



Surfing for Knowledge

Darifenacin:

A New Drug for the Overactive Bladder.

Darifenacin is a new drug emerging for the treatment of detrusor instability (overactive bladder). It is a potent competitive muscarinic receptor antagonist that targets the M3 receptor, with lower affinity for non-M3 receptor subtypes. This entails high efficacy with low side effects profile. Darifenacin is available in once daily 7.5 and 15 mg tablets. The recommended dosage for Darifenacin is 7.5 mg to start, once daily.

Maximum plasma level is reached approximately 7 hours after dosing with Darifenacin. Steady-state plasma levels are reached by the sixth day of treatment. In 4 Phase III clinical trials, patients taking both doses of Darifenacin experienced reductions in as early as 2 weeks and continuing throughout the course of a 12-week trial. Based on controlled clinical trials, patients should begin to see results in approximately 2 weeks. Then, according to individual response, the dose may be titrated as early as 2 weeks after starting therapy.

As other M3 receptor blockers, it should be administered with caution to patients with clinically significant bladder outflow obstruction, gastrointestinal obstructive disorders, severe constipation, ulcerative colitis, or myasthenia gravis. In patients being treated for narrow-angle glaucoma, it should be used only with caution and only if the potential benefits outweigh the risks. No dose adjustment is recommended for patients with mild hepatic impairment. For patients with moderate hepatic impairment, the daily dose of Darifenacin should not exceed 7.5 mg. Darifenacin is not recommended in patients with severe hepatic impairment. No dose adjustment is needed for most patients, including older patients (>65 years old) and patients with renal or mild hepatic impairment.

Dosage should not exceed 7.5 mg once daily when coadministered with potent CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, nefazodone). Caution should be used when Darifenacin is coadministered with medications that are predominantly metabolized by CYP2D6 and have a narrow therapeutic window (eg, tricyclic antidepressants, flecainide, thioridazine).

Source:<http://www.medscape.com/pages/sites/info/site/enablex/article-faq#10>

FDA approves Inhaled Insulin
“Exubera” for Type 1 and 2 Diabetes.

Exubera, an inhaled insulin, was approved on 27/01/06 by the FDA for adults with types 1 or 2 diabetes, marking the first new delivery system for insulin since it was developed “Exubera is a rapid-acting, dry powder human insulin that is inhaled through the mouth into the lungs prior to eating, using the handheld Exubera Inhaler, Exubera would be available by mid-year”, said Pfizer.

The FDA noted that the safety and efficacy of Exubera have been studied in approximately 2,500 adult patients with type 1 and type 2 diabetes. In clinical studies, said the FDA, peak insulin levels were achieved at 49 minutes (range 30 to 90 minutes) with Exubera inhaled insulin, compared with 105 minutes (range 60 to 240 minutes) for short-acting insulin. In type 1 diabetes, inhaled insulin may be added to longer acting insulins as a replacement for short-acting insulin taken with meals, said the FDA. In type 2 diabetes, inhaled insulin may be used alone, along with oral non-insulin pills that control blood sugar, or with longer acting insulins.

Exubera, said the FDA, should not be used by smokers, or those who quit smoking in the previous six months. It was also contraindicated for patients with asthma, bronchitis, or emphysema. The FDA recommended baseline tests for lung function before treatment begins, and the agency said they should be repeated every six to 12 months thereafter. Exubera is a product of collaboration between Pfizer and Nektar Therapeutics. Pfizer recently reached an agreement to acquire the Sanofi-Aventis worldwide rights to Exubera. The two companies were previously in a worldwide alliance to co-develop, co-promote and co-manufacture Exubera.

Source:<http://www.medpagetoday.com/ProductAlert/Prescriptions/tb2/2573?pf=101&spc=239>

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