

Formulary Update – Topamax® Capsules & Tablets

Issue

On March 27, 2009, the U.S. Food and Drug Administration (FDA) approved generics to Ortho-McNeil-Janssen Pharmaceuticals Topamax® (topiramate), a medication commonly for the treatment of seizures and prevention migraines. Generics are now available to the 15mg and 25mg sprinkle capsules and the 25mg, 50mg, 100mg and 200mg tablets.

Now that generics are established in the marketplace, Express Scripts will enact a procedure that will result in the removal of the brand Topamax from Express Scripts formularies, replacing them with equivalent generic topiramate tablets. This procedure is being enacted because Topamax is marked with an '*' on the formularies, indicating a potential conversion to non-formulary status with the availability of generics.

Take-Away Points

- Generic topiramate are AB-rated generics to Topamax® and are now available in the marketplace.
- The brand-name product, Topamax, will be converted to non-formulary status on May 15, 2009.
- This procedure is being enacted because Topamax is marked with an '*' on the formularies, indicating a potential for conversion to non-formulary status with the availability of generics.

In addition to Topamax, several other drugs are scheduled to lose patent protection in 2009. The drugs listed in the table below are some of the drugs that will also be designated as "non-formulary" when generics are established in the market. However, keep in mind that although a key drug patent expires, generic products are not always readily available. There are many issues that may delay their availability, including litigation, patent settlements, final approval from FDA, and additional patents and granted exclusivities.

Drug	Therapeutic class	Patent expiration
Adderall XR (Mixed Amphetamine Salts – Shire)	ADHD	April 1
Cardizem LA (diltiazem e.r. – Biovail)	High Blood Pressure	April 1
CellCept (mycophenolate – Roche)	Transplant	May 3
Prandin (repaglinide – Novo Nordisk)	Diabetes	September 14
Alphagan P (brimonidine – Allergan)	Glaucoma	September 15
Allegra-D® (fexofenadine/pseudoephedrine – sanofi-aventis)	Allergies	November 1
Acular (ketorolac – Allergan)	Anti-inflammatory	November 5
Prevacid Naprapac (lansoprazole/naproxen – Takeda)	Ulcers	November 10
Activella (estradiol/noreth ac – Novo Nordisk)	Hormone replacement therapy.	December 28
Valtrex (valacyclovir – GlaxoSmithKline)	Viral Infections	4 th Quarter
Ambien CR (zolpidem e.r. – sanofi-aventis)	Sleep	Litigation
Concerta (methylphenidate e.r. – Johnson & Johnson)	AHDH	Litigation
Dynacirc CR (isradipine e.r. – GlaxoSmithKline)	High Blood Pressure	Expired*
Lovenox (enoxaparin – sanofi-aventis)	Anticoagulant	Citizen's Petition
Protopic (tacrolimus – Astellas)	Atopic Dermatitis	Expired*
Skelaxin (metaxalone – King)	Muscle relaxant	Citizen's Petition

* Generics not available

