

LDI Specialty Drug News

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Internet Medication Purchases - Buyer Beware

The FDA cannot warn consumers enough about the potential hazards of purchasing medications on-line from sources that may not be reputable. Prescription and even over-the-counter drugs may not be safe and could put people's health at risk.

When consumers purchase medication on-line from a company they are not familiar with they may not know what they are actually getting. Most web-sites do operate legally and offer convenience and savings but there are disreputable sites that do not operate within the law. Even though the website may look professional and have all the bells and whistles of being legitimate, buyers need to do their research to make sure they are not being scammed.

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One way consumers can verify if a website is reputable is by checking for the VIPPS-approved seal. VIPPS is the National Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practice Sites Seal. Only sites that meet the state licensure requirements and other VIPPS criteria receive the seal. Legitimate pharmacies that carry the VIPPS seal are listed on their website at www.vipps.info.

Safe web sites should have the following criteria:

- Be located in the United States
- Be licensed by the state of board of pharmacy where the web site is operating (visit www.nabp.info for a list of state boards of pharmacy)
- Have a licensed pharmacist available to answer questions
- Require a prescription from your doctor or other health care professional who is licensed to prescribe medicines
- Provide contact information and allow you to talk to a person if you have problems or questions

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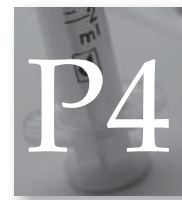
High Cost of Treating Glaucoma



Mail Order and Generics Provide a "One-Two" Punch



January Awareness Month



Upcoming Generics

High Cost of Treating Glaucoma

Physicians have a number of factors to take into consideration when treating patients with glaucoma.

Not the least of which is cost. Glaucoma medications can range anywhere from \$150.00 per year for generics all the way up to \$838.00 per year for branded medications.

In the United States, direct costs for management of glaucoma run about \$1.9 billion. It is estimated that 38% to 52% of that amount is for prescription medications.

The goal of healthcare providers is to give the best, most cost-effective care to their glaucoma patients. However, by requesting and utilizing generics as first-line treatment patients have the opportunity to lower their overall out-of-pocket costs while still maintaining a high standard of care.

Mailorder and Generics Provide a “One-Two” Punch

Pick up any healthcare publication now days and you can almost bet that it features an article on the rising costs of prescription drugs. Self-funded employer groups walk a thin line as it relates to providing a good prescription benefit yet still maintaining a viable plan.

Statistics show that in the United States a total of 3,309,155,973 prescriptions were filled at retail pharmacies in 2006. Mail order pharmacies accounted for only 232 million prescriptions or 6.8% of the overall total of prescriptions filled.*

Member education about the advantages of utilizing mail order pharmacy to fill maintenance medications should be a top priority of employer groups. The member takes advantage of the convenience of 90-days of medication delivered directly to their home and the plan benefits from the deeper discounts available through mail service.

Healthcare plans also should not overlook the fact that generic drugs offer significant savings over branded medications. Educating participants to the fact that generic drugs share the same quality, strength and safety as branded drugs will help drive patients to select generics over brand. The only difference between brand and generics is in the price and appearance.

Why are generic drugs more cost effective? Generic manufacturers don't have the investment cost necessary for the development of a new drug. Branded drugs are developed under patent protection. The patent protects the investment of the drug including all the research, development, marketing, and promotion-by giving the manufacturer sole right to sell the drug while the patent is in effect. Generic manufacturers do not have the same development cost, therefore they can sell the drugs at a substantial discount. Competition from other generic manufacturers also keeps the cost down.

The following are frequently asked questions about generics from the FDA website:

1. What are generic drugs?

A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.

2. Are generic drugs as safe as brand-name drugs?

Yes. FDA requires that all drugs be safe and effective. Since generics use the same active ingredients and are shown to work the same way in the body, they have the same risks and benefits as their brand-name counterparts.

3. Are generic drugs as strong as brand-name drugs?

Yes. FDA requires generic drugs to have the same quality, strength, purity and stability as brand-name drugs. *continued - page 3*

*Source: Kaiser and FDA

**JANUARY
AWARENESS**

-Glaucoma Awareness

-Birth Defects Prevention Month

-Volunteer Blood Donor Month

Continued - Mailorder and Generics Provide a “One-Two” Punch -

4. Do generic drugs take longer to work in the body?

No. Generic drugs work in the same way and in the same amount of time as brand-name drugs.

5. Are brand-name drugs made in more modern facilities than generic drugs?

No. Both brand-name and generic drug facilities must meet the same standards of good manufacturing practices. FDA won't permit drugs to be made in substandard facilities. FDA conducts about 3,500 inspections a year to ensure standards are met. Generic firms have facilities comparable to those of brand-name firms. In fact, brand-name firms are linked to an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name.

6. If brand-name drugs and generic drugs have the same active ingredients, why do they look different?

In the United States, trademark laws do not allow a generic drug to look exactly like the brand-name drug. However, a generic drug must duplicate the active ingredient. Colors, flavors, and certain other inactive ingredients may be different.

7. Does every brand-name drug have a generic counterpart?

No. Brand-name drugs are generally given patent protection for 20 years from the date of submission of the patent. This provides protection for the innovator who laid out the initial costs (including research, development, and marketing expenses) to develop the new drug. However, when the patent expires, other drug companies can introduce competitive generic versions, but only after they have been thoroughly tested by the manufacturer and approved by the FDA.

8. What is the best source of information about generic drugs?

Contact your physician or pharmacist. You can also visit the FDA website at <http://www.fda.gov/cder/ogd/index.htm>.

9. What is Generic Initiative for Value and Efficiency (GIVE)?

On October 4, 2007, FDA launched the GIVE program. The initiative will use existing resources to help FDA modernize and streamline the generic drug approval process.

For information on how LDI Integrated Pharmacy Services can help you or your plan save healthcare dollars by utilizing mail order and generics, please contact us at (866) 516-2121 ext. 189.

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Unsafe web sites:

- Typically don't know your medical history or the details about your current illness or condition
- Send you drugs with unknown quality or origin
- Could give you the wrong medicine or another dangerous product for your illness
- May sell prescription drugs even without a prescription – which is against the law
- May not protect your personal information

Wise consumers know their medicine. Before getting a new medicine for the first time, talk to your physician or your local pharmacist about the medication. In addition:

- Any time you get a prescription refilled, check the physical appearance: color, texture, and shape of the drug. Even if all of these characteristics appear to be okay, there may be a problem if the medication doesn't taste like it has in the past.
- Pay special attention to altered or unsealed containers or changes in product packaging.
- Alert your pharmacist, or whoever is providing treatment, if you notice any differences or anything unusual about the product packaging.
- Make sure that you only use drugs that have been prescribed by your doctor who is licensed in the United States to prescribe medications.

Patients need to be aware that some medicines sold online:

- Are too old, too strong or too weak
- Aren't FDA approved
- Aren't made using safety standards
- Aren't safe to use with other medicines or products
- Aren't labeled, stored, or shipped correctly.

Counterfeit drugs are another huge concern when purchasing medications over the internet. These are fake or copycat medicines that are extremely difficult to identify. The deliberate and fraudulent practice of counterfeiting drugs can apply to both brand and generic medication. Counterfeit drugs may:

- Be contaminated
- Not help the condition or disease the medicine is intended to treat
- Lead to dangerous side effects
- Contain the wrong active ingredient
- Be made of the wrong amounts of ingredients
- Contain no active ingredients at all or contain too much of an active ingredient
- Be packed in phoney packaging that looks legitimate

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Examples of counterfeit drugs identified by the FDA purchased over the internet were:

- Ambien
- Xanax
- Lexapro
- Ativan

Instead of the intended drug, several consumers received a product that contained haloperidol, a powerful anti-psychotic drug. This resulted in emergency medical treatment for symptoms such as difficulty breathing, muscle spasms and muscle stiffness – all problems that can occur with haloperidol. Another example was a consumer who purchased drugs over the internet who was told that the products were manufactured in the United States and were being sold from Canada. The drugs he actually received were fake “knockoffs” from India.

The best advice is to protect yourself.

- Only buy from state-licensed pharmacy sites based in the U.S. (preferably from VIPPS-certified sites, when possible).
- Don't buy from sites that sell prescription drugs without a prescription from your doctor.
- Don't buy from sites that offer to prescribe a medication for

the first time without a physical exam by your doctor.

- Check with your state board of pharmacy or the NABP to see if an online pharmacy has a valid pharmacy license and meets state quality standards.
- Sites ending in “.com” are usually commercial sites selling products (they may or may not be legitimate). Sites that end in “.gov” (government), “.edu” (universities or medical schools), or “.org” (not-for-profit groups) may be good sources of health information.
- Use legitimate web sites that have a licensed pharmacist to answer your questions.
- Look for privacy and security policies that are easy to find and easy to understand.
- Don't give any personal information, such as social security number, credit card information, or health history, unless you are sure the web site will keep your information safe and private.
- Make sure that the site will not sell your personal information, unless you agree.
- Report web sites that may be problematic at www.fda.gov/buyonline and click “Notify FDA about problem websites.”

For a list of drugs that you should NOT buy online because of specialty safety restrictions, visit www.fda.gov/cder/consumer-info/dontBuyonNet.htm

Upcoming Generics

2008 is a big year for medications that will be losing their patent. The following reflects which drugs will be coming off patent this year and their indication for use:

Brand Drug Name	Indication for Use
Advair	Asthma
Altace	Hypertension
Camptosar	Colon Cancer
Depakote	BiPolar Disorder, Migraine, Epilepsy
Dovonex	Psoriasis
Effexor XR	Major Depressive Disorder
Fosamax	Osteoporosis
Imitrex	Migraine
Kytril	Chemo/Radiation Induced Nausea
Paxil CR	Depression, Panic Disorder
Prograf	Organ Transplant Rejection

Brand Drug Name	Indication for Use
Pulmicort	COPD, Asthma
Reminyl	Dementia
ReQuip	Restless Leg Syndrome
Risperdal	Schizophrenia
Sarafem	Pre-menstrual Dysphoric Disorder
Serevent	Asthma
Sonata	Insomnia
Trusopt	Glaucoma
Wellbutrin XL	Depression
Zerit	HIV
Zymar	Conjunctivitis

Disclaimer: The information provided has been compiled from a variety of sources and is for informational purposes only. This information should not be relied upon solely for decision making purposes. Factors affecting the accuracy of this information include but is not limited to the difficulty in predicting the timing and outcome of legal proceedings: patent related matters such as patent challenge settlements and patent infringement cases; the outcome of litigation arising from challenging the validity or non-infringement of patents covering products; the difficulty of predicting the timing of FDA approvals; court and FDA decisions on exclusivity periods; the ability of competitors to extend exclusivity periods for their products; at risk generic launches; originator manufacturers launching authorized generics prior to patent expiration.

For more information regarding LDI's Specialty Newsletter, please contact us:

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Specialty Medication Listing by Disease/Condition

AIDS/HIV

Daunoxome
Doxil
Intron A
Roferon-A
Serostim
Taxol
Fuzeon

Alpha1 - Proteinase Inhibitor Deficiency

Aralast
Prolastin
Zemaira

Antihemophilic Agents

Antihemophilic Factor
Advate
Alphanate
Bioclote
Helixate FS
Hemofil M
Humate P
Hyate C
Koate DVI
Kogenate FS
Monarc M
Monoclate P
Recombinate
ReFacto

Anti-nausea

Aloxi
Anzemet
Emend
Kytril
Zofran

Asthma

Xolair

Cancer/Related

Adriamycin
Adrucil
Alkeran
Aredia
Avastin
BiCNU
Blenoxane
Busulfex
Campath
Camptosar
Cerubidine
Cosmegen
Cytarabine
Cytoxan
Depocyt

Doxil
DTIC-Dome
Eligard
Ellence
Erbitux
Ethyol
Faslodex
Fludara
Gemzar
Gleevec
Herceptin
Hycamtin
Idamycin
IFEX
Intron A
Leucovorin
Leukine
Leustatin
Lupron Depot
Lupron Depot-Ped
Mesnex
Mustargen
Mutamycin
Mylotarg
Navelbine
Nexavar
Nipent
Novantrone
Oncaspar
Ontak
Paraplatin
Platinol AQ
Proleukin
Rituxan
Roferon-A
Sutent
Tarceva
Taxol
Taxotere
Temodar
Thyrogen
Toposar
Trelstar Depot
Trelstar LA
Trisenox
VePesid
Vinblastine
Vincasar
Vumon
Xeloda
Zanosar
Zoladex
Zometa

Contraceptives

Depo-Provera

Crohn's Disease

Remicade

Dystonia

Botox
Myobloc

Factor IX Concentrates

Alphanine SD
Benefix
Mononine
Profilnine SD
Proplex T
Bebulin VH

Gaucher's Disease

Ceredase
Cerezyme
Zavesca

Growth Hormone Deficiency

Genotropin
Humatrope
Norditropin
Nutropin
Nutropin AQ
Saizen

Hematologics

Arixtra
Aranesp
Epogen
Fragmin
Innohep
Lovenox
Neulasta
Neumega
Neupogen
Procrit

Hepatitis C

Copegus
Infergen
Intron A
Pegasys
Peg-Intron
Rebetron
Roferon-A

Hormone Deficiency

Delatestryl
Delestrogen
Depo-Estradiol
Depo-Testosterone

Hunter Syndrome

Elaprase

Primary Immunodeficiency

Carimune NF
Gamimune N
Gammagard S/D
Gammar-P
Gamunex
Iveegam EN
Panglobulin
Panglobulin NF
Polygam S/D
Venoglobulin-S

Miscellaneous

Alferon-N
Milrinone
Zincard

Multiple Sclerosis

Avonex
Betaseron
Copaxone
Novantrone
Rebif
Tysabri

Osteo/ Rheumatoid/ Psoriatic Arthritis

Enbrel
Humira
Hyalgan
Kineret
Orencia
Remicade
Supartz
Synvisc

Osteoporosis

Forteo
Miacalcin

Psoriasis

Amevive
Enbrel
Raptiva
Remicade

Respiratory Syncytial Virus

Synagis

Rh Hemolytic Disease

BayRho-D
Micro-Rhogam
Rhogam
WinRho-SDF