

## SEVERITY SCALE

This section of the questionnaire relates to questions about your seizures and how they affect you physically, mentally and socially.

Some of the questions in this section will refer to your auras/warnings. An aura/warning is a feeling that you usually experience e.g. tummy pain or fuzzy head, which can occur on its own or suggests that an attack is likely to follow.

PLEASE ANSWER THE FOLLOWING QUESTIONS WITH REFERENCE TO HOW YOU HAVE BEEN OVER THE LAST FOUR WEEKS.

Please tick the appropriate box

1. My attacks are
  - a) always at a particular time of the day or night [ ]
  - b) mostly at one particular time of the day or night [ ]
  - c) sometimes at one particular time of the day or night [ ]
  - d) my attacks can occur at any time of the day [ ]
  
2. Over the last four weeks when my attacks have happened
  - a) I have always been able to predict when I will have seizures [ ]
  - b) I have usually been able to predict when I will have seizures [ ]
  - c) I have occasionally been able to predict when I will have seizures [ ]
  - d) I have not been able to predict when I will have seizures [ ]
  
3. Over the past four weeks
  - a) I have always been able to fight off my attacks [ ]
  - b) I have usually been able to fight off my attacks [ ]
  - c) I have sometimes fought off my attacks [ ]
  - d) I have not been able to fight off my attacks [ ]

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Please tick the appropriate box

4. Over the last four weeks
- a) I have had an aura or warning with all my attacks [ ]
  - b) I have usually had an aura or warning with my attacks [ ]
  - c) I sometimes have had an aura or warning with my attacks [ ]
  - d) I have not had an aura or warning with my attacks [ ]
5. How much control do you feel you have over your attacks
- a) Very good control [ ]
  - b) Moderate control [ ]
  - c) Little control [ ]
  - d) No control at all [ ]
6. Over the last four weeks when I have had my attacks
- a) they have all occurred in clusters with quite long periods between attacks [ ]
  - b) they have mostly occurred in clusters with quite long periods between some attacks [ ]
  - c) they have sometimes occurred in clusters [ ]
  - d) they have not occurred in clusters [ ]
7. My attacks are
- a) always when I am asleep [ ]
  - b) mostly when I am asleep [ ]
  - c) sometimes when I am asleep [ ]
  - d) never when I am asleep [ ]

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Please tick the appropriate box

8. My attacks

- a) stop me doing all of the things I want to do
- b) stop me doing a lot of the things I want to do
- c) stop me doing a few of things I want to do
- d) don't stop me doing anything I want to do at all

9. Most commonly when I have blanked out over the last four weeks

- a) I blank out for less than 1 minute
- b) I blank out between 1 - 2 minutes
- c) I blank out between 2 - 5 minutes
- d) I blank out for more than 5 minutes

10. Over the last four weeks when I have recovered from my attacks

- a) I felt very confused
- b) I felt moderately confused
- c) I felt slightly confused
- d) I haven't felt confused at all

11. In the last four weeks when I have recovered from my attacks my confusion lasts for

- a) less than 1 minute
- b) between 1 - 5 minutes
- c) between 6 minutes - 1 hour
- d) over 1 hour

12. When I have recovered from my attacks over the last four weeks

- a) I have always had a headache
- b) I have usually had a headache
- c) I have sometimes had a headache
- d) I have not had a headache

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13. When I have recovered from my attacks over the last four weeks
- a) I have always felt sleepy [ ]
  - b) I have usually felt sleepy [ ]
  - c) I have sometimes felt sleepy [ ]
  - d) I haven't felt sleepy [ ]
14. When I have recovered from my attacks over the last four weeks
- a) I have always found that I have wet myself [ ]
  - b) I have usually found that I have wet myself [ ]
  - c) I have sometimes found that I have wet myself [ ]
  - d) I have not wet myself [ ]
15. When I have recovered from my attacks over the last four weeks
- a) I have always found that I have bitten my tongue [ ]
  - b) I have usually found I have bitten my tongue [ ]
  - c) I have sometimes found that I have bitten my tongue [ ]
  - d) I have not bitten my tongue [ ]
16. When I have recovered from my attacks over the past four weeks (other than biting my tongue)
- a) I have always found that I have injured myself [ ]
  - b) I more often than not have found that I have injured myself [ ]
  - c) I have sometimes found that I have injured myself [ ]
  - d) I have not injured myself [ ]

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Please tick the appropriate box

17. In the past four weeks when I have had my attacks I can usually return to what I was doing

- a) in less than 1 minute
- b) between 1 - 5 minutes
- c) between 6 minutes - 1 hour
- d) over 1 hour

18. Over the last four weeks my attacks have been mostly

- a) very severe
- b) moderately severe
- c) mild
- d) very mild

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ACTIVITIES OF DAILY LIVING

1. Here is a list of things which people do in their spare time. We are interested in how your epilepsy may affect your daily activities.

Please tick the box (only one) which most applies to your situation.

A lot = 6 - 7 days or times  
 A fair amount = 3 - 5 days or times  
 A little = 1 or 2 days or times  
 None = 0

In the last week on how many days have you engaged in:-

	DAYS			
	6-7	3-5	1-2	0
a) Doing the washing up	[ ]	[ ]	[ ]	[ ]
b) Listening to the radio	[ ]	[ ]	[ ]	[ ]
c) Going out for a walk, drive etc.	[ ]	[ ]	[ ]	[ ]
d) Working on the house	[ ]	[ ]	[ ]	[ ]
e) Going to a meeting, church etc.	[ ]	[ ]	[ ]	[ ]
f) Going to the pub, club, dancing etc.	[ ]	[ ]	[ ]	[ ]
g) Washing clothes, sheets etc.	[ ]	[ ]	[ ]	[ ]
h) Watching TV	[ ]	[ ]	[ ]	[ ]
i) Reading	[ ]	[ ]	[ ]	[ ]
j) Just lying or relaxing for longer than half an hour	[ ]	[ ]	[ ]	[ ]
k) Visiting a friend or relatives at their home	[ ]	[ ]	[ ]	[ ]
l) Playing records	[ ]	[ ]	[ ]	[ ]
m) Entertaining friends or relatives at your home	[ ]	[ ]	[ ]	[ ]
n) Looking after children/relatives	[ ]	[ ]	[ ]	[ ]
o) Doing some household shopping	[ ]	[ ]	[ ]	[ ]
p) Cooking	[ ]	[ ]	[ ]	[ ]
q) Spending time on a hobby or pastime	[ ]	[ ]	[ ]	[ ]
r) Tidying the house	[ ]	[ ]	[ ]	[ ]
s) Going out with friends or relatives	[ ]	[ ]	[ ]	[ ]

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SUMMARY QUESTIONS WHERE INDICATED

These questions should be completed at the end of each of the treatment programmes

Please tick the appropriate box

1. Over the last ... months
- a) I feel I can do much more than previously
  - b) I feel I can do a few more things than previously
  - c) I feel nothing has changed
  - d) I feel I can do less things than previously

2. Over the last ... months
- a) my attacks have been much less severe
  - b) my attacks have been less severe
  - c) my attacks remained unchanged
  - d) my attacks have been more severe
  - e) my attacks have been far more severe

3. Do you feel that the treatment you have received over the last ... months
- a) has resulted in a considerable improvement
  - b) has resulted in a slight improvement
  - c) has made no change
  - d) has made me worse
  - e) has made me much worse

4. I think that the additional treatment in last ... month was
- a) an active drug
  - b) was a dummy tablet
  - c) I don't know

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Please tick the appropriate box

5. In terms of the treatment which you have received recently

- a) I would like to continue with this particular additional treatment [ ]
- b) I am indifferent to whether I continue or not on this particular additional treatment [ ]
- c) I would not wish to continue with this particular additional treatment [ ]

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SOCIAL QUESTIONNAIRE

This section relates to questions about your personal, social and financial circumstances.

Please tick the appropriate box

1. Housing (Everyone answer)

- |  |           |                       |                       |                     |
|--|-----------|-----------------------|-----------------------|---------------------|
| a) Are your housing conditions adequate for you and your family's needs? | Adequate  | Slightly inadequate   | Markedly inadequate   | Severe inadequate   |
|  | [ ]       | [ ]                   | [ ]                   | [ ]                 |
| b) How satisfied are you with your present accommodation?                | Satisfied | Slightly dissatisfied | Markedly dissatisfied | Severe dissatisfied |
|  | [ ]       | [ ]                   | [ ]                   | [ ]                 |

2. Work

FOR ALL MEN AND WOMEN WORKING OUTSIDE THE HOME

Tick box if not applicable

- |   |             |                       |                       |                     |
|---|-------------|-----------------------|-----------------------|---------------------|
| a) How satisfied are you with your present job?                         | Satisfied   | Slightly dissatisfied | Markedly dissatisfied | Severe dissatisfied |
|   | [ ]         | [ ]                   | [ ]                   | [ ]                 |
| b) Do you have problems getting on with any of the people at your work? | No problems | Slight problems       | Marked problems       | Severe problems     |
|   | [ ]         | [ ]                   | [ ]                   | [ ]                 |

FOR HOUSEWIVES WITH NO OUTSIDE WORK

Tick box if not applicable

- |  |           |                       |                       |                     |
|--|-----------|-----------------------|-----------------------|---------------------|
| c) How satisfied are you with being a housewife? | Satisfied | Slightly dissatisfied | Markedly dissatisfied | Severe dissatisfied |
|  | [ ]       | [ ]                   | [ ]                   | [ ]                 |

FOR HOUSEWIVES WITH A FULL OR PART-TIME JOB OUTSIDE THE HOME

Tick box if not applicable

- |   |           |                       |                       |                     |
|---|-----------|-----------------------|-----------------------|---------------------|
| d) How satisfied are you with working and running a home? | Satisfied | Slightly dissatisfied | Markedly dissatisfied | Severe dissatisfied |
|   | [ ]       | [ ]                   | [ ]                   | [ ]                 |

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FOR THOSE WHO ARE NOT WORKING (RETIRED, UNEMPLOYED OR OFF SICK)

Tick box if not applicable [ ]

e) How satisfied are you with this situation?	Satisfied	Slightly dissatisfied	Markedly dissatisfied	Severely dissatisfied
	[ ]	[ ]	[ ]	[ ]

Please tick the appropriate box

3. Financial circumstances (Everyone answer)

a) Is the money coming in adequate for you and your family's needs?	Adequate	Slightly inadequate	Markedly inadequate	Severely inadequate
	[ ]	[ ]	[ ]	[ ]
b) Do you have any difficulties in meeting bills and other financial commitments?	No difficulties	Slight difficulties	Marked difficulties	Severe difficulties
	[ ]	[ ]	[ ]	[ ]
c) How satisfied are you with your position?	Satisfied	Slightly dissatisfied	Markedly dissatisfied	Severely dissatisfied
	[ ]	[ ]	[ ]	[ ]

4. Social contacts (Everyone answer)

Please tick the appropriate box

a) How satisfied are you with the amount of time you are able to go out?	Satisfied	Slightly dissatisfied	Markedly dissatisfied	Severely dissatisfied
	[ ]	[ ]	[ ]	[ ]
b) Do you have any problems with your neighbours?	No problems	Slight problems	Marked problems	Severe problems
	[ ]	[ ]	[ ]	[ ]
c) Do you have any problems getting on with any of your friends?	No problems	Slight problems	Marked problems	Severe problems
	[ ]	[ ]	[ ]	[ ]
d) How satisfied are you with amount of time you see your friends?	Satisfied	Slightly dissatisfied	Markedly dissatisfied	Severely dissatisfied
	[ ]	[ ]	[ ]	[ ]

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Please tick the appropriate box

e) Do you have any problems getting on with any close relative? (include parents, in-laws or grown-up children)	No problems [ ]	Slight problems [ ]	Marked problems [ ]	Severe problems [ ]
--	--------------------	------------------------	------------------------	------------------------

f) How satisfied are you with the amount of time you see your relatives?	Satisfied [ ]	Slightly dissatisfied [ ]	Markedly dissatisfied [ ]	Severely dissatisfied [ ]
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5. Marriage and boyfriends/girlfriends

a) What is your marital status?	Single [ ]	Married/ cohabitating [ ]	Widowed [ ]	Separated [ ]	Divorced [ ]
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FOR ALL THOSE WHO ARE MARRIED OR HAVE A STEADY RELATIONSHIP

Tick box if not applicable [ ]

b) Do you have difficulty confiding in your partner?	No difficulty [ ]	Slight difficulty [ ]	Marked difficulty [ ]	Severe difficulty [ ]
--	----------------------	--------------------------	--------------------------	--------------------------

c) Are there any sexual problems in your relationship?	No problems [ ]	Slight problems [ ]	Marked problems [ ]	Severe problems [ ]
--	--------------------	------------------------	------------------------	------------------------

d) Do you have any other problems getting on together?	No problems [ ]	Slight problems [ ]	Marked problems [ ]	Severe problems [ ]
--	--------------------	------------------------	------------------------	------------------------

e) How satisfied in general are you with your relationship?	Satisfied [ ]	Slightly dissatisfied [ ]	Markedly dissatisfied [ ]	Severely dissatisfied [ ]
---	------------------	------------------------------	------------------------------	------------------------------

f) Have you recently been so dissatisfied you have considered separating from your partner?	No [ ]	Sometimes [ ]	Often [ ]	Yes, planned or recent separation [ ]
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FOR ALL THOSE WHO ARE NOT MARRIED / DO NOT HAVE A STEADY RELATIONSHIP

Tick box if not applicable

g) How satisfied are you with this situation?	Satisfied	Slightly dissatisfied	Markedly dissatisfied	Severely dissatisfied
	[ ]	[ ]	[ ]	[ ]

6. Domestic life

FOR THOSE WITH CHILDREN UNDER 18

Tick box if not applicable [ ]

a) Do you have any difficulties with your children?	No difficulties	Slight difficulties	Marked difficulties	Severely difficult
	[ ]	[ ]	[ ]	[ ]
b) How satisfied do you feel with your relationship with the children?	Satisfied	Slightly dissatisfied	Markedly dissatisfied	Severely dissatisfied
	[ ]	[ ]	[ ]	[ ]

FOR THOSE WITH CHILDREN OF SCHOOL AGE

Tick box if not applicable [ ]

c) Are there any problems involving children at school?	No problems	Slight problems	Marked problems	Severe problem
	[ ]	[ ]	[ ]	[ ]

FOR ALL THOSE WITH OTHER ADULTS LIVING WITH THEM (INCLUDING RELATIVES BUT EXCLUDING SPOUSE)

Tick box if not applicable [ ]

d) Do not have any problems about sharing household tasks?	No problems	Slight problems	Marked problems	Severe problem
	[ ]	[ ]	[ ]	[ ]
e) Do you have any difficulties with the other adults in your household?	No difficulties	Slight difficulties	Marked difficulties	Severely difficult
	[ ]	[ ]	[ ]	[ ]
f) How satisfied are you with this arrangement?	Satisfied	Slightly dissatisfied	Markedly dissatisfied	Severely dissatisfied
	[ ]	[ ]	[ ]	[ ]

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7. Legal matters (Everyone answer)

Please tick the appropriate box

a) Do you have any legal problems (custody, maintenance, compensation etc.)?	No problems [ ]	Slight problems [ ]	Marked problems [ ]	Severe problem [ ]
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8. For those who are living alone

Tick box if not applicable

a) Do you have any difficulties living and managing on your own?	No difficulties [ ]	Slight difficulties [ ]	Marked difficulties [ ]	Severe difficulties [ ]
b) How satisfied are you with living on your own?	Satisfied [ ]	Slightly dissatisfied [ ]	Markedly dissatisfied [ ]	Severely dissatisfied [ ]

9. Other (Everyone answer)

Please tick the appropriate box

a) Do you have any other social problems or problems?	No problems [ ]	Slight problems [ ]	Marked problems [ ]	Severe problems [ ]
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If so, please specify.....

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10. Have you noticed any improvements in your family or social circumstances over the last ... months

Please tick the appropriate box

No improvement	Slight improvement	Marked improvement	Substanti improve
[ ]	[ ]	[ ]	[ ]

If so, please specify .....

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EMPLOYMENT

11. Does your epilepsy affect your work in any way at present?  
Does it affect ...

	YES	NO
the type of work you can do	[ ]	[ ]
the amount of work you can do	[ ]	[ ]
the sort of conditions you can work in your attendance at work	[ ]	[ ]
anything else	[ ]	[ ]

If so please specify .....

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Please tick the appropriate box

12. Have there been any occasions since you entered the study, when you did not get a job you applied for?

YES	NO
[ ]	[ ]

a) What happened?

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b) Do you think this might have been because of your epilepsy?

YES	NO	UNCERTAIN
[ ]	[ ]	[ ]

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13. Do you think your epilepsy makes it more difficult for you than for other people to find a job?

YES	NO
[ ]	[ ]

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a) Why do you think that?

DRIVING

Please tick the appropriate box

14. How important is it for you to be able to drive?  
Would you say it is ...

very important [ ]

fairly important [ ]

or not very important [ ]

15. How much does it bother you that you cannot drive  
because of your epilepsy? Would you say ...

a lot [ ]

some [ ]

just a little [ ]

or not at all [ ]

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HEALTH PROFILE

This section of the questionnaire is concerned with how you feel both physically and emotionally.

Listed below are some problems people may have in their daily life. Look down the list and put a tick in the box under YES for any problem you have at the moment.

Tick the box under NO for any problem you do not have.

PLEASE ANSWER EVERY QUESTION. If you are not sure whether to say YES or NO, tick whichever answer you think is more true at the moment.

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	YES	NO		YES	NO
I'm tired all the time	[ ]	[ ]	I lie awake for most of the night	[ ]	[ ]
I have pain at night	[ ]	[ ]	I feel as if I'm losing sleep	[ ]	[ ]
Things are getting me down	[ ]	[ ]	I'm in pain when I'm standing	[ ]	[ ]
I have unbearable pain	[ ]	[ ]	I find it hard to dress myself	[ ]	[ ]
I take tablets to help me sleep	[ ]	[ ]	I soon run out of energy	[ ]	[ ]
I've forgotten what it's like to enjoy myself	[ ]	[ ]	I find it hard to stand for long	[ ]	[ ]
I'm feeling on edge	[ ]	[ ]	I'm in constant pain	[ ]	[ ]
I find it painful to change my position	[ ]	[ ]	It takes me a long time to get to sleep	[ ]	[ ]
I feel lonely	[ ]	[ ]	I feel I am a burden to people	[ ]	[ ]
I can only walk about indoors	[ ]	[ ]	Worry is keeping me awake	[ ]	[ ]
I find it hard to bend	[ ]	[ ]	I feel that life is not worth living	[ ]	[ ]
Everything is an effort	[ ]	[ ]			
I'm waking up in the early hours of the morning	[ ]	[ ]			

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Please tick the appropriate box

	YES	NO		YES	NO
I'm unable to walk at all	[ ]	[ ]	I sleep badly at night	[ ]	[ ]
I'm finding it hard to make contact with people	[ ]	[ ]	I'm finding it hard to get on with people	[ ]	[ ]
The days seem to drag	[ ]	[ ]	I need help to walk about outside	[ ]	[ ]
I have trouble getting up and down stairs or steps	[ ]	[ ]	I'm in pain when going up or down stairs or steps	[ ]	[ ]
I find it hard to reach for things	[ ]	[ ]	I wake up feeling depressed	[ ]	[ ]
I'm in pain when I walk	[ ]	[ ]	I'm in pain when I'm sitting	[ ]	[ ]
I lose my temper easily these days	[ ]	[ ]			
I feel there is nobody I am close to	[ ]	[ ]			

Now we would like you to think about the activities in your life which may be affected by health problems. In the list below, tick YES for each activity in your life which is being affected by your state of health. Tick NO for each activity which is not being affected, or which does not apply to you.

Is your present state of health causing problems with your .....

	YES	NO		YES	NO
Job of work (That is, paid employment)	[ ]	[ ]	Sex life	[ ]	[ ]
Looking after the home (eg. cleaning and cooking)	[ ]	[ ]	Interests and hobbies	[ ]	[ ]
Social life (eg. going out, seeing friends)	[ ]	[ ]	Holidays	[ ]	[ ]
Home life (eg. relationships with other people in your home)	[ ]	[ ]			

H.A.D. SCALE

Read each item and place a firm tick in the box opposite the reply which comes close to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. Consider the following questions .....

Please tick the appropriate box

1. I feel tense or 'wound up':
  - a) most of the time
  - b) a lot of the time
  - c) time to time, occasionally
  - d) not at all
  
2. I still enjoy the things I used to enjoy:
  - a) definitely as much
  - b) not quite so much
  - c) only a little
  - d) hardly at all
  
3. I get a sort of frightened feeling as if something awful is about to happen:
  - a) very definitely and quite badly
  - b) yes, but not too badly
  - c) a little, but it doesn't worry me
  - d) not at all
  
4. I can laugh and see the funny side of things:
  - a) as much as I always could
  - b) not quite so much now
  - c) definitely not so much now
  - d) not at all

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Please tick the appropriate box

5. Worrying thoughts go through my mind
- a) a great deal of the time
  - b) a lot of the time
  - c) from time to time but not too often
  - d) only occasionally

6. I feel cheerful:
- a) not at all
  - b) not often
  - c) sometimes
  - d) most of the time

7. I can sit at ease and feel relaxed:
- a) definitely
  - b) usually
  - c) not often
  - d) not at all

8. I feel as if I am slowed down:
- a) nearly all the time
  - b) very often
  - c) sometimes
  - d) not at all

9. I get a sort of frightened feeling like 'butterflies'  
in the stomach:
- a) not at all
  - b) occasionally
  - c) quite often
  - d) very often

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Please tick the appropriate box

10. I have lost interest in my appearance:
- a) definitely
  - b) I don't take so much care as I should
  - c) I take just as much care
  - d) I take more care than I have previously

11. I feel restless as if I have to be on the move:
- a) very much indeed
  - b) quite a lot
  - c) not very much
  - d) not at all

12. I look forward with enjoyment to things:
- a) as much as I ever did
  - b) rather less than I used to
  - c) hardly at all
  - d) not at all

13. I get sudden feeling of panic:
- a) very often indeed
  - b) quite often
  - c) not very often
  - d) not at all

14. I can enjoy a good book or radio or TV programme:
- a) often
  - b) sometimes
  - c) not often
  - d) very seldom

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SELF ESTEEM SCALE

The statements below describe how people sometimes feel about themselves. Thinking about yourself, do you strongly agree, agree, disagree or strongly disagree with the statements?

Please tick the appropriate box

	Strongly agree	Agree	Disagree	Strongly disagree
a) I feel that I'm a person of worth, at least on an equal basis with others	[ ]	[ ]	[ ]	[ ]
b) I feel that I have a number of good qualities	[ ]	[ ]	[ ]	[ ]
c) All in all, I am inclined to feel that I am a failure	[ ]	[ ]	[ ]	[ ]
d) I am able to do things as well as other people	[ ]	[ ]	[ ]	[ ]
e) I feel I do not have much to be proud of	[ ]	[ ]	[ ]	[ ]
f) I take a positive attitude towards myself	[ ]	[ ]	[ ]	[ ]
g) On the whole, I am satisfied with myself	[ ]	[ ]	[ ]	[ ]
h) I wish I could have more respect for myself	[ ]	[ ]	[ ]	[ ]
i) I certainly feel useless at times	[ ]	[ ]	[ ]	[ ]
j) At times I think I am no good at all	[ ]	[ ]	[ ]	[ ]

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MASTERY SCALE

The next set of statements describe how people sometimes feel about their lives. Thinking about your own life, over the last few weeks, do you strongly agree, agree, disagree, strongly disagree with the statements?

Please tick the appropriate box

	Strongly agree	Agree	Disagree	Strongly Disagree
a) There is really no way I can solve some of the problems I have	[ ]	[ ]	[ ]	[ ]
b) Sometimes I feel that I'm being pushed around in life	[ ]	[ ]	[ ]	[ ]
c) I have little control over things that happen to me	[ ]	[ ]	[ ]	[ ]
d) I can do almost anything I set my mind to	[ ]	[ ]	[ ]	[ ]
e) I often feel helpless in dealing with the problems of life	[ ]	[ ]	[ ]	[ ]
f) What happens to me in the future mostly depends on me	[ ]	[ ]	[ ]	[ ]
g) There is little I can do to change many of the important things in my life	[ ]	[ ]	[ ]	[ ]

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HAPPINESS SCALE

During the past few weeks, did you ever feel .....

Please tick the appropriate box

	YES	NO
a) Particularly excited or interested in something	[ ]	[ ]
b) Bored	[ ]	[ ]
c) Pleased about having accomplished something	[ ]	[ ]
d) So restless that you couldn't sit long in a chair	[ ]	[ ]
e) That things were going your way	[ ]	[ ]
f) Depressed or very unhappy	[ ]	[ ]
g) Proud because someone complemented you on something you had done	[ ]	[ ]
h) Very lonely or remote from other people	[ ]	[ ]
i) On top of the world	[ ]	[ ]
j) Upset because someone criticised you	[ ]	[ ]

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MOOD PROFILE

Below is a list of words that describe feelings people have. Please read each one carefully, then circle the one number to the right of the word to indicate the answer which best describes the extent to which you have had this feeling during the past week.

The numbers refer to these phrases

0	Not at all
1	A little
2	Moderately
3	Quite a lot
4	Extremely

For example ANXIOUS 0 1 [2] 3 4 would indicate that you have been feeling anxious, to a moderate extent, during the past week.

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		Extremely Quite a lot   Moderately     A little       Not at all			Extremely Quite a lot   Moderately     A little       Not at all
(1)	Tense	0 1 2 3 4	(19)	Resentful	0 1 2 3 4
(2)	Angry	0 1 2 3 4	(20)	Nervous	0 1 2 3 4
(3)	Worn out	0 1 2 3 4	(21)	Lonely	0 1 2 3 4
(4)	Lively	0 1 2 3 4	(22)	Muddled	0 1 2 3 4
(5)	Confused	0 1 2 3 4	(23)	Cheerful	0 1 2 3 4
(6)	Shakey	0 1 2 3 4	(24)	Exhausted	0 1 2 3 4
(7)	Peeved	0 1 2 3 4	(25)	Gloomy	0 1 2 3 4
(8)	Sad	0 1 2 3 4	(26)	Sluggish	0 1 2 3 4
(9)	Active	0 1 2 3 4	(27)	Rebellious	0 1 2 3 4
(10)	On edge	0 1 2 3 4	(28)	Weary	0 1 2 3 4
(11)	Energetic	0 1 2 3 4	(29)	Bewildered	0 1 2 3 4
(12)	Hopeless	0 1 2 3 4	(30)	Alert	0 1 2 3 4
(13)	Relaxed	0 1 2 3 4	(31)	Efficient	0 1 2 3 4
(14)	Unworthy	0 1 2 3 4	(32)	Bad tempered	0 1 2 3 4
(15)	Uneasy	0 1 2 3 4	(33)	Forgetful	0 1 2 3 4
(16)	Guilty	0 1 2 3 4	(34)	Unable to concentrate	0 1 2 3 4
(17)	Fatigued	0 1 2 3 4	(35)	Vigorous	0 1 2 3 4
(18)	Annoyed	0 1 2 3 4	(36)	Shattered	0 1 2 3 4

THE END

CARERS SEVERITY QUESTIONNAIRE

This section of the questionnaire should be completed by a named relative or friend of the patient. It is important that the same named person complete the carers section on each occasion. Could you please answer the questions in terms of how your relative has been over the last four weeks.

Please tick the appropriate box

1. It is impossible to get a sensible response from your relative/friend during
  - a) all of their attacks
  - b) most of their attacks
  - c) some of their attacks
  - d) none of their attacks
  
2. When your relative/friend blanks out it is
  - a) for less than 1 minute
  - b) between 1 - 2 minutes
  - c) between 2 - 5 minutes
  - d) more than 5 minutes
  
3. Does your relative/friend smack their lips, fidgets or behave in an unusual way
  - a) during all of their attacks
  - b) during most of their attacks
  - c) during some of their attacks
  - d) during none of the attacks
  
4. Is your relative/friend confused after
  - a) all of the attacks
  - b) most of the attacks
  - c) some of the attacks
  - d) none of the attacks

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Please tick the appropriate box

5. Is your relative/friend very confused and a danger to themselves or others during or after their attacks
- a) all the time
  - b) most of the time
  - c) some of the time
  - d) none of the time
6. Is your relative/friend confused during and after their attacks
- a) for less than 1 minute
  - b) between 1 - 5 minutes
  - c) between 6 minutes - 1 hour
  - d) more than 1 hour
7. How satisfied is your relative/friend with the control they have over their attacks
- a) Extremely satisfied
  - b) Very satisfied
  - c) Moderately satisfied
  - d) Not satisfied at all
8. Over the last four weeks how would you rate your relative/friends attacks
- a) Very severe
  - b) Moderately severe
  - c) Mild
  - d) Very mild

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**APPENDIX A11**

**SCALES USED IN MOOD AND QUALITY OF LIFE QUESTIONNAIRE**

## SCALES USED IN MOOD AND QUALITY OF LIFE QUESTIONNAIRE

The rationale for development of a patient-based, health-related quality of life measure for use in epilepsy is only briefly summarised here. Further information will be available separately (Baker et al, in preparation).

Scales were selected to measure variables which are common consequences of intractable epilepsy.

Part of the questionnaire required information on seizure frequency, seizure severity (discussed above) and a general health assessment using the Nottingham Health Profile (Hunt et al 1980).

Patients with epilepsy may be socially disadvantaged. To look at patient satisfaction with a range of pertinent social issues the Social Problems Questionnaire was used (Corney and Claire 1985).

To monitor any disturbance of mood occurring as a consequence of refractory seizures two scales were used. The Hospital Anxiety and Depression Scale (HAD) (Zigmond and Snaith 1983) measures negative aspects of mood, and the Affect Balance Scale (Bradburn 1969) considers positive aspects of mental health. These were supplemented by the Profile of Moods States (McNair et al 1987); this addresses a range of emotional states not detectable by the HAD or Affect Balance Scales.

Self-esteem was assessed using the Rosenberg Self-Esteem Scale (Rosenberg 1965) and Mastery by the scale of Pearlin and Schooler (1978).

All the above scales have previously been used in patients with epilepsy of varying severity. Although the scales were not specifically developed for use in patients with epilepsy there was an acceptable level of internal consistency and validity in this patient population (Baker et al, in preparation).

The simple Likert scoring systems used for each scale are shown in the table below. The exception was the scoring using for the Nottingham Health Profile.

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SCALES USED IN MOOD AND QUALITY OF LIFE QUESTIONNAIRE

SCALE	AUTHORS	FORMAT	RANGE OF SCORES	INTERPRETATION
NOTTINGHAM HEALTH PROFILE	Hunt et al (1980)	38 statements: YES/NO Covering 6 domains (sleep, energy, emotional reaction, social isolation, physical mobility, pain)	1 for a positive response in each domain	Higher scores indicate greater perceived dysfunction
SOCIAL PROBLEMS QUESTIONNAIRE	Corney & Clare (1985)	33 statements: not at all to severely dissatisfied Covering 8 domains (housing, occupation, finance, leisure, leisure, friendship, relationship with parents, legal)	0-2 for each item in each domain	Higher scores indicate greater dissatisfaction
HOSPITAL ANXIETY & DEPRESSION	Zigmond & Snaith(1983)	7 statements in each subscale. Mild to severe, Never to always	0-21	Cases (>10), borderline cases (8-10), non-cases (<8)
AFFECT BALANCE	Bradburn (1969)	10 statements: YES (+1), NO (-1)	-10 to 10	High scores = high level of well-being
PROFILE OF MOOD STATES	McNair et al (1981)	36 statements Not at all to extremely. Covering 6 domains (tension, depression, anger, vigour, fatigue, confusion) Subtract vigour score from sum of the other scores.	-24 to 120	Higher scores indicate greater disturbance of mood
SELF-ESTEEM	Rosenberg (1965)	10 statements: Strongly agree to strongly disagree	10-40	High scores = high levels of self-esteem
MASTERY	Pearlin & Schooler (1978)	7 statements: Strongly agree to strongly disagree	7-28	High scores = high levels of mastery

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**Review and Evaluation of Clinical Data  
NDA 20-764**

**Sponsor:** Glaxo  
**Drug:** Lamictal Chewable Dispersible Tablets  
**Proposed Indication:** Lennox-Gastaut Syndrome  
**Material Submitted:** Response to Approvable Letter  
**Correspondence Date:** February 23, 1998  
**Date Received:** February 24, 1998

**Background:** An Approvable Letter was sent on December 3, 1997. That letter requested a safety update which the sponsor has provided. The total safety database encompassed by this NDA and the first safety update included 399 patients (cutoff date August 31, 1996). This second safety update expands that safety database to include a total of 1091 patients under the age of 16 years of age (308 in controlled trials, 783 in uncontrolled trials). The current cutoff date is October 31, 1997.

Because of our concern about the serious rashes reported in the original cohort of 399, the sponsor performed an extensive focused safety review of rash in pediatric populations. That review was presented in submissions dated July 22 and October 21, 1997. That review encompassed 1071 patients under the age of 16 years of age, effectively the same total as the safety database in the current safety update. Therefore, the sections of labeling dealing with risk of rash in pediatric populations will not be affected by the current safety update.

**Deaths:** There were no additional deaths in the *expanded safety database*. There were 6 deaths reviewed in the NDA safety review.

Between September 1, 1996 and October 31, 1997 there were 4 deaths reported from *Non-US Compassionate Plea/Local Operating Company Trials* (not included in the safety database of 1091 patients). Three were sudden unexplained deaths and 1 was a case of multiorgan failure in the setting of status epilepticus. There were 12 deaths in *Compassionate Plea/Local Operating Company Trials* reported in the original NDA.

Between September 1, 1996 and October 31, 1997 there were 9 pediatric deaths reported from *Post-Marketing Experience* according to the sponsor; I count 12 newly reported deaths in Appendix D (including 1 stillbirth and

1 death in a neonate born to a mother who used Lamictal) which would bring the total number of post-marketing reports of death to 25.

Of the 12 new reports, 2 patients were found dead and 1 patient died due to cardiac arrest during a seizure. One patient died of complications of TEN, 1 with complications of sepsis (having presented with rash and fever, followed by seizures and status epilepticus), and 1 with complications from varicella. One patient died with severe dehydration from vomiting, 1 patient died from aspiration pneumonia, and 1 patient died of an unrelated respiratory problem. One death occurred without further explanation 2 months after Lamictal was stopped. Additionally, where mothers were exposed to Lamictal during pregnancy, there was 1 stillbirth and 1 death in a neonate with congenital heart problems.

Of the 25 post-marketing reports of deaths in pediatric populations, 3 are directly or indirectly related to SJS/TEN. The ages of these patients were 8 years, 12 years, and 14 years. Only one of the 3 patients was on concomitant VPA.

**Serious AEs:** Sponsor's Table 5.39 provides the incidence of serious/life-threatening treatment emergent AEs on Lamictal in all pediatric studies. Of the 1091 pediatric patients, 113 patients (10.4%) experienced serious or life-threatening AEs.

**Incidence of AEs Leading to Discontinuation of Lamictal in All Pediatric Studies:** Sponsor's Table 5.44 summarizes the incidence of AEs leading to discontinuation of Lamictal in all pediatric studies. Of the 1091 pediatric patients, 103 (9.4%) patients discontinued due to AEs. Rash, maculo-papular rash, erythema multiforme, and SJS combined led to discontinuation in 52 (4.8%) of patients treated.

**All AEs:** Sponsor's Table 5.29 lists the incidence of treatment emergent AEs in all pediatric studies where such data was collected.

**Conclusions:** The safety profile of Lamictal has not changed appreciably with the new information provided above.

**/S/**

John Feeney, M.D.  
Medical Officer  
May 22, 1998

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cc:  
HFD-120  
NDA 20-764  
HFD-120/Leber/Katz/Feeney/Ware

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