ISSN 2230 – 8741

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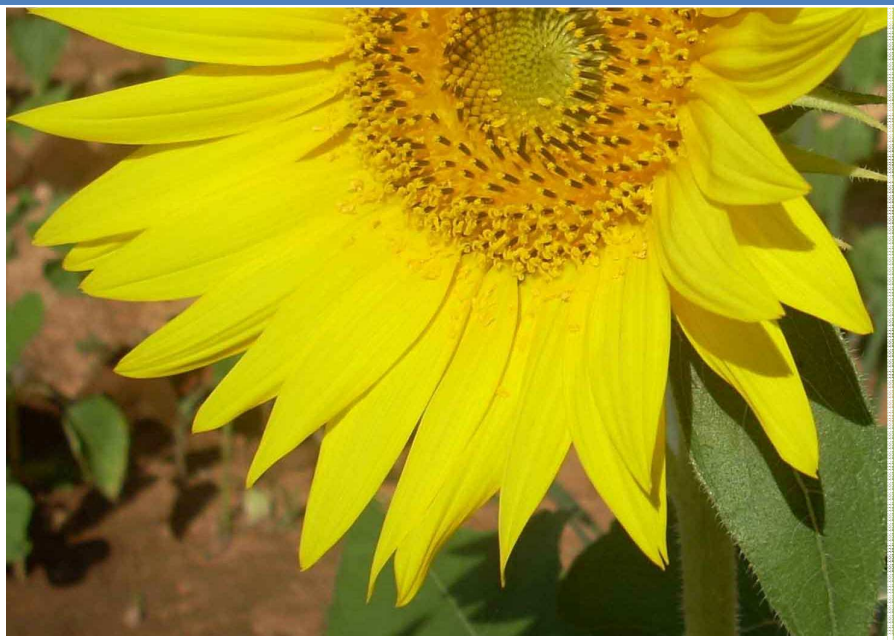

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RIPER PDIC Bulletin, June 2012, Volume 3, Issue 23

RIPER PDIC Bulletin

RIPER Poison & Drug Information Center (PDIC),

RDT HOSPITAL, Bathalapalli, A.P. &

Raghavendra Institute of Pharmaceutical Education and Research

(RIPER)

VOLUME 3, ISSUE 23

JUNE 2012

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RIPER PDIC Bulletin

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Editorial

ISPOR India - Andhra Pradesh Regional Chapter

With pleasure, I would like to inform you that we have started the ISPOR India - Andhra Pradesh Regional Chapter. International Society of Pharmacoeconomics and Outcomes Research (ISPOR) founded by Marilyn Dix Smith in 1995. ISPOR promotes the science of pharmacoeconomics *(health economics)* and outcomes research *(the scientific discipline that evaluates the effect of health care interventions on patient well-being including clinical, economic, and patient-centered outcomes)* and facilitates the translation of this research into useful information for healthcare decision-makers to increase the efficiency, effectiveness, and fairness of health care to improve health.

Sincerely yours,

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ypreddyatp@rediffmail.com

Join ISPOR

We invite the professionals in Andhra Pradesh who are working in the area of Pharmacoeconomics and outcomes research to join in our regional chapter of ISPOR. This is a member driven society with lots of academic and research activities. With your participation we could work together to make better efforts in the respected areas from India. Student who have this area of interest are also welcome to join. In the international society we could see a multi-professional gathering. Doctors, nurses, pharmacists, public health specialists, medical social workers, statisticians and other professionals are working together in ISPOR.

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Please also read some of the interesting articles published in this issue, especially one need more attention is the first write up on brand versus generic drugs by Sarah.

Best Regards,

Mr. Dixon Thomas, M.Pharm, M.S., M.Sc.
President-elect, the ISPOR, India-Andhra Pradesh Chapter
HOD, Pharmacy Practice, RIPER & Editor, RIPER PDIC Bulletin, dixon.thomas@gmail.com

Dispense as written: considerations in the brand versus generic debate

Sarah Glaholt

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Prescribing practices vary widely among clinicians, and are influenced in part by education, experience, and setting.[1] However, all practitioners are faced with a common question when drug therapy is warranted: dispense as written or substitution permitted?

The US Food and Drug Administration (FDA) identifies a generic drug as one that is "identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use."[2] Specifically, FDA-approved generics are required to contain the same active ingredients; be identical in strength, dosage form, and route; carry the same indications; be bioequivalent; meet requirements for identity, strength, purity, and quality; and be manufactured according to the FDA's good manufacturing practice regulations.[2] It is important to note that while the active ingredients must be the same, inactive ingredients may differ between both brand and generic products, as well as among generic products. This is of particular importance in those patients with sensitivities or allergies to inactive ingredients, such as lactose, gluten, and dyes, as these individuals may by intolerant to specific product substitution.[3]

History of Generic Approval

Historically, in bringing a generic product to market, drug manufacturers were obligated to submit a new drug application (NDA), providing the same level of safety and degree of efficacy trial data that was required for the brand, or "innovator" drug. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, simplified the approval process by making available the abbreviated new drug application (ANDA). The ANDA draws on the innovator's safety and efficacy trial data, thereby shortening the time required to bring generic products to market. As an added incentive, a generic manufacturer may be granted 180 days of market exclusivity if they are the first to submit an application to the FDA.[4]

The Orange Book

Numerous resources are available to assist healthcare providers with drug product substitutions; however, the standard in the United States is the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, otherwise known as the "Orange Book". Proper use of the Orange Book depends, in part, on an understanding of the terms used to compare drug products. "Pharmaceutical equivalents" are products that contain the same active ingredients, are produced in the same dosage form, have the same route of administration, and have the same strength or concentration. "Pharmaceutical alternatives" are products that differ in the salt, ester, moiety complex, dosage form, or strength. "Therapeutic equivalents" are drug products which meet the requirements for pharmaceutical equivalence, and which produce the same clinical effect and safety profile.

"Bioavailability" refers to the rate and extent of absorption achieved by the active ingredient from a drug product and its availability at the intended site of action. Finally, in being "bioequivalent", a generic product is absorbed at a rate and extent that does not differ significantly from the comparator drug. For a generic to be considered bioequivalent, the area under the curve (AUC) and maximum plasma concentration (C_{max}) must demonstrate a 95% confidence interval that falls within 80% to 125% of the innovator drug's AUC and C_{max} values.[5]

Orange Book Equivalence Ratings

When evaluating therapeutic equivalents information provided in the Orange Book, it is important to have a working knowledge of the ratings used to ensure proper substitution. "A" codes indicate therapeutic equivalence (e.g., AA, AN) with no known bioequivalence problems when compared with pharmaceutically equivalent products. Therapeutic equivalent products with resolved bioequivalence issues will be denoted AB. Some drug products with the AB rating are also assigned a numerical value, such as AB1, AB2, or AB3. The numerical values do not convey quality or hierarchy; they merely indicate the products are not interchangeable amongst one another. A generic rated AB1 may be substituted for another AB1, but it is improper to substitute an AB1 generic for an AB2 product. One common example involves the drug nifedipine, available in two formulations: Adalat® CC and Procardia® XL. While generic equivalents of both products are available, they are not interchangeable with each other as Adalat® CC carries an AB1 rating and Procardia® XL carries an AB2 rating. "B" codes (e.g., B*, BC, BD) indicate the drug is not therapeutically equivalent to available pharmaceutically equivalent products.[5] A complete list of therapeutic equivalent codes is provided in Table 1. The electronic version of the Orange Book can be found online at www.fda.gov.

Table 1. Orange Book Therapeutic Equivalence Ratings[5]

Therapeutic equivalence	Rating
Therapeutically equivalent	AA, AN, AO, AP, AT
Not Therapeutically equivalent	B*, BC, BD, BE, BN, BP, BR, BS, BT, BX

Narrow Therapeutic Index

Narrow therapeutic index (NTI) drugs are those in which small alterations in dose carry the potential for significant changes in systemic concentrations and the body's pharmacodynamic response. Drugs that are commonly associated with having an NTI include cyclosporine, carbamazepine, digoxin, levothyroxine, lithium, phenytoin, and warfarin. Many factors can influence the pharmacodynamics of NTI drugs, including patient age and illness, drug interactions, improper administration, and the use of different formulations.[6] Case reports offer details of supra-therapeutic levels and toxicity following chronic use of drugs such as lithium.[7] In the case of warfarin, patients have been found to be sub-therapeutic following generic substitution, despite no changes in extrinsic factors.[8] Variation may arise, due in part to differences in the evaluation of content uniformity between the United States Pharmacopeia (USP) and the innovator drug manufacturer. The USP guideline for content uniformity requires tablets to fall between 85% and 115% of the labeled strength; however, it has been noted that some manufacturers self-impose a more

stringent requirement.[8,9] Unless generic manufacturers adopt the brand drug's more rigorous standard, there is the potential for "tablet overlap", in which two different strengths potentially may contain the same amount of active ingredient, as illustrated in Table 2.[6,8]

Table 2.Content Uniformity of USP and DuPontPharma for Coumadin® Tablets[a]

Stage	Sample	USP Requirements	DuPontPharma[b] Requirements
1	10 tablets	85 to 115% of labeled strength	92.5 to 107.5% of labeled strength
		<6% SD for sample	<3% SD for sample
2	First 10, plus 20 additional tablets	All tablets 75% to 125% of labeled strength, 0 or 1 tablet <85% or >115% of labeled strength <7.8% SD for sample	All tablets 87.5% to 112.5% of labeled strength, 0 or 1 tablet <92.5% or >107.5% of labeled strength <3.9% SD for sample
	Example: 5 mg tablet	**Stage 1: 4.20 to 5.75 mg variation** **Stage 2: 3.75 to 6.25 mg variation**	**Stage 1: 4.625 to 5.375 mg variation** **Stage 2: 4.375 to 5.625 mg variation**

SD = standard deviation

[a]Table adapted from Hope KA, Havrda DE. Ann Pharmacother 2001;35:183-7.[8]

[b]Coumadin® tablets currently manufactured by Bristol-Myers Squibb®[10]

Many factors contribute to the decision to substitute or request a prescription be dispensed as written. Availability of a generic product, the therapeutic equivalency rating of the product, and the potential for pharmacodynamic challenges due to a narrow therapeutic index are three examples. Cost of the generic versus the brand product must also be considered, as patients prescribed a brand-name product who cannot afford to purchase it, may be better off with a generic formulation that offers adequate therapeutic concentrations. In such cases where the less expensive generic product does not produce similar brand-name results, dosages may need to be adjusted or monitoring of drug concentrations may need to be increased / initiated to provide the appropriate therapeutic response. In the end, the decision to substitute should be a joint effort between the prescriber, patient, and pharmacist, working in concert to ensure the best health outcomes.

References

1. Davidson W, Molloy DW, Somers G, Bedard M. Relation between physician characteristics and prescribing for elderly people in New Brunswick. CMAJ. 1994 Mar 15;150(6):917-21.
2. US Food and Drug Administration. Generic Drugs: Questions and Answers. Available at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
3. Pifferi G, Restani P. The safety of pharmaceutical excipients. Farmaco. 2003 Aug;58(8):541-50.
4. US Food and Drug Administration. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). Available at:

http://www.fda.gov/newsevents/testimony/ucm115033.htm.
5. US Food and Drug Administration. Orange Book Preface. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm.
6. Burns M. Management of Narrow Therapeutic Index Drugs. J Thromb Thrombolysis. 1999 Apr;7(2):137-43.
7. Toronjadze T, Polena S, Santucci T, et al. Prolonged Requirement of Ventilatory Support in a Patient with Eskalith Overdose. Proc West Pharmacol Soc. 2005;48:148-9.
8. Hope KA, Havrda DE. Subtherapeutic INR Values Associated with a Switch to Generic Warfarin. Ann Pharmacother 2001;35:183-7.
9. US Pharmacopeial Convention. Uniformity of dosage units. Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/2011-02-25905UNIFORMITYOFDOSAGEUNITS.pdf.
10. Coumadin® [package insert]. Princeton, NJ: Bristol-Myers Squibb; 2011.

The role of the pharmacist in bone density loss

Paul J. Oesterman

Roseman University of Health Sciences, Henderson, NV USA

Abstract

Pharmacists can play a key role in helping our senior population reduce the risks of fractures. This overview describes opportunities for interventions to assist in bone density loss and reduce the risk of falls and fractures. This overview encourages the reader to further pursue the information presented.

Introduction

As new strategies evolve; allowing people to live longer lives, the role of the pharmacist gains its importance. Loss of bone density or bone demineralization associated with aging is one area where the pharmacist can have a significant impact and play a key role. Osteoporosis complications and resultant fractures are preventable. Significant is the direct correlation between morbidity and mortality associated with fractures due to bone loss. There are both significant direct and indirect costs associated with treating falls and fractures. With our older population increasing and the goal of high quality of life; the prevention and treatment of conditions like osteoporosis becomes all the more important.

Natural loss of bone density starting with osteopenia and progressing to osteoporosis affects millions of people worldwide. In India, estimates are that 12.5% of males and 33% of females suffer from osteoporosis. Two relatively unique features to India are: 1) the relative low age of peak incidence (55 years old versus 75 years for most western countries) and 2) the relatively high incidence of hip fractures amongst males (almost equal to females). It is the hip fracture that raises the greatest concern, as there is a nearly 20% increase in mortality within one year following a fracture.

Pathophysiology

Much like hypertension, bone density loss is often a silent asymptomatic disease. Bone density is a balance of bone formation and resorption, with peak bone mass being achieved around age 30. When bone loss occurs at a rate greater than development, the bones become weakened and the patient becomes at risk for falls and fractures. There are a number of contributing factors (Table 1).

Table 1. Significant Factors Associated With Osteoporosis
Select Medications- Anticonvulsants (Select), Glucocorticoid steroids, Lithium
Low estrogen- Post-menopausal women
Low Calcium and Vitamin D intake
Sedentary lifestyle
Excessive Alcohol consumption
Tobacco use
Family history of fractures

Diagnosis

In addition to a complete history and physical examination by the physician, pharmacists can administer the World Health Organization's Fracture Risk Calculator (known as FRAX to estimate the

10-year probability of risk for a fracture). When used in association with a Bone Mineral Density (BMD) the FRAX study has demonstrated significant fracture predictability. The most widely used BMD tool is a dual energy X-ray (DXA) measurement. The DXA scan provides a T-score or Z-score with the result being quantified into the appropriate risk category. Pharmacists are able to offer a low cost alternative using peripheral bone density measurements in the pharmacy.

Therapies

The treatment of osteopenia and osteoporosis is aimed at fracture prevention and requires a multifaceted approach, which may include non-drug therapy, and non-prescription drug therapy in addition to prescription therapy.

Non-drug therapy measures can include weight bearing exercises like walking or water fitness programs. Tobacco and alcohol use elimination should be considered when indicated in applicable patients. Education on fall risk reduction should be provided including home safety analysis, appropriate footwear, decreased night-time urination, reduce dehydration risk, and safe medication regimens.

Supplemental Calcium and Vitamin D should be considered to assure patients receive at least 1600 mg of elemental calcium spread over the day in addition to a minimum of 800 IU of Vitamin D daily, to help the body absorb the Calcium. The salt form of calcium must be considered in light of side effect profiles.

A number of prescription drug products are available including the bisphosphonates which have demonstrated an ability to reverse bone loss. Calcitonin has demonstrated an ability to partially block osteoclast activity. Estrogen use can be considered for post-menopausal women as it has been shown to impair osteoclast communication with improved BMD. Potential adverse events associated with estrogen use must be considered. Commercial selective estrogen receptor modulators work similarly to estrogens. Several studies have demonstrated the benefits associated with parathyroid hormone in patients who experience repeated fractures.

Conclusions

As practitioners, we will be seeing an increase in patients with osteoporosis. There are many sources of information available on the internet, but pharmacists have the opportunity to interact on a personal level with their patients to perform peripheral bone density studies, recommend proper Vitamin D and calcium therapy, non-drug therapy as well as appropriate drug regimen.

Further reading

1. Damodaran P, Subramaniam R, Omar SZ, Nadkarni P, Paramsothy M. Profile of a menopause clinic in an urban population in Malaysia. Singapore Med J 2000 Sep; 41(9): 431-5.
2. Outlook, http://www.outlookindia.com (Retrieved 2012-05-23).
3. Osteoporosis Society of India (2003) Action Plan Osteoporosis: Consensus statement of an expert group. New Delhi
4. Sambrook PN, Seeman E, Phillips SR and Ebeling PR. Preventing osteoporosis: outcomes of the Australian Fracture Prevention Summit. Med J Aust 2002 176 Suppl:S1.
5. Brian K Alldredge; Koda-Kimble, Mary Anne; Young, Lloyd Y.; Wayne A Kradjan; B. Joseph Guglielmo. Applied therapeutics: the clinical use of drugs. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins. 2009, 101–3.
6. Susan Ott. Fracture Risk Calculator. http://courses.washington.edu/bonephys/FxRiskCalculator.html (Retrieved 2012-05-23).

HINARI access to research in health program

HINARI Team

World Health Organization

HINARI Program set up by World Health Organization (WHO) together with major publishers, enables developing countries to gain access to one of the world's largest collections of biomedical and health literature. More than 8,500 journals and 7000 e-books (in 30 different languages) are now available to health institutions in more than 100 countries, areas and territories benefiting many thousands of health workers and researchers, and in turn, contributing to improve world health.

HINARI Access to Research in Health Program provides free or very low cost online access to the major journals in biomedical and related social sciences to local, not-for-profit institutions in developing countries.

HINARI was launched in January 2002, with some 1500 journals from 6 major publishers: Blackwell, Elsevier Science, the Harcourt Worldwide STM Group, Wolters Kluwer International Health & Science, Springer Verlag and John Wiley, following the principles in a Statement of Intent signed in July 2001. Since that time, the numbers of participating publishers and of journals and other full-text resources has grown continuously. Today more than 150 publisher partners are offering more than 15,000 information resources in HINARI and many others are joining the program.

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Institutions in countries with at least one of the following criteria may be eligible for free access: inclusion in the LDCs; an HDI of less than 0.63; or GNI per capita at or below $1600.
Institutions in countries that do not match at least one of the above criteria and with either a GNI per capita less than $5000 or HDI at or below 0.67 may be eligible to pay a fee of $1000 per year.

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- If your institution is in Group B (low-cost access) country, and you cannot or choose not to pay the annual fee, your institution will still be eligible for free

access to a number of information resources.

Other Initiatives

PERI

PERI is a specific program of support to information production, access and dissemination for researchers and professionals.

eIFL - Electronic Information for Libraries

eIFL aims to facilitate affordable access to electronic scholarly resources by libraries in countries in transition. In its present form, eIFL covers well over 40 countries served by the Soros Foundations network. Along with its services promoting access to content in social sciences and humanities as well as science and technology, eIFL also offers various programs that support library consortium building in countries in transition.

Liblicense Developing Nations Initiatives

Yale Library has list a number of organizations developing or publicizing programs designated to bring high quality, peer-reviewed sciences journals for free or very cheaply to developing nations. This site identifies such programs and provides links where readers may learn more about them.

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The Monitoring Medicines (MM) project

Hanna Lindroos

'Monitoring Medicines' is a project, running for 42 months, funded by the Seventh Framework Program (FP-7) of the Research Directorate of the European Commission (EC). The agreement between the EC and the Uppsala Monitoring Centre came into force on 1 September 2009. The overall aim of 'Monitoring Medicines' will help to learn more about why adverse drug events occur so that we can act to reduce patient deaths and negative health impacts arising from undetected medicines safety problems globally. This will be achieved by advancing application, co-ordination and optimal use of pharmacovigilance evidence, and strengthening the links between the various individuals, national pharmacovigilance centers and experts involved. Importantly, the project will also strive to advance consumer involvement in reporting of ADRs, and to mobilize and sustain political commitment to working on drug safety issues. The project partners represent a wide range of organizations dedicated to improving public health through the safe use of medicines:

- The Uppsala Monitoring Centre (UMC), Sweden;
- WHO;
- Copenhagen HIV Programme, Denmark;
- University of Ghana Medical School, Ghana;
- Pharmacy and Poisons Board, Kenya;
- Centre Anti Poison et de Pharmacovigilance du Maroc, Morocco;
- Lareb, Netherlands Pharmacovigilance Centre;
- Zuellig Family Foundation, the Philippines;
- Medical Products Agency, Sweden;
- Elliot Brown Consulting Ltd, UK;
- National Patient Safety Agency, UK.

In an increasing number of countries consumers are being encouraged to report adverse reactions to medicines. Organizations such as WHO and the European Commission acknowledge the role of the consumer in spontaneous reporting. Representatives of national pharmacovigilance centers requested WHO in 2008 to develop a handbook on how to establish a reporting system for medicine-related problems for the general public. The implementation of the task became feasible under the objectives of the Monitoring Medicines project. A WHO guidance document 'Safety Monitoring of Medicinal Products – Reporting system for the general public' is now available as a direct project deliverable. Anne Kiuru, Medical Products Agency, Sweden and Linda Härmark, Netherlands Pharmacovigilance Centre, Lareb, kindly assisted WHO in writing the original manuscript. It was later reviewed by members of the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) and selected national experts, and is an important step forward in strengthening patients around the world.

Further reading:

Monitoring Medicines project: http://www.monitoringmedicines.org

Drug News

Acetylcysteine Solution was recalled due to visible glass particles

According to FDA safety alerts, one lot of Acetylcysteine Solution (Roxane Laboratories) was recalled due to the discovery of a single visible glass particle in a vial within the lot. Acetylcysteine is indicated as an adjuvant therapy for the patients with abnormal, viscid, mucous secretion. Acetylcysteine is also indicated as an antidote to prevent or lessen hepatic injury with hepatotoxic quantity of acetaminophen (paracetamol). Acetylcysteine for inhalation is usually delivered via a Nebulizer, but can also be delivered via direct instillation into a tracheostomy, or into the bronchial-pulmonary tree during bronchosopy. Glass particles can cause airway obstruction resulting in symptoms of choking, wheezing, difficulty breathing, coughing and potentially hemoptysis. Use of an inhaled product with glass particles has the potential to cause choking which could be life-threatening. Aerosolization of small glass particles in the airways could result in recurrent infections (due to obstruction of airways, and decreased clearance of airway secretions).
Further reading:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm290219.htm

Boxed warning change for Lotensin (benazepril hydrochloride) tablets

Wording in the boxed warning changed with the new evidences about benazepril hydrochloride tablets. There is a warning of fetal toxicity. The drug is categorized as pregnancy risk category D. Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue Lotensin as soon as possible. These adverse outcomes are usually associated with use of these drugs in the second and third trimester of pregnancy. (Information collected from the prescriber information by the manufacturer).
Further reading:
http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019851s042lbl.pdf

Safety update on aliskiren containing medicines

Concomitant use of aliskiren with ARBs or ACEIs in patients with diabetes is contraindicated because of the risk of renal impairment, hypotension, and hyperkalemia. Avoid use of aliskiren with ARBs or ACEIs in patients with renal impairment where GFR < 60 mL/min. Patients should not stop taking aliskiren without talking to your healthcare professional. Stopping aliskiren suddenly can cause problems if your high blood pressure (hypertension) is not treated.
Further reading:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm301120.htm

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