

Updates for *Essentials of Nonprescription Medications and Devices* December 2014

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Chapter	Page	Heading/subheading	Update
3	39	Proton Pump Inhibitors	<p>New Products: The FDA approved the switch of esomeprazole 20 mg from Rx to OTC status on March 28, 2014. Pfizer, the manufacturer, markets esomeprazole as Nexium 24HR. Esomeprazole is classified as a proton pump inhibitor (PPI) of gastric acid secretion. It has the same indications, treatment of frequent heartburn, for use as the two other approved PPIs, omeprazole (Prilosec OTC) and lansoprazole (Prevacid 24 HR). The definition of frequent heartburn is the occurrence of heartburn symptom 2 or more times a week. The dose for esomeprazole for individuals over 18 years of age is 20 mg once a day for a maximum of 14 days.</p> <p>Both esomeprazole and lansoprazole should not be used by individuals who have liver disease or who may be vomiting blood or passing bloody or dark stools. There are significant drug interactions and individuals taking warfarin, oral antifungal drugs, digoxin, tacrolimus, and antiviral drugs for HIV infections should consult their healthcare professional before use. Esomeprazole also has drug interactions with theophylline.</p> <p>References:http://www.nexium24hr.com/about?gclid=CJK1uM6Xtr4CFYFQOgodtRgAzg. Accessed April 14, 2014. http://www.walgreens.com/search/results.jsp?NH-Prevacid24HR. Accessed December 20, 2014.</p>
4	71	Antihistamines: Products	<p>New Product: Mucinex Allergy contains the antihistamine fexofenadine which is indicated for relief of allergy symptom, including runny nose, watery, itchy eyes, sneezing, and nasal congestion. This product's name may cause confusion because all previous Mucinex products contain guaifenesin which is used as an expectorant in the treatment of symptoms for coughs and colds.</p> <p>Note: Description and directions for use of fexofenadine appear in the Update submitted for June 2011.</p>

	72		<p>Reference: http://www.drugstore.com/mucinex-allergy-24-hour-adult-tablets/qxp518675?catid=183018. Accessed May 18, 2014.</p> <p>New Product: Clear Quil is an addition to the list that contain loratadine, an antihistamine, used for relief of allergy symptoms.</p> <p>New product formulation: Zyrtec Dissolve Tablets Citrus 10 mg. This product is the same as Zyrtec Tablets 10 mg, but the tablet dissolves in the mouth and has a citrus flavor. The directions for use and the drug warnings are the same as listed on page 72.</p> <p>Reference: www.drugstore.com/zyrtec-dissolve-tablets-citrus/qxp5148477catid?=183018. Accessed June 4, 2014.</p>
4	73	Allergies/ Glucocorticoids (New Category)	<p>Triamcinolone acetonide was approved as a Rx-to-OTC switch by the FDA for the temporary relief of nasal allergy symptoms and is now available as Nasacort Allergy 24 HR. This drug represents a new pharmacological mode of action to prevent allergy symptoms and is usually much more effective than antihistamines.</p> <p>The body's response to an allergen results in the activation of the immune system with the release of histamine, leukotriene, and other inflammatory mediators. Antihistamines acts by blocking the receptor sites in tissues, preventing histamine and relieving allergy symptoms.</p> <p>Glucocorticoids suppress the immune response, thus preventing the symptoms associated with allergic reactions in a more effective manner. This product is used as a nasal spray once a day, providing relief from nasal congestion, runny nose, watery secretions, itching and sneezing. It is most effective when used prior to expose of the allergen. Triamcinolone does not cause drowsiness like most antihistamines.</p> <p>The warnings for proper use of triamcinolone and all glucocorticoids are extensive because the suppression of the immune system that may result in more serious health issues. Individuals should consult their doctor before using triamcinolone if they have:</p>

1. been exposed to people infected with chicken pox;
2. measles or tuberculosis;
3. any infection (persistent fever)
4. any vision changes while taking triamcinolone;
5. recent nose ulcers, nose surgery, severe or frequent nose bleeds;
6. been using any prescription steroid drugs for asthma, allergy or skin rashes;
7. any eye infections, glaucoma or cataracts

Triamcinolone is only approved for the relief of symptoms due to allergy. It is not to be used for treating the common cold.

When using a new bottle of Nasacort 24 HR spray or a bottle that has not been used for for 2 weeks, the bottle must be primed before use. This means that the first couple of sprays should not be inhaled because they will not contain a full dose of triamcinolone.

Adults and children over 12 years of age should inhale 2 sprays in each nostril once a day. Relief may occur in a day or two but may take as long and 1 week. The dose may be reduced to one spray daily. If there is no relief of symptoms after one week, the doctor should be consulted. The drug is not to be sprayed into the eyes or mouth.

Children between 6 and 12 years old should only use one spray per nostril under supervision by an adult. Only one spray a day should be used for the first week. If there is no symptomatic relief, two sprays per nostril may be used for the second week, and then reduced to one spray per nostril. If there is no improvement of symptom after 2 weeks, the doctor should be consulted.

Reference: FDA Approves over-the-counter Nasacort Allergy 24 HR to treat hay fever and nasal allergies. Available at:
<http://fda.gov/drugs/newsevents/ucm/370973.htm>.
<http://nasacort.com/how-to-use.aspx#simple-instruction>. Accessed: May 18, 2014.

4	73	Decongestants	<p>The FDA approved Flonase Allergy on July 24, 2014 as a nasal spray containing 50 mcg fluticasone propionate. This product is also a glucocorticoid. It will not be on the market until the spring of 2015. GlaxoSmithKline, the manufacturer, has not yet released the drug information label for the product.</p> <p>Reference: http://gsk.cpm/en-us/media.press-releases/2014/fda-approves-flonase-allergy-relief-for-sale-over-the-counter-in-the-united-states/ Accessed August 12, 2014.</p> <p>Westport Pharmaceuticals released a new formulation of pseudoephedrine, Zephrex-D, for use as an oral decongestant in the spring of 2014. The manufacturer claimed the new formulation made it extremely difficult for diversion for methamphetamine production. The product was intended for OTC sale without the restrictions required for pseudoephedrine products already on the market. Current restrictions for sale of pseudoephedrine include an individual be over the age of 18, presentation of photo identification, and signature in a register that is kept in the pharmacy. The Drug Enforcement Agency (DEA) stopped the OTC sale of Zephrex-D in December 2014, claiming that the product is able to be converted to methamphetamine even though it may be difficult.</p> <p>Reference: http://www.medicaldaily.com/dea-halts-over-the-counter-sales-cold-and-allergy-drug-zephrex-d-use-methamphptamine-still-possible. Accessed December 21, 2014.</p>
8	160 163	Table 8.3 and Insect bite and sting treatment	<p>New product: Allegra Intensive Relief Anti-itch cream. This product contains diphenhydramine, a topical antihistamine. This product's name may cause confusion because all previous Allegra products contain the oral antihistamine fexofenadine, and are indicated only for the relief of allergy symptoms.</p> <p>Reference: http://www.drugstore.com/allegra-intensive-relief-anti-relief-cream.qxp464157?catid=195677. Accessed May 18, 2014.</p>