

# First Time Generic (Rx-to-OTC) Market Entry

## Estimated Dates

As of July 2011

**Note: Estimated dates are subject to change due to patent litigation, additional patents, exclusivities...**

**Year -- Period -- Brand Name -- Generic name -- Common use(s)**

- 2012 1Q (Mar) *Avandaryl*® glimepiride/rosiglitazone Type 2 diabetes
- 2012 1Q (Mar) *Avapro*® irbesartan High blood pressure
- 2012 1Q (Mar) *Avalide*® irbesartan/hydrochlorothiazide High blood pressure
- 2012 2Q (Apr) *Provigil*® modafinil Excessive sleepiness
- 2012 2Q (May) *Plavix*®3 clopidogrel (approved 1/06 and briefly launched 8/06) Prevent blood clots
- 2012 2Q (May) *Viramune*® nevirapine HIV infection
- 2012 2Q (Jun) *Lescol*® and *Lescol*® XL fluvastatin High cholesterol
- 2012 3Q (Jul) *Tricor*® fenofibrate High cholesterol
- 2012 3Q (Aug) *Singulair*® montelukast Asthma, allergysymptoms
- 2012 3Q (Aug) *Actos*® pioglitazone Type 2 diabetes
- 2012 3Q (Aug) *Xopenex*® (not HFA)4 levalbuterol inhalation solution Asthma
- 2012 3Q (Sep) *Revatio*® sildenafil Pulmonary arterial hypertension
- 2012 3Q (Sep) *Diovan*® and *Diovan*® HCT5 valsartan and valsartan/hydrochlorothiazide High blood pressure
- 2012 3Q (Sep) *Detrol*® tolterodine Overactive bladder
- 2012 4Q (Nov) *Lidoderm*® lidocaine topical patch Pain due to postherpetic neuralgia
- 2012 4Q (Dec) *Atacand*® and *Atacand* HCT® candesartan and candesartan/hydrochlorothiazide High blood pressure
- 2012 4Q (Dec) *Evoxac*® cevimeline Sjögren's syndrome
- 2012 4Q (Dec) *Maxalt*® and *Maxalt-MLT*® rizatriptan Migraines
- 2012 4Q (Dec) *Actoplus Met*® pioglitazone/ metformin Type 2 diabetes
- 2013 1Q (Jan) *Opana*® ER oxymorphone extended-release tablet (previously approved, not launched 6/10) Pain
- 2013 1Q (Jan) *Zometa*® zoledronic acid injection Hypercalcemia of malignancy, reduce bone complications from cancer
- 2013 1Q (Mar) *Valcyte*® valganciclovir Viral infections
- 2013 2Q (May) *Zomig*® zolmitriptan Migraines

- 2013 2Q (Jun) *Fosamax Plus D*<sup>TM</sup> alendronate / cholecalciferol Osteoporosis
- 2013 2Q (Jun) *Vivelle-DOT*<sup>®</sup> estradiol extended-release film Menopausal symptoms
- 2013 2Q (Jun) *Rilutek*<sup>®</sup> riluzole (generic approved, not launched 1/03) Amyotrophic lateral sclerosis
- 2013 3Q (Aug) *Temodar*<sup>®</sup>6 temozolomide (generic approved, not launched 3/10) Glioblastoma multiforme
- 2013 3Q (Sep) *Niaspan*<sup>®</sup> niacin extended-release tablet High cholesterol
- 2013 3Q (Sep) *Advicor*<sup>®</sup> lovastatin/niacin High cholesterol
- 2013 4Q (Nov) *AcipHex*<sup>®</sup> rabeprazole (tablets approved but not launched 2/07)
- 2013 4Q (Dec) *Cymbalta*<sup>®</sup> duloxetine Depression, anxiety, nerve/musculoskeletal pain, fibromyalgia
- 2014 1Q (Jan) *Rapamune*<sup>®</sup> sirolimus Prevent organ rejection
- 2014 1Q (Jan) *Micardis*<sup>®</sup> and *Micardis*<sup>®</sup> HCT telmisartan and telmisartan/hydrochlorothiazide High blood pressure
- 2014 1Q (Jan) *Loestrin*<sup>®</sup> 24 Fe7 ethinyl estradiol/ norethindrone Contraception
- 2014 1Q (Jan) *Asacol*<sup>®</sup> mesalamine delayed-release tablet Ulcerative colitis
- 2014 1Q (Feb) *Renagel*<sup>®</sup> sevelamer Chronic kidney disease
- 2014 1Q (Feb) *Avelox*<sup>®</sup> moxifloxacin Bacterial infections
- 2014 1Q (Mar) *Evista*<sup>®</sup> raloxifene Osteoporosis, reduce risk of breast cancer
- 2014 2Q (Apr) *Viracept*<sup>®</sup> nelfinavir HIV infection
- 2014 2Q (May) *Nexium*<sup>®</sup> esomeprazole GERD, ulcers
- 2014 2Q (May) *Celebrex*<sup>®</sup> celecoxib Pain \$1,497 2014 2Q (May) *Lunesta*<sup>®</sup> eszopiclone Insomnia
- 2014 2Q (Jun) *Actonel*<sup>®</sup>8 risedronate Osteoporosis
- 2014 2Q (Jun) *Xeloda*<sup>®</sup> capecitabine Colorectal, breast cancers
- 2014 2Q (Jun) *Tazorac*<sup>®</sup> gel Tazarotene gel Acne
- 2014 3Q (Jul) *Nasonex*<sup>®</sup> mometasone nasal spray Allergic rhinitis
- 2014 3Q (Aug) *Teveten*<sup>®</sup> eprosartan High blood pressure
- 2014 3Q (Aug) *Lumigan*<sup>®</sup> bimatoprost ophthalmic solution Glaucoma, ocular hypertension
- 2014 4Q (Nov) *Copaxone*<sup>®</sup> glatiramer injection Multiple sclerosis
- 2015 1Q (Jan) *Cipro*<sup>®</sup> HC ciprofloxacin/ hydrocortisone otic suspension Bacterial external and middle ear infections
- 2015 1Q (Jan) *Norvir*<sup>®</sup> ritonavir HIV infection
- 2015 1Q (Jan) *Namenda*<sup>®</sup> memantine (generic approved 4/14/10, not launched) Alzheimer's disease
- 2015 1Q (Feb) *Tarka*<sup>®</sup> trandolapril/verapamil High blood pressure
- 2015 1Q (Mar) *Hepsera*<sup>®</sup> adefovir dipivoxil Chronic hepatitis B
- 2015 1Q (Mar) *Sustiva*<sup>®</sup> efavirenz HIV infection
- 2015 1Q (Mar) *Renvela*<sup>®</sup> sevelamer Chronic kidney disease
- 2015 1Q (Mar) *Lovaza*<sup>®</sup> omega-3-acid ethyl esters High triglycerides
- 2015 2Q (Apr) *Namenda*<sup>®</sup> memantine oral solution Alzheimer's disease
- 2015 2Q (Apr) *Oxytrol*<sup>®</sup> oxybutynin extended release film Overactive bladder

- 2015 2Q (Apr) *Abilify*® aripiprazole Schizophrenia, bipolar disorder, autistic disorder, depression
- 2015 2Q (May) *Zyvox*® linezolid Bacterial infections
- 2015 2Q (May) *Avodart*® dutasteride Benign prostatic hyperplasia
- 2015 2Q (Jun) *WelChol*® colesevelam High cholesterol
- 2015 2Q (Jun) *Travatan*® and *Travatan Z*® travoprost ophthalmic solution Glaucoma, ocular hypertension
- 2015 3Q (Jul) *Aggrenox*® aspirin/dipyridamole extended-release capsule Prevent blood clots
- 2015 3Q (Jul) *Gleevec*® imatinib Chronic myeloid leukemia, gastrointestinal stromal tumors
- 2015 3Q (Aug) *AndroGel*® testosterone gel Low testosterone
- 2015 4Q (Oct) *Aloxi*® palonosetron Nausea, vomiting
- 2015 4Q (Dec) *Pataday*™ olopatadine ophthalmic solution Allergic conjunctivitis
- 2015 4Q (Dec) *Patanol*® olopatadine ophthalmic solution Allergic conjunctivitis
- 2015 4Q (Dec) *Combivent*® albuterol/ipratropium inhalation
- 2015 4Q (Dec) *Fuzeon*® enfuvirtide injection HIV infection
- 2015 4Q (Dec) *Coreg CR*® carvedilol extended-release capsules High blood pressure
- 2015 4Q (Dec) *Ortho Tri-Cyclen Lo*® ethinyl estradiol/ norgestimate Contraception
- 2016 2Q (May) *Ortho Evra*® ethinyl estradiol/ norelgestromin transdermal system Contraception
- 2016 2Q (Jun) *Focalin XR*® dexamethylphenidate extended-release capsule
- 2016 3Q (Jul) *Crestor*® rosuvastatin calcium High cholesterol
- 2016 4Q (Oct) *Benicar*® & *Benicar HCT* olmesartan & olmesartan/ High blood pressure
- 2016 4Q (Oct) *Spectracef*® cefditoren pivoxil Bacterial infections
- 2016 4Q (Oct) *Azor*® amlodipine 10mg/ olmesartan 20mg High blood pressure
- 2016 4Q (Dec) *Zetia*® ezetimibe High cholesterol
- 2017 1Q (Jan) *Sandostatin*® octreotide injection Acromegaly, carcinoid syndrome
- 2017 2Q (Apr) *Vytorin*® ezetimibe/simvastatin High cholesterol
- 2017 2Q (May) *Velcade*® bortezomib injection Multiple myeloma, lymphoma
- 2017 2Q (May) *Strattera*® atomoxetine
- 2017 2Q (Jun) *Relpax*® eletriptan Migraines
- 2017 2Q (Jun) *Tamiflu*® oseltamivir capsules Influenza
- 2017 3Q (Sep) *Cancidas*® caspofungin injection Fungal infections
- 2017 4Q (Dec) *Exforge*® amlodipine/valsartan High blood pressure
- 2018 2Q (May) *Cialis*® tadalafil Erectile dysfunction
- 2018 3Q (Sep) *Nitrostat*® nitroglycerin sublingual tablets Angina
- 2018 4Q (Oct) *NuvaRing*® ethinyl estradiol/ etonogestrel vaginal ring Contraception
- 2018 4Q (Oct) *Sensipar*® cinacalcet Hyperparathyroidism, hypercalcemia
- 2018 4Q (Nov) *Tarceva*® erlotinib Non-small cell lung cancer
- 2019 1Q (Jan) *Exelon Patch* rivastigmine extended-release film Alzheimer's disease
- 2019 1Q (Jan) *Tekturna*® and *Tekturna HCT*® aliskiren and aliskiren/hydrochlorothiazide High blood pressure

- 2019 2Q (May) *Vesicare*® solifenacin Overactive bladder
- 2019 2Q (Jun) *Reyataz*® atazanavir HIV infection
- 2019 2Q (Jun) *Lyrica*® pregabalin Fibromyalgia, nerve pain, seizures
- 2019 4Q (Oct) *Revlimid*® lenalidomide Multiple myeloma, myelodysplastic syndromes
- 2020 1Q (Mar) *Vigamox*® moxifloxacin ophthalmic solution Bacterial conjunctivitis
- 2020 2Q (Apr) *Bystolic*® nebivolol High blood pressure
- 2020 2Q (Apr) *Viagra*® sildenafil Erectile dysfunction
- 2020 2Q (May) *Detrol*® LA tolterodine Overactive bladder
- 2020 2Q (Jun) *Dexilant*® dexlansoprazole delayed-release capsule GERD, erosive esophagitis
- 2020 2Q (Jun) *Lialda*® mesalamine delayed-release tablet Ulcerative colitis
- 2020 3Q (Jul) *Byetta*® exenatide injection Type 2 diabetes
- 2020 4Q (Nov) *Chantix*® varenicline Smoking cessation
- 2021 2Q (May) *Zomig*® spray zolmitriptan nasal spray Migraines
- 2021 3Q (Aug) *Crixivan*® indinavir HIV infection
- 2021 3Q (Aug) *Sutent*® sunitinib Renal cell carcinoma, GIST, pancreatic neuroendocrine tumors
- 2021 3Q (Sep) *Truvada*® tenofovir/emtricitabine HIV infection
- 2022 2Q (Apr) *Oracea*® doxycycline Rosacea
- 2022 3Q (Aug) *Victoza*® liraglutide injection Type 2 diabetes
- 2023 2Q (May) *Boniva*® ibandronate Osteoporosis
- 2023 2Q (Jun) *Vyvanse*® lisdexamfetamine ADHD
- 2023 3Q (Sep) *Proair*® HFA albuterol inhalation Asthma
- 2023 4Q (Dec) *Thalomid*® thalidomide Multiple myeloma, erythema nodosum leprosum
- 2025 1Q (Jan) *Trilipix*® fenofibric acid High cholesterol
- 2026 4Q (Oct) *Janumet*® metformin/sitagliptin Type 2 diabetes
- 2026 4Q (Oct) *Januvia*® sitagliptin Type 2 diabetes
- 2027 1Q (Mar) *Spiriva*® tiotropium powder for inhalation

^ Dollar amount reflects combined sales of all strengths and formulations of the product, unless otherwise indicated; source IMS Health

1. Several companies have announced the settlement of patent litigation relating to Desloratadine Tablets, 5 mg (Clarinet). Pursuant to these settlements, the generic manufacturers will have the right to market Desloratadine Tablets, 5 mg, in the U.S. on July 1, 2012, or earlier in certain circumstances. Clarinet and Clarinet D will likely be switched to OTC availability prior to generic availability.

2. Lexapro's '712 patent was originally slated to expire in December 2009, which included an additional six months of pediatric exclusivity. The U.S. Patent & Trademark Office granted the patent an 828-day extension in March 2006. Therefore, the estimated date for generic availability changed to March 2012. A recent patent litigation decision has also sided with Forest, upholding the validity of a key patent on Lexapro and keeping generics off the market until patent expiration in 2012.

3. Generic Plavix was approved 1/20/06 with paragraph IV certification giving Apotex 180-day exclusivity. Apotex launched their generic "at risk" on August 8, 2006. A preliminary injunction was granted on August 31, ordering Apotex to halt its sales of

generic Plavix. The judge did not require Apotex to recall clopidogrel that had already been distributed. Bristol-Myers Squibb/Sanofi's patent infringement trial against Apotex began January 22, 2007.

4. Mylan launched their first-time generic for Xopenex inhalation solution 0.25% with 180 day exclusivity in September 2009. In April 2008, Breath Limited received FDA approval for their generic Xopenex inhalation solution 0.021%, .0042%, and 0.0103%. Sepracor settled a patent dispute with them which will allow Breath to market generic versions of the drug beginning August 2012 with a 180-day exclusive license. In March 2009, Sepracor entered into a Settlement and License Agreement with Teva and Barr. The agreement permits Barr and Teva to launch generic versions of Xopenex inhalation solution dosages under terms of a non-exclusive license commencing on February 17, 2013.

5. Diovan received pediatric exclusivity, extending the drug's patent protection in the US until September 2012.

6. Patent litigation is ongoing between Teva and Merck with regard to Temodar. The U.S. Court of Appeals for the Federal Circuit court is reviewing an appeal by Merck. If the Appeals court agrees that Merck's patent for Temodar is unenforceable, Teva may launch their generic at any time.

[Source: [http://www.medcohealth.com/art/corporate/anticipatedfirsttime\\_generics.pdf](http://www.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf) Aug 2011 ++]