointment (test and/or consultation) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |
| • Waiting times between the booking and the appointment (test and/or consultation) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |
| • Waiting times in relation to the time of the appointment (for a test and/or consultation) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |
| • Waiting times for collection of reports | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |
| • Information received from the center's healthcare personnel | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |
| • General level of services of your treating center | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |
| • Convenient location/easy access to your treating center from your home | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |
| • Number of doctors / nurses working in your treating clinic / center | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 |

Q. 36. In general, do you encounter or have you encountered any difficulties when, for example, you need to book tests or consultations? If so, could you please indicate what difficulties or issues you have encountered?

_____ open _____

Q. 37. How inconvenient do you find it to go to your treating center for periodic examinations or tests? To answer, take into consideration the journey between your home and the center, the time it takes to do the tests, the frequency with which you have to do them, etc. Please answer by giving a rating from 1 to 10 where 1 indicates "I don't find it at all inconvenient" and 10 indicates "I find it highly inconvenient".

1 2 3 4 5 6 7 8 9 10

Q. 38. Do you have any ideas or suggestions or can you think of any particular service that could be put in place by your treating center or a pharmaceutical company to make this aspect easier?

_____ open _____

Q. 39. If a special home-care service were available for patients affected by Chronic Spontaneous Urticaria - for example, to help you find the medicines required for treatment or provide support during injection of the medicine in the event that you require an injection therapy, how useful would you rate this service? Please answer by rating it from 1 to 10 where 1 indicates "absolutely useless" and 10 indicates "definitely useful".

1 2 3 4 5 6 7 8 9 10

Q. 40. The very last question. Is there some service, activity, special aspect that you believe could be of help and support for a person who, like you, is affected by Chronic Spontaneous Urticaria? To answer, think of all the services and forms of support you have benefitted from or, on the contrary, to all the things you need now and aren't being given or would have needed in the past but were not given. _____ open _____

We have reached the end of the interview. Complete the grid below with your socio-demographic profile.

Q. 41. You are ... a man a woman

Q. 42. How old are you? |__|__|

Q. 43. What's the composition of your family?

- I live alone
- I live with my family of origin (parents)
- I live with my partner without children
- I live with my partner and have children
- I live alone with my children

Q. 44. What's your occupation?

