

COASTAL NEUROLOGICAL MEDICAL GROUP, INC.

Dee E. Silver, M.D. / Frederick J. de la Vega, M.D. / Naira Kocharian, M.D. / Kevin P. Kolostyak, M.D.

We're here to help!

Movement Disorders
Neurodegenerative Diseases
Neuro-Ophthalmology
Botulinum Toxin Injection
Headache

9850 Genesee Avenue Suite 740
La Jolla, California 92037
Phone 858-453-3842 Fax 858-535-9390
www.neurologychannel.com/coastal/
www.pdasd.org

Neurological Rehabilitation
DBS Programming
Electromyography
Electroencephalography
Electronystagmography

March 21, 2008

To Our Patients:

The product Neupro (rotigotine) has been recalled and will not be available in the pharmacies. We will need to taper off the medication in our patients and possibly adjust other medications. This will require the patients to be seen by us to help affectively manage the withdrawal of the Neupro (rotigotine). This is the most appropriate way to handle the withdrawal of the medication from the patient and also to manage the issues of the discontinuance of the medicine, at least for now on the market. The problem that occurred with the Neupro (rotigotine) patch was that there was a polymorph crystal-like substance that occurred in the matrix or in the solution. The polymorph crystal is a solid state-like substance which is apparently the drug. It is possible, that this would not allow the drug to be transmitted through the membrane and absorbed in the skin. These structures look like snowflakes under a microscope, and it was found in some of the patches. The main concern is that of efficacy (effectiveness, benefit). The efficacy could be compromised. They have checked the patches that had crystals and there were no problems with adverse side effects. We would not expect any adverse side effect with this phenomenon, because predominately the polymorph crystallization would give less drug from the patch. They tested it and there was the usual adverse side effects including skin reaction. The drug company and others involved have recommended we taper off the patch from the patient's therapeutic format. There will be no available patches in the United States at any of the doses, 2mg, 4mg, or 6mg. This may be permanent or may be a temporary phenomenon.

We are going to request that the patients make appointments to see one our doctors in the group to explain the issues and to manage the withdrawal of the medication. This is the best way to accomplish this medication withdrawal because there may need to be other medications that will need to be adjusted, for example, increase in levodopa or adding a dopamine agonist. Also we want to make sure there are no side effects that are unexpected, however that would be very unlikely. We will request the patient to come in and see one of the doctors and we will have a withdrawal schedule. The withdrawal schedule will be switching the patches to a lower dose and then discontinue the drug. If the patient is on 6mg we will reduce to 4mg for 2 days, then 2mg for 2 days then stop. In some cases there will be definite worsening of the clinical features, so we'll need to make appropriate adjustments. Dr. Silver will probably not be able to see all his patients, so we will approach this as a team effort with Dr. dela Vega, Dr. Kocharian, and Dr. Kolostyak seeing the patients during this needed return visit.

I'm sure this will be easily adjusted and the patient will do well with the tailoring and individualizing the treatment with other drugs. There are significant side effects that can occur with rapid withdrawal of any dopaminergic medication including dopamine agonists like Rotigotine. Do not just suddenly stop your medication.

Thank you.

Dee E. Silver, M.D.