

New Drug Approvals for the Month of April, 2010

The drugs listed below have recently been approved by the Food and Drug Administration (FDA). These products may not yet be available at pharmacies. Most drugs reach the market place very quickly after approval. However, there are situations where the availability of a newly approved drug could be delayed.

Brand Medications

The FDA considers these to be new drug products. No generic equivalents are available.

Brand-name drug	Description
Oxycontin	New formulation of Oxycontin CR, designed to help discourage misuse and abuse of the medication.
Pancreaze	For the treatment of exocrine pancreatic insufficiency due to such conditions as cystic fibrosis.
Oravig	New antifungal buccal tablet for the treatment of oral thrush.
Vimpat	New oral solution of existing medication for the treatment of partial-onset seizures.
Hyphanox	New brand of existing antifungal (itraconazole) for the treatment of fungal toenail infections.
Vimovo	New combination drug of two existing drugs (naproxen and Nexium) for the relief of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis; as well as, to decrease the risk of ulcers in patients at risk of developing NSAID-associated ulcers.

First Time Generic Medications

These drug products are new generic equivalents to the Brand drug listed.

Brand-name drug	Generic Option	Description
Cozaar	Losartan	For the treatment of hypertension, diabetic nephropathy, proteinuria and for stroke prophylaxis.
Hyzaar	Losartan/HCTZ	For the treatment of hypertension and for stroke prophylaxis.
Mirapex 0.75mg	Pramipexole 0.75mg	New strength for existing drug (Pramipexole) for the treatment of Parkinson's disease and Restless Legs Syndrome (RLS).
Tofranil PM	Imipramine Pamoate	For the treatment of major depression, including patients with schizophrenia or psychosis.
Augmentin XR	Amoxicillin/Clavulanate potassium XR	For the treatment of certain types of bacterial infections.
Desoxyn	Methamphetamine	For the treatment of ADHD.
Vfend	Voriconazole	For the treatment of certain types of systemic fungal infections.

Specialty Medications

The FDA considers these to be new drug products.

Brand-name drug	Description
Tarceva	New indication added for existing drug: approved as <i>maintenance</i> treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC).
Zortress	For prophylaxis of organ rejection in adults receiving a kidney transplant.
Provenge	New therapeutic vaccine for the treatment of prostate cancer.