King's Fund

An Angel in your Pocket?

The Characteristics and Experiences of the First Betaferon® Users

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Summary

INTRODUCTION

As part of our work for North Thames Research and Development, the King's Fund collected data on all Betaferon users from December 1995 to September 1996 in the North Thames region, an area encompassing Greater London north of the Thames and the counties of Essex, Hertfordshire and Middlesex. We also organised discussion groups with 24 potential or actual users of the drug. Please be aware that our work only covered the drug Betaferon (beta interferon 1b) and the information we are passing on here may not be applicable to other MS drugs.

WHO'S TAKING BETAFERON

The first Betaferon users in the North Thames region tended to be

- under forty years of age
- diagnosed in the past four to five years
- experiencing on average three attacks every two years prior to treatment

Over ninety percent had experienced some form of side effect with injection site reactions, mild or severe flulike symptoms and fatigue being the most common. The majority had not suffered a relapse while on treatment, but most had only been taking the drug for less than two months and would not have expected one in that period of time.

EXPERIENCES ON BETAFERON

Although almost everyone had heard of Betaferon, most did not think about trying it until their GP, or more often, their neurologist suggested it. Since the neurologist was usually the one who first proposed the drug, neither the assessment interview nor obtaining the drug was difficult.

Prime considerations in making a decision about taking Betaferon were willingness to self-inject and ability to overcome fears about short and long term side effects.

The first injection was the most difficult, and usually the worst side effects were experienced at this time. Some suffered very severe side effects and others reported none at all. After several weeks, side effects gradually reduced for most.

Most felt it was too soon to tell if Betaferon was working, but a few reported that relapses were less severe. Nearly a year after the discussion groups took place, just under three quarters of the participants were still using the drug.

USERS' ADVICE TO OTHERS

- Be imaginative when seeking out further information and get as many people as possible to keep an eye out.
- Don't make a decision about taking Betaferon when you've just come out of a relapse or have not yet come to terms with your MS.
- Get someone to be with you for the twelve hours after you've had your first injection.
- Time the injections to occur when you're ready for bed.
- Painkillers may reduce some of the side effects.
- Don't let Betaferon take over your life.

Introduction

BACKGROUND

From October 1995 to February 1997, the King's Fund, a charity which supports and develops health services, was commissioned by North Thames Research and Development to look at the introduction of Betaferon. We were asked to talk with representatives from voluntary organisations and drug companies, neurologists and their teams, GPs and health authority managers to get their opinions on what worked well (and not so well) in order to provide some possible ideas for managing future high cost, controversial drugs.

As part of this work, we organised discussion groups with potential and actual users of the drug. One of the most powerful messages that came from these groups was that people with MS would like more information on Betaferon. To that end, the Multiple Sclerosis Society has funded the writing of this report.

AIM

We are writing for two groups of people with MS: those who are considering taking the drug but have not yet made a decision and those currently taking Betaferon. We hope this report will help the former to make a more informed choice; and provide the latter with useful feedback from fellow users.

In particular, we intend to answer three questions:

1. Who's taking Betaferon?
2. What have their experiences been?
3. What can help to make using Betaferon easier?

We stress that our information is only for the drug Betaferon (interferon beta 1b). We do not know if there are any similarities with other interferon beta drugs such as Avonex™ and REBIF, as we did not collect any information from users of these drugs.

SOURCES OF INFORMATION

Our information comes from two sources. The first is a database covering North Thames Region which provides detailed information on all users of Betaferon in the region from the drug's licensing in December 1995 to September 1996. The second source is the information given to us by users during the discussion groups.

STRUCTURE OF THE REPORT

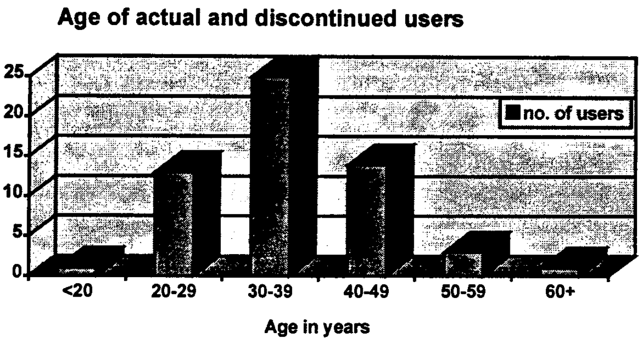
Data from the first source on age, frequency of attacks, side effects, number of weeks on treatment and so on is displayed in charts with explanations in the first section of the report. Information from users on their experiences with Betaferon are presented in the form of quotations and case studies. Some of the topics covered in this section are reasons for taking and refusing Betaferon, side effects reactions, advice for incorporating Betaferon into your life long-term and tips for making injections easier.

Characteristics of Betaferon Users

From December 1995 to the end of September 1996, 57 people out of just under seven million in North Thames had used Betaferon. Fifty two were still using the drug in September 1996, while five had stopped. Unless stated otherwise, all of the following charts refer to both continuing and discontinued users.

AGE

Figure 1

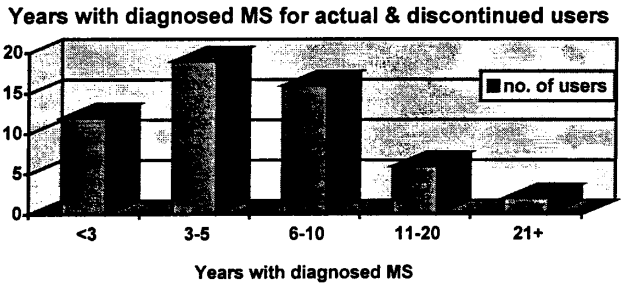


NB Age calculated from September 1996

The youngest user of Betaferon was 19 and the oldest 63. The average age was 36 and over two thirds were aged under 40.

YEARS WITH DIAGNOSED MS

Figure 2

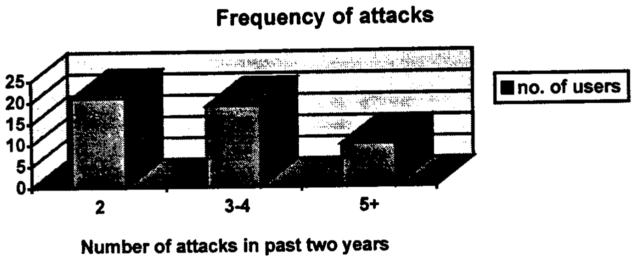


Data not known = 2
NB Years calculated from 1996

People had been diagnosed with MS for as little as one year or as many as 32. The average was 6.6 years. Half of the users had been diagnosed for four years or less.

FREQUENCY OF ATTACKS

Figure 3

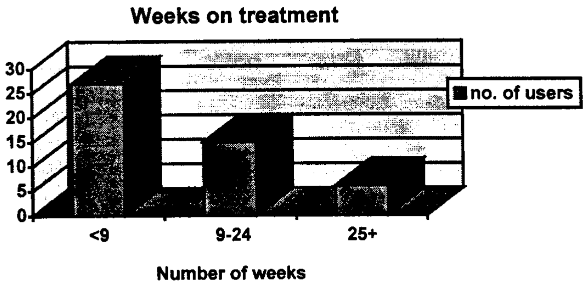


NB Data missing for 7 cases

In order to be prescribed Betaferon, a candidate had to have suffered at least two relapses in the past two years and over 40% had experienced exactly this number . The most severely affected had suffered twelve. The average was 3.4 and sixty percent of users had experienced three attacks or fewer in the previous two years.

WEEKS ON TREATMENT

Figure 4

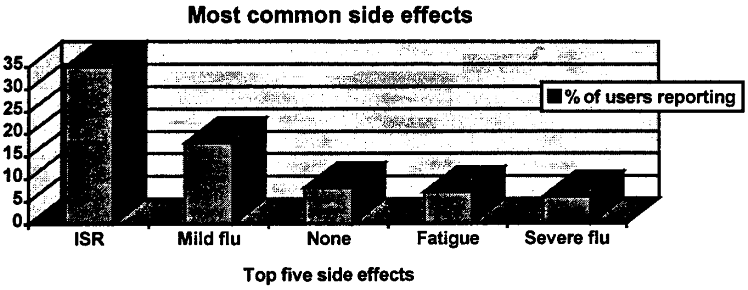


NB Four cases missing and only current users included so total =48
Weeks calculated from date of first injection to 30 September 1996

The number of weeks on treatment ranged from under one week to 35 (nearly nine months). The average was 10.6 weeks, but over half of the users (56%) had been injecting for no more than eight.

SIDE EFFECTS

Figure 5



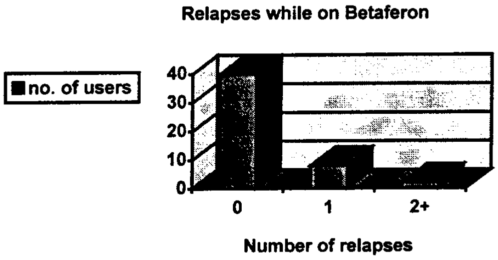
NB Total not equal to 57 as each person may have more than one reaction.
Data missing for 3 cases
"ISR" = Injection site reactions

By far the most common side effect was injection site reactions with 35% of users experiencing soreness, bruising or inflammation. Eighteen percent had mild flulike symptoms while six percent suffered a more severe flulike reaction. Seven percent felt more fatigued than usual. Eight percent did not report any side effects.

Other side effects include a reduction in white count (4%), loss of mobility (4%), headaches (3%), loss of bladder control (3%), hot flushes (2%) and mildly elevated liver function (2%). Only one instance each was recorded for menstrual disturbances, euphoria, palpitations, depression, leg aches and urine retention.

RELAPSES WHILE ON TREATMENT

Figure 6



NB Data not available for 7 cases

Over two thirds of Betaferon users (70%) had not experienced an attack while on treatment, but this is to be expected as many had not been on the treatment for longer than two months. Eight people (14%) had suffered one attack; one person had had two and the worst affected had had five since starting Betaferon.

DISCONTINUED USERS

Five of the 57 (9%) had stopped using Betaferon sometime before 30 September 1996. Four discontinued because of side effects and one stopped because s/he was fed up with injections. Those who stopped because of side effects did so early on in the treatment (8 weeks, 2 days and 1 day) while the person who discontinued use because of the injections was on Betaferon for 32 weeks. These data were not available for one case.

SUMMARY

The first Betaferon users in the North Thames region tended to be under forty years of age. Most had been diagnosed in the past four to five years and had a relatively mild form of the disease with an average of one and a half attacks every year. Over ninety percent had experienced some form of side effect with injection site reactions, mild or severe flulike symptoms and fatigue being the most common. The majority had not suffered a relapse while on treatment, but most had only been taking the drug for less than two months and would not have expected one in that period of time.

Personal experiences of Betaferon

BACKGROUND ON THE DISCUSSION GROUPS

Numbers attending

We held five discussion groups with between three and twelve people in each group in October and November 1996. Twenty four people with MS attended of whom nineteen were currently using the drug; two had stopped because of side effects and three had refused Betaferon. Sixteen carers were also present.

Characteristics of participants

Data from twenty two of the twenty four discussion participants were included in the previous section and analysed separately to see if there were any differences between the larger group and those who attended the discussions. Two of the young women who declined the drug and came to the discussions were not included as data were not available for them.

In some respects, the data for the people with MS who were present at the discussions are very similar to the data from all North Thames users. Both groups had an average of three attacks in the past two years; the type of side effects experienced were similar, and the absence of relapses was common.

The differences were that the discussion participants tended to be older with the majority aged between 40 and 49 rather than between 30 and 39. They had also been diagnosed for longer with twice as many having confirmed MS for eleven or more years. Group participants had been using the drug longer as most had injected for somewhere between two and five months. The range in the severity of side effects was greater in that a few had very unpleasant reactions as well as a greater number having reported no side effects.

FIRST STEPS

Information

Almost everyone commented that they had heard of the drug long before considering treatment. The most common sources of initial information were television, national press (both newspapers and magazines), the MSS and friends with MS. Several said they first heard of it from relatives abroad, in particular the United States and Ireland.

A few who tried to find out more information said it was quite difficult. One looked on the Internet and discovered the original trial data; another requested a medical literature search from a university where her mother worked. Three people were even more resourceful.

> *I had to ring neurologists abroad because you can't get the same kind of information out of an English neurologist. They (neurologists abroad) are much more frank with you.*
>
> *I asked a friend who was a pharmacist to get information from the drug company.*
>
> *A nurse from Wales advertised in the 'Nursing Journal' asking to speak to anyone with MS, so I wrote to her and she said she'd just started with Betaferon and she was having a wonderful experience.*

Discussions with GPs and neurologists

For a few, a GP was the initial source of information and the first to suggest the possibility of using Betaferon. For many others, it was the neurologist or a member of the MS team.

> *My neurologist told me about it and said there was no reason why I couldn't take this on.*
>
> *I was phoned by (the co-ordinator of her neurologist's team) and she informed me that there was a new drug and would I be interested in coming to a meeting to discuss it.*

Out of the twenty four participants with MS, only a quarter said they actively asked for Betaferon: two went to their GP and four to their usual neurologist. This means most had waited for their GP or neurologist to suggest it.

Negative GPs and neurologists

Because many GPs and neurologists are not convinced of the benefits of Betaferon, very few are proposing the drug and a handful are discouraging if a patient brings it up first. In a telephone survey we carried out with 52 GPs, two commented that they had given negative opinions to four or five of their patients, even though those patients might have been suitable candidates.

Totally negative neurologists were even more likely than GPs to influence potential users against asking for Betaferon.

> *If you come up against a brick wall, a neurologist who doesn't hold with the drug, you think this man is knowledgeable, this is his field and he thinks this drug is not right. So you go away and don't ask for a second opinion.*

Keeping in mind that just six people proactively asked for Betaferon, only one said she had difficulty in convincing their neurologist to prescribe.

> *My neurologist said, "I wouldn't stick something strange like this into myself". And I said, "But you don't have MS." I had to have a tantrum to get it, but I think it was more a case of him not knowing me well enough than him not wanting me to have the drug*

People who are interested in taking Betaferon and think they meet the criteria (see Appendix 1) do have the right to a second opinion, if their GP is willing to refer them.

MAKING A DECISION

Timing

Several participants commented that the neurologist told them about the drug when they were first diagnosed or soon after an attack, which is a particularly vulnerable time for someone with MS.

> *I think when I was introduced I was still in shock from the diagnosis....My dad died from chronic progressive MS two years ago so anything that came along I'd grab it.*
>
> *I had a relapse and I thought I'll take anything to not have this again.*
>
> *When you've just come out of an attack they could have been injecting me with water and I wouldn't have cared.*

Since most participants only saw their neurologist at diagnosis and during relapses, they felt that this was an appropriate time to learn of the drug, but not necessarily to make a decision about taking it.

> *I feel you have to come to terms first with your MS before you go on this drug, which is not easy.*
>
> *Making a rational decision when you've just been diagnosed is very difficult. Your whole life has just been turned upside down....I'd only been diagnosed six months ago and I'd already had so much grief I decided not to give myself anymore. But if the drug had come out during my second attack, I would have taken it but that wouldn't have been good because it wasn't a rational decision.*

Influences in making a decision

Betaferon is a live protein and can only be administered by injection, so users had to consider whether they would be willing to self-inject.

> *I didn't like the injections or the thought of the injections.*
>
> *It's quite a traumatic thing to inject yourself every other day.*

The possibility of severe short term side effects and unknown long term ones also needed to be thought through.

> *Me and my husband thought about it quite deeply. I just felt that by that stage I could try the drug, see what the side effects were and if they were too bad give up. Or, not try the drug and not know and then six months down the line have a bad relapse and wish I had taken the drug. I really didn't feel I had a choice. I had to give it a go.*

Assessment interview

Everyone went through an assessment interview with a prescribing neurologist, who was not necessarily their usual neurologist, to see if they met the criteria for Betaferon. Usually, candidates walked a hundred or more yards (some with a stick and some without), had blood and other tests, gave a detailed medical history and had an opportunity to ask the neurologist questions. All of the candidates from one area were given a psychological exam to test for depression, which many said was useless as it was very clear what answer was expected.

Some said they were very anxious throughout the interview. Others were not nervous in the least, partly because they were not bothered about having the drug and partly because they were aware that the assessment process was designed at this particular centre so that only the most likely candidates ever got as far as the interview.

> *It could be extremely disappointing for someone to think they could go on it and then be told they couldn't. That would be devastating. So I think the way they did it with us where people were channelled through who they thought would get it was good.*

Reasons for taking the drug

Many said that they decided to take Betaferon because it gave hope and was the first note of optimism. Several talked about wanting to reduce the number of relapses.

> *I wanted a break from this downward spiral because every time I have a relapse something else packs up.*

A few spoke honestly about their hopes that the drug would do even more than reduce the number and severity of attacks.

> *When I first read about it, I thought it was a cure and I hoped it was. But once I spoke to my GP, I realised it wasn't.*

> *I hoped that if I did have a relapse, it wouldn't be so severe. But inside I hoped I wouldn't have any more.*

Interestingly, a couple of people also mentioned that they wanted Betaferon in order to be known to the NHS when future, possibly more effective drugs are licensed.

> *One of the reasons I agreed to go on this drug was so that I'd be here when something else came along.*

> *I went on Betaferon because I'm waiting for a cure. And here we are, it's Friday night and there's still no cure*

Reasons for refusing the drug

The three women who declined the drug reported that side effects, both short and long-term, and the mildness of their disease were the main factors in their decision.

> *In some ways, the side effects were worse than some aspects of the MS. Quite honestly, it didn't sound like it would be an improvement for me.*

> *Who knows? I might want to have babies and how does this drug affect them? Does it do something to their genes? That kind of stuff scares me.*

> *I wouldn't take it at the moment because I haven't had an attack in over a year. But if I had lots of attacks or worse ones I would.*

THE FIRST FEW WEEKS

Self-injecting

No one liked injecting and one mentioned that she didn't like mixing it up. A few commented that it took them quite a while to learn how to do it.

> *[After talking with others using Betaferon]...I was relieved that I wasn't the only one who couldn't get the hang of the needle.*

> *I'd put the needle right through my thumb when I put the cap back on.*

Eventually, everyone found ways to become easier and more proficient at self-injecting.

> *The video [from Schering, the drug company which produces Betaferon] was good because it made me feel better about injections.*
>
> *I felt better about it once I saw the nurse inject herself. It sounds funny, but she just stuck it in her thigh and said, 'See it's not a problem'.*
>
> *My husband said, 'Let's take some of the anxiety out of this. You mix 'em and I'll whack 'em."*

First injection

The first injection with Betaferon was seen as the hardest. A few were prepared for the worst and were pleasantly surprised when they noticed very little effect.

> *I had flu just for the next day and my second injection I took a half day off work and I was fine.*
>
> *I was told a week of flu after the first injection and I only had one and half days.*

The majority had somewhat more severe reactions which disturbed their daily routines.

> *I wasn't immobilised by it, but by the next day I couldn't get up and when you've got to get a seven year old ready for school and you can't get out of bed that seven year old has to become eighteen very fast.*

A few were very hard hit.

> *(Someone in their group) had the injection and wanted to get up at two o'clock to go to the toilet and he couldn't. He couldn't even crawl to the toilet.*
>
> *I just collapsed. My husband had to literally pick me up and carry me to bed because I couldn't stand up.*

The two group participants who were most severely affected reported that they were paralysed from the neck down and lost all bladder control after the first injection. One of them, who described it as a "tonic seizure", stopped taking the drug immediately although his neurologist thinks that it may have been a relapse and not a reaction to Betaferon. The other carried on for over six months and did not experience this type of reaction again. Currently, data on users throughout the UK are being collected and eventually they may be analysed to see if these experiences were freak occurrences or more common.

For these type of severe reactions, neurologists are required to submit a "yellow card" to the pharmaceutical company. This explains what the reaction has been and gives the neurologist's opinion on the possibility that the adverse event may be due to the drug. People who take Betaferon and suffer from severe reactions should ask their doctor if a yellow card has been completed.

Injection site reactions and other difficulties

With longer term use, there were fresh difficulties after mastering self-injection and injecting for the first time. Almost everyone seemed to be affected by injection site reactions and those with less fat on their bodies suffered particularly badly.

> *I look like a map of the Channel Islands.*

One mentioned that as she revisited sites that had been used before she felt more pain as the previous bruising had not yet healed. Another, who had been injecting for four months, found tough skin a problem

> *The more I inject into these legs, the harder it is to get the needle in. I think the skin's getting harder.*

Others did not find any further problems once they learnt how to inject.

> *I seem to be managing all right on my legs and tummy.*

Feelings about taking injections

After several weeks of injecting, many users were quite confident and did not get anxious before injecting. Others were less so.

> *I have my 'days on' when I inject and 'days off' when I don't. When it's a day on, I get fraught several hours before and am really worked up by the time I actually inject. The next day I don't feel very well in the morning, until I go back to my old self in the evening. Then the next day I'm fine until I remember I have to inject again that night.*

Advice on taking injections

Since reactions to the drug seem to be most severe with the first injection, many stressed that the first injection should not be taken alone.

> *You need to have someone stay with you for twelve hours after the first injection in case you crash.*

One Betaferon user, who was interviewed separately and was never able to inject himself, arranged to have a district nurse come to his home every other night after nine o'clock to administer it for him.

Another user who was thin and suffered bad injection site reactions suggested that anyone having problems should get themselves injected in their bottoms where there is more fat.

Side effects

Types of side effects

As well as injection site reactions, flu symptoms and fatigue were most commonly reported. A few felt it was much worse than they could have imagined.

> *We were never told it could be this bad. We were told flu symptoms but not being able to get up and go to the loo is frightening.*
>
> *I've been falling asleep a lot at work since I've started taking it. It's funny that this drug is supposed to help us keep on working, yet I was actually reprimanded for falling asleep on the job.*

Many mentioned other side effects as well.

> *Since taking Betaferon, I've had vertigo very severely but I never had it before with my MS in fifteen years. I get terrible headaches and the room spins around.*
>
> *We've noticed that since she's been on it her walking's got worse.*
>
> *I was just waking up and having shivers and it was like a panic attack. And the next morning I'd wake up and be dragging my leg then the next day I'm great.*
>
> *Being so irritable is one of the worst side effects for me. My husband had to lock himself in the bathroom once as I would have gone for his eyes.*

Two people mentioned that they feel euphoric after injecting, and one said that she never drove a car as she didn't think she'd be safe on the roads. Two often felt like they'd had one drink too many, one enjoyed this feeling and the other didn't.

Positive reactions

Despite this long list of possible negative side effects, four of the twenty one who tried the drug did not mention having any. Interestingly, one of the two who mentioned paralysis after the first injection had found that in general he coped with minor infections much better.

> *Since taking Betaferon, I no longer am bedbound when I have a cold or flu.*

Advice on coping with side effects

Several mentioned that they always took the injections at night, just before going to bed. This way, they would sleep through any side effects.

Another said that she took paracetamol a half hour to an hour before injecting and that seemed to help diminish them somewhat. Many others mentioned using painkillers when the side effects started up; some found it helpful and others couldn't tell a difference.

For two case studies on side effects, please see Appendix 2.

LONG TERM CONSIDERATIONS

Being flexible about injecting

One mentioned that it was important "not to let Betaferon rule your life". She gave the example that if it was a Saturday night and she didn't get back from a club until 4 am she would take her injection then rather than missing out the fun.

Travelling

There were also a couple of stories of travelling with Betaferon. One person had gone camping, using a cool box with extra ice for transportation and storing it in the camping ground's refrigerator on arrival.

Three others had taken Betaferon abroad on holiday. One, who went to Turkey, said

> *I rang the Turkish Embassy to find out what papers I needed and so forth and I was told that I didn't need to bring my drugs with me because they had lots of good drugs in Turkey. I didn't believe I could actually get it there, so I got a letter from the drug company, another from my neurologist and another from the nurse. When I got to Customs, they put it through the x-ray machine and the needles must have shown up but nobody asked me. They searched everyone's bag and asked me "What's in the bag". I said drugs and she said "That's okay then".*

Another person who had flown out of Stansted said that customs had not been interested in the drugs but the kind of ice.

Taking other drugs

In one group there was a lively discussion about whether steroids could be taken while on Betaferon and they eventually came to the conclusion that it depended on the neurologist.

Others were worried about drugs that could possibly be contraindicated, mentioning specifically the contraceptive pill and certain analgesics. A couple were sure that there would be no problem.

> *We did check because I like my drugs.*
>
> *We've been told we can take anything. It's in that booklet we've got.*

Antibodies

The issue of neutralising antibodies came up in two groups. In one, a participant felt that it had been played down by the drug company and in another a user was angry that the possibility of neutralising antibodies had only been mentioned after she had been on the drug for several months.

> *I've been told that I have to have blood tests at every follow up and they'll freeze them until an antibody test has been developed. That seems silly to me because what if I've got antibodies now and they don't get a test for them for another year ? Then I'll have been taking it and it won't be working. I think that before marketing these drugs the company should make sure that they have all the tests needed.*

EFFECTIVENESS OF BETAFERON

A cautionary note

When thinking about how successful Betaferon has been, it is helpful to remember that most people who were at the discussions had not been using the drug for very long and so would not be expected to see an improvement. If they were being questioned ten months later, at the time of writing this report, their responses might be very different.

Secondly, as one person said, it is a good idea to keep in mind that

> *Each individual's response to this drug is different because each person's MS is different.*

Finally, remember that the purpose of Betaferon is not in making something happen, but preventing something, namely a relapse, from happening. So, in effect the adage of "no news is good news" definitely applies.

Opinions on effectiveness

When asked if they felt they had benefited from Betaferon, most said that it was too soon to tell.

> *Anybody I ask, do you feel better for it say I feel just about the same.*

One group, as the following exchange demonstrates, were particularly negative.

> *The initial build-up is that you know it's not a cure but you expect some sort of miracle and it doesn't come.*
>
> *Yes, I'm still taking it and I'm still waiting for something to happen and it hasn't yet.*
>
> *I'm disappointed.*
>
> *I'm very, very disappointed.*
>
> *I seem to be the only one who's benefited.*

In another group, three out of four felt positive about Betaferon. The one who didn't described her experience as "so-so".

A third group was very positive with one saying

> *No longer are we unlucky having MS but we're lucky having Betaferon.*

Relapses

The number of relapses reported by participants at discussion groups was higher than the number according to the database. This could be because some relapses had been experienced since the data were collected two to six weeks previously. Another possible reason for the difference is that people with MS may consider certain symptoms as relapses which health professionals do not.

Out of six people from one group, four said they had had relapses while three out of four from another group had reported attacks while taking the drug. However, many mentioned that the relapses were negligible compared to those before they took Betaferon.

> *In the job I do there's two very, very stressful times a year. And last year (while on Betaferon) the first time nothing happened and the second I had a few symptoms but not an attack. For me, all I can see is that it's done me good.*

Numbers on still on treatment as of July 1997

Ten to eleven months after the discussion groups, we rang nurses to find out how many of the nineteen users were still taking Betaferon. Fourteen (73%) had continued with Betaferon and the nurses reported that many were happy as they had skipped or minimised attacks over the past year.

Four of the five who had discontinued using the drug were from the negative group mentioned above. One other person stopped taking Betaferon as his condition worsened into progressive MS and he no longer met the criteria.

SUMMARY OF EXPERIENCES ON BETAFERON

Although almost everyone had heard of Betaferon, most did not think about trying it until their GP, or more often, their neurologist suggested.

Prime considerations in making a decision about taking Betaferon were willingness to self-inject and ability to overcome fears about short and long term side effects. Others thinking about taking Betaferon were advised to make a decision when feeling in good condition, i.e. not just after a relapse or diagnosis.

The first injection was the most difficult, and usually the worst side effects were experienced at this time. The most common side effects mentioned were injection site reactions, flu (mild or severe) and fatigue, although other previously undocumented side effects like irritability and temporary paralysis were reported. Side effects tended to diminish over time.

Most felt it was too soon to tell if Betaferon was working, but a few reported that relapses were less severe. Nearly a year after the discussions took place, just under three quarters of the participants were still using the drug.

In summing up her Betaferon experience, one commented.

I've had good times. I've had bad times. But it's certainly given me a laugh.

Appendix 1

Criteria for prescription with Betaferon

- Over 18 years old
- Mobile
- Confirmed relapsing remitting MS
- If female, not pregnant or breastfeeding
- At least two attacks in the past two years followed by complete or partial recovery

Betaferon may not be prescribed to those with

- a history of severe depressive illness and or suicidal tendencies
- decompensated liver disease
- other specific conditions such as uncontrolled epilespsy

Sources: Executive Letter (95)97 and Royal London Hospitals Trust Guidelines 1996

Appendix 2

Case Studies of Side Effects

Introduction

Since everyone we spoke with had had a very individual response to Betaferon, it is difficult to pick out a "typical" case. The two case studies below exemplify someone who has had a fairly good experience with Betaferon and someone who has not.

Case 1

The first case concerns a 53 year old woman who had been diagnosed with MS for four years. She had had two relapses in the past two years and had been taking Betaferon for 10 weeks.

> *I had the fluey symptoms [at first]. I get them occasionally now and sometimes I get headaches but I take a paracetamol and they go away. I felt pretty ropey after my first injection and next day but then I was okay. In total, I had side effects for about six weeks I would say but I could still go to work and everything. They weren't that bad. I have red blobs on my legs, but I can touch them. I'm going back on sites and they hurt a bit.*

Case 2

The second case is another woman who was 48 years old at the time of the discussion groups. She had been diagnosed with MS for eight years and had experienced two relapses in the past two years. She stopped taking Betaferon after eight weeks.

> *My first initial injection with the side effects were horrendous. I fell, had double vision and had terrible pains in my legs. I couldn't sleep because of the high body temperatures. Paracetamol and Ibuprofen made no difference and I was taking a lot. The next day I still felt awful but the following day I was all right, but then I had to take another injection.*
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> *It was awful, not anywhere as severe as the first, but I couldn't sleep. The following day was awful. I was holding on to everything. This went on for weeks. Within eight weeks I had swallowed over 200 paracetamol tablets along with the Ibuprofen. My quality of life had been reduced and I needed to get on with my life and I couldn't do anything.*
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> *Although I didn't have depression, I felt it could lead to this with the high body temperatures and not being able to do anything. I decided after speaking with my husband that I had to come off and get on with my life. My nurse said the side effects should have worn off after eight weeks.*