



# Compliance Alert

January 29, 2008

## **Express Scripts Formulary Update – Colazal® Tablets Emerging Therapeutics**

Updated: January 25, 2008

On December 28, 2007, the U.S. Food and Drug Administration (FDA) approved AB-rated generics to Salix Pharmaceuticals' Colazal (balsalazide) capsules, a product used for the treatment of ulcerative colitis. Currently, several manufacturers are supplying generic balsalazide capsules to the market.

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

### ***Take-Away Points***

- Generic balsalazide capsules are AB-rated generics to Colazal® capsules and are now available in the marketplace.
- The brand-name product, Colazal capsules, will be converted to non-formulary status on March 1, 2008.
- This procedure is being enacted because Colazal is marked with an '\*' on the formularies, indicating a potential for conversion to non-formulary status with the availability of generics.

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In addition to Colazal, several other drugs are scheduled to lose patent protection in 2008. The drugs listed in the table below 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, final approval from FDA, and additional patents and granted exclusivities.

Drug – Therapeutic Class – Patent Expiration

Allegra-D® (fexofenadine/pseudoephedrine – sanofi-aventis) Allergies	Expired*
CiproDex ( ciprofloxacin/dexamethasone Otic – Alcon) Infection	February 11, 2008
Concerta® (methylphenidate, e.r. – McNeil PPC) ADHD	Expired*
Cosopt (dorzolamide/timolol – Merck) Glaucoma	October 28, 2008
Depakote (divalproex – Abbott) Seizures	July 29, 2008
Dynacirc CR (isradipine e.r. – Reliant) Blood Pressure	July 9, 2008
Fosamax (alendronate – GlaxoSmithKline) Osteoporosis	February 6, 2008
Imitrex (sumatriptan – GlaxoSmithKline) Migraines	4 <sup>th</sup> Quarter 2008
Kytril (granisetron – Roche) Antiemetic	Expired*
Lamictal (lamotrigine – GlaxoSmithKline) Seizures	2 <sup>nd</sup> half of 2008
Metadate CD® (methylphenidate e.r. – UCB) ADHD	Expired*
Ortho Tri-Cyclen Lo (norgestimate/EE – J&J) Oral contraceptive	Litigation
Protopic (tacrolimus topical – Astellas) Atopic dermatitis	April 8, 2008
Risperdal (risperidone – Johnson & Johnson) Antipsychotic	June 29, 2008
Trusopt (dorzolamide – Merck) Glaucoma	October 28, 2008
Wellbutrin XL 150 mg (bupropion e.r. – GlaxoSmithKline) Depression	2008

# Generics not yet available

***This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.***

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