

Movectro[®] (cladribine)

Oral treatment for MS

Movectro (cladribine tablets) withdrawn as a treatment for MS

Merck Serono has announced that they will be voluntarily withdrawing Movectro (cladribine tablets), an oral medication for the treatment of relapsing-remitting multiple sclerosis (MS). The company has advised that this is the result of the decision not to pursue the global approval process for the medication.

Movectro was approved by the Therapeutic Goods Administration (TGA) in September 2010; however, Merck Serono has faced significant challenges in gaining registration through similar regulatory bodies in Europe and the United States of America. Approval in these countries would require a new clinical trial program, taking several years to complete, which the company has chosen not to pursue.

Existing trials with cladribine tablets will continue until completion, but will not be offered to any new patients. People currently participating in the Movectro Patient Familiarisation Program are able to continue treatment until the program concludes.

MS Australia – ACT/NSW/VIC urges people with MS who may be affected by this decision to contact their treating neurologist for advice.

MS Australia – ACT/NSW/Vic does not recommend any specific treatment for people living with MS. Decisions about any treatment should be made in careful consultation with your neurologist.

What is Movectro?

Movectro, an oral (tablet) form of cladribine, is an investigational treatment for people with relapsing forms of MS. Cladribine is a small molecule that may interfere with the behaviour and reduce the number of certain white blood cells, particularly lymphocytes, which are thought to be involved in the MS disease process.

In MS, these small white blood cells play a role in destroying myelin, the protective sheath that surrounds the nerve fibres and helps with the efficient flow of nerve signals or messages to and from various parts of the body.

What are the possible side effects of Movectro?

Merck Serono's decision to withdraw Movectro is not based on a change of the benefit/risk profile of cladribine tablets, which remains the same.

Movectro was generally well tolerated by participants in clinical trials. The main side effect experienced by the groups on cladribine tablets was lymphopenia, an abnormally low level of lymphocytes (white blood cells) in the blood. For most people who experienced this side effect, it was mild to moderate.

Other common side effects included headache, nasopharyngitis (swelling of the nasal passage and upper throat), nausea, and respiratory infection. In a small number of participants, infections that were dormant were reactivated.

The potential long term side effects are still unknown. Merck Serono intends to complete the clinical trials already underway and proceed with the ongoing Premiere registry, which follows people who have participated in cladribine studies.

Clinical trials of Movectro (cladribine tablets) in relapsing-remitting MS

- **CLARITY (CLADribine Tablets treating MS orally)**
A two-year Phase III trial designed to evaluate the efficacy and safety of cladribine tablets as a therapy in people with relapsing-remitting MS.
- **CLARITY extension study**
A two-year Phase III study designed to provide data on the long-term safety and efficacy of extended administration of cladribine for up to four years.
- **ORACLE MS (ORAI CLadribine in EARLY MS)**
A two-year Phase III trial designed to evaluate the efficacy and safety of cladribine as a treatment for people with clinically isolated syndrome (CIS) who are at risk of developing MS. The study is comparing the time to diagnose MS between a group taking cladribine and a group taking an inactive placebo therapy.
- **ONWARD (Oral cladribine added ON to interferon beta-1a in patients WITH Active Relapsing Disease)**
A Phase II trial designed to evaluate the safety and tolerability of adding cladribine tablets as treatment for patients with relapsing forms of MS, who continue to experience disease activity while on established interferon-beta therapy.
- **PREMIERE (PRospective observational long-term safEty registry of Multiple sclerosis patIEnts who have participated in cladrIBINE clinical trials)**
An observational registry of people who have participated in cladribine tablets clinical trials, designed to support the evaluation of the long-term safety of cladribine tablets as a treatment for relapsing forms of MS.

For more information on treatments for MS

- **Speak to your neurologist** about what treatment best suits your individual circumstances.
- **MS Australia** provides information on treatments currently available in MS: www.msaustralia.org.au
- **MS Research Australia (MSRA)** provides information on the latest research and clinical trials in MS: www.msra.org.au
- **Our Immunotherapy Support Program** offers information, training and ongoing support in managing your immunotherapy treatment. Call the MS Australia office in your state on **1800 042 138**.

BIBLIOGRAPHY

- Merck Serono. Regulatory update on cladribine tablets. News release, Merck Serono, Geneva, 22 June 2011.

For information about MS and MS Australia services:

Free call: 1800 042 138

Web: www.msaustralia.org.au

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