

ACTIVA[®]

Deep Brain Stimulation

"On" Time Diary *for Parkinson's Disease*

2 out of 3 patients with Activa DBS
wished they had received their
Activa DBS sooner¹

Jerry W. and his wife, Gail.
Jerry received Activa DBS
soon after medication
became less effective.



¹ Based on a patient survey of 143 implanted patients.
Data on file at Medtronic.

YOUR LOGO HERE

Goal of Parkinson's disease treatments

The goals of current Parkinson's disease treatments are to:

1. Increase periods of symptom control and good mobility ("on" time)
2. Minimize side effects from treatments

Achieving these goals is relatively simple in the early stages of Parkinson's disease. However, as the disease progresses, your doctor has to increase the doses of your medications you're on, as well as introduce new ones to continue providing you with good symptom control.

Complications with medication treatment

At some point this can lead to complications like "off" time (periods of poor symptom control), dyskinesias (involuntary excessive movements), or other troublesome side effects. When this happens, you and your doctor will need to make decisions on how to maximize symptom control and minimize side effects by adjusting your medication regimen.



Claire A.
Claire received Activa DBS when medications alone were insufficient.

Why keep an "On" Time Diary?

You can help your doctor make good treatment decisions by keeping an "On" Time Diary. A well-kept diary provides your physician with a clear picture of when you are taking your medications, when you are feeling well, and when you are not feeling so well, allowing your doctor to adjust and optimize your treatment.

What can I do when "off" time, dyskinesias, or other complications arise despite medication treatment?

At some point in your journey with Parkinson's disease, you may find that medications are no longer providing you with consistent symptom control and good mobility throughout the day, or that you are experiencing side effects. *If this happens, Activa® Deep Brain Stimulation (DBS) may provide you with symptom control and good mobility.* The "On" Time Diary will help your doctor determine when Activa DBS may be right for you.

How do I find out if Activa DBS is right for me?

1. Complete the three-day "On" Time Diary.
2. Once you have completed the diary, share the results with your doctor and discuss recommended treatment options.
3. Learn more about Activa DBS by calling 1-877-438-3574 and requesting a private phone call with a Nurse Educator or a Patient Ambassador already using Activa DBS. Visit the following website: www.activadb.com.

Daily Diary

Day 1	Daytime													Evening						
	5:00 AM	6:00 AM	7:00 AM	8:00 AM	9:00 AM	10:00 AM	11:00 AM	12:00 PM	1:00 PM	2:00 PM	3:00 PM	4:00 PM	5:00 PM	6:00 PM	7:00 PM	8:00 PM	9:00 PM	10:00 PM	11:00 PM	
Asleep																				
"On" Time with Troublesome Dyskinesias																				
"On" Time																				
"Off" Time																				
Parkinson Medications (tablet strength in mg)																				
Sinemet [®] , Parcopa [®] levodopa (mg)																				
Sinemet CR [®] levodopa (mg)																				
Stalevo [®] levodopa/entacapone (mg)																				
Mirapex [®] pramipexole (mg)																				
Requip [®] ropinirole (mg)																				
Comtan [®] entacapone (mg)																				
Symmetrel [®] amantadine (mg)																				
Other: (mg)																				

Notes

Daily Diary

Day 2	Daytime													Evening					
	5:00 AM	6:00 AM	7:00 AM	8:00 AM	9:00 AM	10:00 AM	11:00 AM	12:00 PM	1:00 PM	2:00 PM	3:00 PM	4:00 PM	5:00 PM	6:00 PM	7:00 PM	8:00 PM	9:00 PM	10:00 PM	11:00 PM
Asleep																			
"On" Time with Troublesome Dyskinesias																			
"On" Time																			
"Off" Time																			
Parkinson Medications (tablet strength in mg)																			
Sinemet [®] , Parcopa [®] levodopa (mg)																			
Sinemet CR [®] levodopa (mg)																			
Stalevo [®] levodopa/entacapone (mg)																			
Mirapex [®] pramipexole (mg)																			
Requip [®] ropinirole (mg)																			
Comtan [®] entacapone (mg)																			
Symmetrel [®] amantadine (mg)																			
Other: (mg)																			

Notes

Daily Diary

Day 3	Daytime													Evening					
	5:00 AM	6:00 AM	7:00 AM	8:00 AM	9:00 AM	10:00 AM	11:00 AM	12:00 PM	1:00 PM	2:00 PM	3:00 PM	4:00 PM	5:00 PM	6:00 PM	7:00 PM	8:00 PM	9:00 PM	10:00 PM	11:00 PM
Asleep																			
"On" Time with Troublesome Dyskinesias																			
"On" Time																			
"Off" Time																			
Parkinson Medications (tablet strength in mg)																			
Sinemet [®] , Parcopa [®] levodopa (mg)																			
Sinemet CR [®] levodopa (mg)																			
Stalevo [®] levodopa/entacapone (mg)																			
Mirapex [®] pramipexole (mg)																			
Requip [®] ropinirole (mg)																			
Comtan [®] entacapone (mg)																			
Symmetrel [®] amantadine (mg)																			
Other: (mg)																			

Notes

Additional patient information

Please answer the following questions

1. How troublesome are your "off" periods (periods when medication is not helping enough and you are experiencing symptoms)? (Circle the option that applies.)

I barely notice
I'm 'off'

I have difficulty
but I can do all
I want to do

I can't do some
things I want to do

I can't do most things
I want to do

2. How troublesome are your dyskinesias (involuntary excessive movements)? (Circle the option that applies.)

I don't have any

I barely notice them
but others do

They interfere with
some activities

They interfere with
most activities

3. What are your most troublesome symptoms?

4. What are your most troublesome side effects? (Circle all that apply.)

Sleepiness

Nausea

Hallucinations

Confusion/other
thinking problems

Lightheadedness
upon standing

Behavioral/personality
changes

Other: _____

Summary

(for healthcare professional use only)

1. Idiopathic Parkinson's disease? YES NO
2. Years since diagnosis: _____ YEARS
3. Good levodopa response (even if brief)? YES NO
4. Recommend Activa DBS evaluation? YES NO

Referring Physician name: _____

Signature: _____

Referring Physician phone number: _____

Activa DBS Center name: _____

Activa DBS Center fax: _____

Center Physician: _____

Center scheduling contact: _____

Scheduling phone number: _____

Patient name: _____

Patient phone number: _____

The next section will be filled out by your healthcare professional.

Activa® Parkinson's Control Therapy: Patients should always discuss the potential risks and benefits with a physician.

Indications: Bilateral stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) using Medtronic® Activa® Parkinson's Control Therapy is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Contraindications: Contraindications include patients who will be exposed to MRI using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area, patients for whom test stimulation is unsuccessful, or patients who are unable to properly operate the neurostimulator. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation system.

Warnings/Precautions/Adverse Events: There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture. Theft detectors and security screening devices may cause stimulation to switch ON or OFF, and may cause some patients to experience a momentary increase in perceived stimulation. Although some MRI procedures can be performed safely with an implanted Activa System, clinicians should carefully weigh the decision to use MRI in patients with an implanted Activa System. MRI can cause induced voltages in the neurostimulator and/or lead possibly causing uncomfortable, jolting, or shocking levels of stimulation. MRI image quality may be reduced for patients who require the neurostimulator to control tremor, because the tremor may return when the neurostimulator is turned off.

Severe burns could result if the neurostimulator case is ruptured or pierced. The Activa System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson's disease, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; or for patients who are pregnant, under 18 years or over 75 years of age. Adverse events related to the therapy, device, or procedure can include: stimulation not effective, cognitive disorders, pain, dyskinesia, dystonia, speech disorders including dysarthria, infection, paresthesia, intracranial hemorrhage, electromagnetic interference, cardiovascular events, visual disturbances, sensory disturbances, device migration, paresis/asthenia, abnormal gait, incoordination, headaches, lead repositioning, thinking abnormal, device explant, hemiplegia, lead fracture, seizures, respiratory events, and shocking or jolting stimulation.

Rx only

Sinemet® and Sinemet CR® are registered trademarks of Merck and Co., Inc.
Requip® is a registered trademark of GlaxoSmithKline, Inc.
Comtan® and Stalevo® are registered trademarks of Novartis Pharmaceuticals.
Mirapex® is a registered trademark of Boehringer Ingelheim.
Symmetrel® is a registered trademark of Endo Pharmaceuticals.
Stalevo® a registered trademark of Novartis Pharmaceuticals.
Parcopa® is a registered trademark of SRZ Properties, Inc.

To schedule an evaluation,
contact us at:

YOUR LOGO HERE

UC200802346 EN NI8298 EN
© Medtronic, Inc. 2007
All Rights Reserved
Printed in USA