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Q&A
Oral Medication Update
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- Will Fampridine also affect energy to improve walking or does it only affect nerves and muscles?
 - Fampridine (now known as Dalfampridine) primarily affects (improves) nerve conduction. And as a consequence of this effect, walking may be improved. To the extent that walking may be improved, energy expenditure in walking may be lessened, thus improving overall energy conservation.
- What is the expected cost of these new oral medications? At the point of this writing (Feb 1 2010) these drug costs have not yet to my knowledge been set.
- What are the side effects of oral medications?
 - Dalfampridine (FDA approved on Jan 22, 2010) - generally well tolerated, but the most common (but relatively infrequent) side effects reported in clinical trials include urinary tract infection, insomnia, dizziness, headache, nausea, weakness, back pain, balance disorder, swelling in the nose or throat, constipation, diarrhea, indigestion, throat pain, and burning, tingling, or itching of skin. At doses greater than the recommended 10 mg twice a day, dalfampridine can cause seizures. Persons with moderate or severe kidney ailments should not take dalfampridine.
 - Other oral medications discussed – cladribine and FTY720 (fingolimod): These still experimental medications have been generally well tolerated by participants in clinical MS studies. Each medication's full side effect profile awaits ultimate review by the FDA.
- Are these oral medications advised for MS patients that have had or have a high risk of cancer?
 - Regarding cladribine and fingolimod, the full recommendations for safest use await FDA review and approval; but if approved, I would anticipate that caution would be advised with these medications, as with many immunosuppressive medications, for use in individuals with a cancer history or who are at high risk for cancer. Clearly, these important issues would need to be fully discussed with your doctor before beginning any chronically immunosuppressive therapy.
 - Regarding dalfampridine, no cancer-associated risks have been identified.
- Are there any age restrictions for women, such as child bearing age, to use these medications?
 - Age restrictions have not been established for any of the discussed medications; none of the discussed medications should be used during pregnancy, but pregnancy and fertility considerations vary among these medications and should be individually discussed with your doctor.



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- Will these medicines be used in conjunction with the ABC drugs?
 - Dalfampridine could be used in conjunction with the currently approved MS therapies (“ABCR”, Novantrone, and Tysabri)
 - Cladribine and fingolimod are being positioned to be used individually by themselves, not in combination with ABCR, Novantrone, or Tysabri.
- Do any of the oral drugs, including those that might not come out for a few years, show significant improvement in MS patients with cognitive and psychiatric symptoms?
 - No data is available yet regarding any of the discussed medications (dalfampridine, cladribine, or fingolimod) pertaining to possible cognitive benefits. However, as cognitive and behavioral aspects of MS become increasingly recognized for their importance, I anticipate that there will more studies in the near future concentrating on these issues.
- As a group, do you feel the oral medications will be as effective, more effective or less effective than the injectable medications?
 - This is, of course, a very important question that unfortunately has only a very general answer. Each new drug is different and, with few exceptions, cross-comparisons between drugs have not been performed. However, in general, cladribine and fingolimod are expected to be comparable in efficacy to the current injectable therapies (ABCR). Whether more or less effective will depend on each individual’s situation with MS, and therefore will have to await FDA approval, and real-life use and experience. Dalfampridine is a symptom management medication, and therefore is not directly comparable to any of the injectable “disease modifying” therapies.
- You mentioned that several of the oral drugs in late phase development have also been tested in transplant patients. Are the side effects, most especially the severe side effects, the same for transplant patients versus MS patients?
 - Occasionally drugs that have been studied in organ transplant situations find themselves looked at as possible treatments for other medical conditions – for instance, certain autoimmune diseases, like MS. Fingolimod would be an example of this. However, because the transplant situation is very different from MS, including medication doses and other concurrent medications and medical conditions, detailed comparisons between side effect profiles of the same medication in MS versus transplantation situations is very difficult, and sometimes misleading.