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MESSAGE FROM THE DIRECTOR

If you have a drug-related question please give us a call. 334-844-4400

Rosuvastatin: Yet Another Statin

Rosuvastatin calcium (Crestor® by AstraZeneca) was approved August 12, 2003 as an adjunct to diet for elevated total-C, LDL-D, ApoB, nonHDL-C and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Type IIa and IIb); for elevated TG levels (Fredrickson Type IV); to reduce LDL-C, total-C and ApoB in patients with homozygous familial hypercholesterolemia in combination with other treatments. It is a member of the class of HMG-CoA reductase inhibitors ("statins") and joins five other class members on the market (see table, page 3).

Based on several trials in a total of about 12,000 patients, the most common side effects have been muscle aches, weakness and gastrointestinal distress. Rare instances of severe muscle pain and kidney damage (secondary to myoglobinuria) are reported. It is contraindicated with active liver disease or unexplained persistent elevations of liver enzymes; liver function monitoring is recommended. It is also Pregnancy Category X due to the role of cholesterol synthesis in fetal development.

The drug is approved in 26 other countries and one of the delays in getting to the US market was the concern about kidney problems at the higher doses (e.g., 80 mg) and this is still being evaluated. Dr. Sydney Wolfe, of the Public Citizen group has compared it to a similar drug pulled from the market a few years ago due to severe muscle complications and deaths (cerivastatin, *Baycol* by Bayer).

Crestor is being heavily promoted as more potent in lowering LDL than the other available

statins, but this will need to be borne out by the clinical evidence. Billions of dollars are on the line. In addition, Astra-Zeneca is pursuing an aggressive pricing strategy to try to gain a foothold in the market quickly. On average, the price is a few cents lower than some popular brands; also, all strengths are priced the same.

Rosuvastatin is available in 5, 10, 20 and 40 mg tablets. Starting dose is 5-20 mg; 40 mg is reserved for the highest LDL levels.

References:

Middleton O. Health: AstraZeneca gets FDA approval for its cholesterol drug Crestor. Wall Street Journal online, 2003 Aug 13. Accessed 8/13/03.

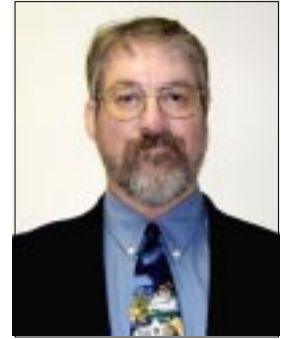
Hensley S. Follow the Money: AstraZeneca aims to gain share with Crestor's strategic pricing. Wall Street Journal online, 2003 Aug 19. Accessed 8/25/03.

FDA Talk Paper (T03-61). FDA approves new drug for lower cholesterol. August 12, 2003. Accessed 8/13/03. <http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01247.html>

Crestor® (rosuvastatin calcium). Package Labeling. AstraZeneca, 08/03. www.crestor.com

Killion K, ed. Drug Facts and Comparisons. eFacts edition. St. Louis: Facts and Comparisons, 2003.

Abramowicz M. Drugs for lipid disorders. Treatment Guidelines from the Medical Letter. 2003 Aug;1:77-82.



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Centers for Disease Control and Prevention. Treatment of **Tuberculosis**, American Thoracic Society, CDC, and Infectious Diseases Society of America. MMWR 2003;52 (No. RR-11): 1-77. <http://www.cdc.gov/mmwr/PDF/RR/RR5211.pdf>

New guidelines for the use of **antiretroviral agents in HIV-1-infected adults and adolescents** were released Monday, July 14th, by the US Department of Health and Human Services (DHHS). To view the complete document of new guidelines, http://www.aidsinfo.nih.gov/guidelines/adult/AA_071403.pdf.

Opium tincture and paregoric associated drug errors. Attached is a link to an FDA safety sheet detailing reports since 1997. http://www.fda.gov/cder/drug/MedErrors/opiumTincture_paregoric.pdf

Household products database is launched by the National Institutes of Health; a consumer's guide that provides information on the potential health effects of more than 2,000 ingredients contained in more than 4,000 common household products. Information is provided to NLM under a collaborative agreement and is derived from publicly available sources, including brand-specific labels and information provided by manufacturers and their Web sites. The list will be updated at least annually.

Tox Town (<http://toxtown.nlm.nih.gov>) was unveiled last year, a site that introduces consumers to the toxic chemicals and environmental risks they might encounter in in everyday places such as schools, office buildings and factories.

Material Safety Data Sheet (MSDS) are also included which are designed to provide workers and emergency personnel with the proper procedures for handling or working with a particular substance; these sheets are produced by the manufacturer of the product as required by Federal law.

The target audience of the Household Products Database is both scientists and the general public. The database allows users to browse a product category, by alphabetical listing or by brand name. Products can also be searched by type, manufacturer, product ingredient, or chemical name. <http://householdproducts.nlm.nih.gov>

Safety in a Power Outage, recommendations just updated by the CDC (8/15/03) may be a good reference to have on hand. Reading before an outage may be even better ... <http://www.bt.cdc.gov/ert2.htm>

FDA 5-Part Strategic Action Plan To "Protect and Advance America's Health." For those who like to keep up with this stuff, the "5 Parts" are:

- 1) Efficient, science-based risk management
 - 2) Patient and consumer safety
 - 3) Better informed consumers
 - 4) Counterterrorism and
 - 5) a strong FDA.
- Additional information about the FDA's

strategic plan, including a list of key action items and objectives, is available online at <http://www.fda.gov/oc/\mcclellan/strategic.html> or <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00934.html>. The full document (37 pages) can be found at <http://www.fda.gov/oc/mcclellanFDA%20Strategic%20Plan.pdf>

A catalog of FDA approved drug products is available at Drugs@FDA. This pilot project is a searchable Web site containing information about approved and tentatively approved prescription, over-the-counter, and discontinued drugs. It includes links to drug approval letters, labels, and review packages. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

Keystone-compliant medication information? For those of you who don't remember a few years ago, the FDA, under HHS Secretary Donna Shalala, proposed mandating and approving patient information to be dispensed with each new prescription, "MedGuides." A "consortium" of groups including professional associations, publishers, pharmacy vendors, etc. convinced the FDA that a private initiative could meet all requirements that would be mandated (developed by the Keystone group in 1996) and the FDA agreed to a timetable for that to happen. A study last year concluded that this had not occurred and now a new "consortium" is attempting to stave off government-mandated and approved patient information.

Aker J. Rx "MedGuides": NACDS urges FDA to defer to private consortium. The Green Sheet 2003 Aug 11;52:1-2.

Update ...

In the last edition of Auburn HealthLink, a Web site was given for an updated edition of a DEA publication, "Drugs of Abuse." They have apparently changed the Web site address which is now, <http://www.usdoj.gov/dea/pubs/abuse/index.html>

National Pharmacy Week 2003, Oct. 19-25 is being promoted by **ASHP and APhA**. ASHP suggests to highlight the role of pharmacists in patient care during National Pharmacy Week; this could include hosting a site visit for your senator, representative or other local lawmakers. Last year some hospitals hosted a tour for several legislators and local officials, who got an up-close look at the operations of a health-system pharmacy. <http://www.ashp.com/pr/event/index.cfm>.

APhA is promoting the official theme of **Know Your Medicines—Know Your Pharmacist**. The intent is to tie together the points of consumer education about proper medication use and the value of pharmacists' patient care services. <http://www.aphanet.org/>

Here is a shocker, health food store recommendations may be faulty!? According to Mills, et al a survey conducted in 34

The “Statins”

Generic Name	Trade Name	Mfg.	Dose Form/ Strengths	Daily Adult Dose Range	Year Approved
atorvastatin	Lipitor	Parke-Davis	Tablets 10, 20, 40, 80 mg	10-80 mg	1996
fluvastatin	Lescol	Novartis	Capsules 20, 40 mg	20-80 mg	1993
	Lescol XL		Tablets, extended release 80 mg		
lovastatin	Mevacor	Merck	Tablets 10, 20, 40 mg	10-80 mg	1987
	lovastatin	various mfr's	Tablets 10, 20, 40 mg		
	Altacor	Andrx	Tablets, extended release 10, 20, 40, 60 mg	10-60 mg	
pravastatin	Pravachol	Bristol-Myers Squibb	Tablets 10, 20, 40, 80 mg	40-80 mg	1991
rosuvastatin	Crestor	AstraZeneca	Tablets 5, 10, 20, 40 mg	5-40 mg	2003
simvastatin	Zocor	Merck	Tablets 5, 10, 20, 40, 80 mg	5-80 mg	1991

Small Doses—continued from pg. 2

health food stores with 8 “interviewers” who memorized a survey form, asked for recommendations for treatment of breast cancer with highly variable results.

Mills E, Ernst E, Singh R, Ross C, Wilson K. Health food store recommendations: implications for breast cancer patients. *Breast Can Res* 2003 Aug 7;5:R170-R174.

<http://breast-cancer-research.com/content/pdf/bcr636.pdf>

Most bang for the buck? GENERICS! A WSJ online/Harris Interactive Health-Care Poll was conducted online Aug. 8-11, 2003, among a national cross section of 2,098 adults over 18 years old. Various categories were weighted (statistical precision of ±3.3%). Of 10 health categories, generic drugs were felt to be of most value for the healthcare dollar. Another big surprise: Health insurance companies and nursing homes were at the bottom.

WSJ online/Harris Interactive Health-Care Poll. Generic Drugs Considered A Better Value by Many. *Wall Street Journal* online, 2003 Aug 19.

Are there really more drugs than there used to be, or does it just seem like it?

20 Years of Drug Development				
Category	1983	1993	2003	2013*
Distinct Rx Brand Names	798	2315	5144	>11,000
Rx Drug Classes	451	865	1597	>3000

* Estimate based on extrapolation.

Based on data from the NACDS Foundation. Staffa EJ, ed. Pharmacists “number” among the key health professionals. *Chain Pharmacist Practice Memo* 2003 Aug;7(12):4.

Yo, dude, like, illicit drugs are back in the news. A small telephone survey study found that it is apparently quite easy to obtain all sorts of prescription-only medications without a prescription over the Internet. However, no sites were found advertising Schedule II substances.

Forman RE. Availability of opioids on the internet. *JAMA* 2003 Aug 20;290:889.

Atopic Dermatitis: An Overview

Katie Hornbuckle, Pharm.D. Candidate

Introduction

Atopic Dermatitis (AD) is a chronic inflammatory disease of the skin that is accompanied by intense itching and inflammation that affects over 15 million Americans. It most often presents during infancy and childhood but, may affect any age group. AD is part of a genetically determined state of hypersensitivity to environmental allergens known as atopy.¹ Other commonly associated disease states include asthma and allergic rhinitis.

The highest incidence of AD is seen in children; approximately 10-20% have symptoms and it is the most common chronic skin disorder in children.^{2,3} It is postulated that the disease occurs more often in urban areas. A family history is reported in up to 70% of patients with AD and up to 50% of patients may also develop asthma or allergic rhinitis.³ AD is not contagious, but it cannot be cured. It therefore must be managed individually with appropriate therapy and avoidance of aggravating factors.

Clinical Presentation

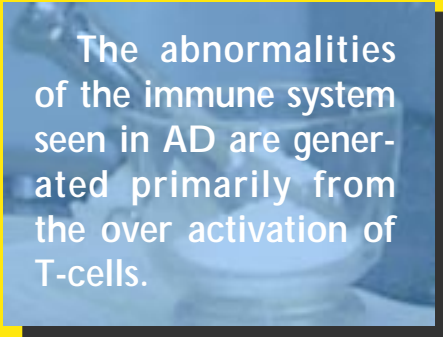
The predominant symptom associated with AD is pruritus (itching). It often presents in a continuous cycle of flare-ups and remissions. Secondary symptoms include erupted papules and lichenification (thickening of the skin). The lesions associated with AD are classified as acute, subacute, or chronic. They are often extremely pruritic and accompanied by small papules and vesicles. Excoriation, exudates, and infections may be a consequence of scratching acute lesions. Subacute lesions are thick, scaly, and erythematous. Chronic lesions are leathery in appearance because of lichenification and fibrotic papules.^{2,3,4}

AD often appears differently throughout certain phases of life. During infancy the lesions usually appear on the chest, face, scalp, neck, or extremities. The lesions are often acute or subacute resulting in intense itching, oozing, and crusting. Childhood lesions are less acute and localized to flexor folds of the neck, elbows, knees, and wrists. More diffuse lesions usually located on the face, hands, or neck, are seen in

adolescents and adults. There is a tendency for drier, lichenified, hyperpigmented plaques in adults and adolescents located in flexor regions and around the eyes.^{2,3,4}

Pathology

The abnormalities of the immune system seen in AD are generated primarily from the over activation of T-cells. This results in the release of inflammatory mediators including eosinophils, histamine, cytokines, and others. The immune response is then seen through vasodilation, increased vascular permeability, and the activation and migration of inflammatory cells to the skin. This produces the symptoms associated with AD such as erythema, edema, and pruritis. The over activation of T-cells evolves into the vicious itch/scratch cycle exacerbating the disease.^{2,3,4}



The abnormalities of the immune system seen in AD are generated primarily from the over activation of T-cells.

Treatment

The goals of treatment for AD include elimination of trigger exposure, decrease itching, suppression of inflammation, and lubrication of the skin.³ Treatment options include lifestyle modifications, emollients, topical corticosteroids, topical immunomodulators, antihistamines, and antibiotics.

Life style modifications are the beginnings of successful management of AD. The skin barrier is often disrupted due to the inflammatory response resulting in enhanced water loss and extremely dry skin. Therefore, patients should avoid irritants such as soaps and detergents, cigarette smoke, perfumes, cosmetics, wool, fresh fruit, meat juices, animal dander, temperature extremes, high humidity, and chemicals. Patients are also advised to avoid excessive bathing and extremely hot water. An emollient or medication should be applied after each bath to keep the skin moist. Recommended emollients include petrolatum and mineral oil.^{2,3,4,5}

Other lifestyle modifications include avoidance of foods and dust mites, which may cause a hypersensitivity response. Food allergens are often associated with children and are outgrown in adulthood. Common foods known to trigger an allergic reaction include eggs, milk, peanuts, soybeans, tree nuts, fish, and wheat. Avoidance of dust mites may be accomplished by using pillow, mattress and boxspring encasings, washing bedding in hot water weekly, removing bedroom carpet, and decreasing indoor humidity.^{2,5}

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New Drug and Biological FDA Approvals (Since June, 2003)

Brand	Generic Name	Manufacturer	Dosage Form	Drug Class	Indication	Date of Approval
<i>Aloxi</i>	palonosetron HCl	MGI Pharma Inc www.aloxi.com	Injection	Serotonin type 3 receptor antagonist	Nausea and vomiting associated with cancer chemotherapy	July 25, 2003
<i>Bexxar</i>	tositumomab + iodine I ¹³¹	Corixa and GlaxoSmithKline www.bexxar.com	Injection	Monoclonal antibody	Non-Hodgkin's lymphoma	June 30, 2003
<i>Crestor</i>	rosuvastatin	AstraZeneca www.crestor.com	Tablet, oral	HMG-CoA reductase inhibitor "statin"	Hyperlipidemia's	Aug. 12, 2003
<i>Cubicin</i>	daptomycin	Cubist Pharmaceutical http://www.cubicin.com/shared/cubicin_label.pdf	Injection	Cyclic lipopeptide antibiotic	Complicated skin infections	Sept. 12, 2003
<i>Emtriva</i>	emtricitabine	Gilead Sciences http://www.emtriva.com	Capsule, oral	Nucleoside reverse transcriptase inhibitor (NRTI)	Treatment of HIV-1 infection in adults	July 2, 2003
<i>FluMist</i>	influenza virus vaccine live, attenuated	MedImmune http://www.medimmune.com	Nasal Mist	Influenza virus vaccine	Active immunization to prevent influenza A and B in healthy children and adults, 5-49 years old.	June 17, 2003
<i>Levitra</i>	vardenafil	Glaxo SmithKline (distributors) www.levitra.com	Tablet, oral	Selective inhibitor of Phosphodiesterase (PDE) 5	Erectile dysfunction	Aug.19, 2003
<i>Reyataz</i>	atazanavir sulfate	Bristol Myers Squibb http://www.reyataz.com/reyataz/home/index-pr.jsp?BV_UseBVCookie=Yes	Capsule, oral	Protease inhibitor	Treatment of HIV-1 infection	June 20, 2003
<i>UroXatral</i>	alfuzosin HCl	Sanofi-Synthelabo http://www.centerwatch.com/patient/drugs/dru833.html	Tablet	Alpha blocker	Benign prostatic hypertrophy	June 12, 2003

...continued—pg. 6

New Drug and Biological FDA Approvals, continued

Brand	Generic Name	Manufacturer	Dosage Form	Drug Class	Indication	Date of Approval
<i>Xolair</i>	omalizumab	Genentech http://www.genentech.com/gene/features/xolair/index.jsp	Injection, subcutaneous	Recombinant DNA-derived humanized IgG1[* In-line.WMF monoclonal antibody that selectively binds to human immunoglobulin E (IgE)	Adults and adolescents (=12 years of age) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen	June 20, 2003
<i>Zavesca</i>	miglustat	Actelion Ltd http://www.actelion.com/Apps/WebObjects/Actelion	Capsules, oral	Glucosylceramide synthetase inhibitor	Gaucher's Disease in adults	July 31, 2003

Small Doses—continued from pg. 3

This, coupled with a new study from the National Center on Addiction and Substance Abuse at Columbia University that tracks teenage attitudes toward substance abuse. It found that high stress, boredom and access to money (e.g., \$25 weekly allowance) increases the chances of teens getting involved with drugs, alcohol and tobacco. Also, there was a significant jump in the percent of kids who felt their school was not drug-free. For those who would like to peruse this 60+ page study, the link is below.

http://www.casacolumbia.org/usr_doc/2003_Teen_Survey.pdf

“Business Casual” has another ally, according to Teng, et al, based on a study in 20 normal males and 20 males with open angle glaucoma, “...a tight necktie may cause an increase in IOP in susceptible individuals and should be included among the confounders of accurate IOP measurement and considered as a risk factor for increased IOP.”

Teng C, Gurese-Ozden R, Liebmann JM, Tello C, Ritch R. Effect of a tight necktie on intraocular pressure. *Br J Ophthalmol* 2003;87:946-8.

A sure bet? Pathological gambling, as a side effect of therapy, has been associated with dopamine agonists in the treatment of Parkinson's Disease. Eight of the nine cases were associated with pramipexole and one with pergolide, but any drug in the class may be suspect. It is a small sample but may raise awareness if a correlation actually exists.

Driver-Dunckley E, Samanta J, Stacy M. Pathological gambling associated with dopamine agonist therapy in parkinson's disease. *Neurology* 2003 Aug;61 (1 of 2):422-3.

Google competition!?! A recent article is touting the benefits of a (new?) search engine, Teoma.com. It is the power behind “Ask Jeeves” and may have some advantages over Google. Also some interesting reading on the (very) brief history of search on

the Web. You may want to check out the site.

Gomes L. Google is most popular search site, but others sometimes do it better. *The Wall Street Journal* online. 2003 Aug 18.

Duhh! A recent study attempted to document the difference between what patients and their physicians would like to talk about and how often it actually happens. In this case it concerns out-of-pocket expenses for medical care. For patients, the good intentions hovered around 63% while actuality was more like 15%. A discussion was more likely to occur if the patient was having significant financial difficulty with medical bills.

Alexander GC, Casalino LP, Meltzer DO. Patient-physician communication about out-of-pocket costs. *JAMA* 2003 Aug 20;290:953-8.

At least some of our messages are getting out, but ... A page one article in *The Wall Street Journal*, July 17, 2003 details the devastating effects on citrus growers, particularly grapefruit, apparently as a result of a message from healthcare about the dangers of **grapefruit and medications**. It's been so effective that some growers are going out of business.

Get Smart: Know When Antibiotics Work ... is the title of a public health campaign by the CDC, FDA, and an alliance of partners including national health organizations, state and local health departments, managed care organizations, pharmaceutical companies, and other groups concerned about this problem. They hope to reverse the public perception that ‘antibiotics cure everything’ by unveiling, **Get Smart: Know When Antibiotics Work**, last week at the American Society of Microbiology's 43rd Interscience Conference on Antimicrobial Agents and Chemotherapy.

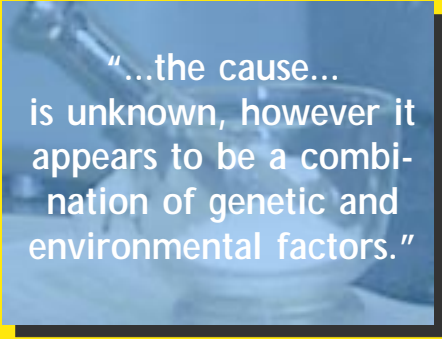
<http://www.cdc.gov/od/oc/media/pressrel/r030917.htm>

<http://www.cdc.gov/getsmart/>

Atopic Dermatitis—continued from pg. 5

Topical corticosteroids are the backbone of AD treatment. High potency agents are often applied during a flare-up in small amounts, 2-3 times per day while lower potency agents are used as maintenance therapy. Unfortunately, the chronic use of topical corticosteroids is associated with many unwanted local and systemic side effects. These may include skin atrophy, development of striae, hypopigmentation, acne, rosacea, telangiectasia, suppression of the HPA-axis, and even glaucoma or cataracts when used extensively around the eyes.^{3,6} Prolonged use of corticosteroids may also cause tolerance to develop and decrease effectiveness of the drug. These drawbacks have prompted the development of new treatment agents for AD.

Topical Immunomodulators (TIM) is a new class of agents that entered the market in 2000. Tacrolimus (*Protopic* by Fujisawa) and pimecrolimus (*Elidel* by Novartis) are the only two TIMs currently on the market and the first new treatment option for AD in 40 years. Their mechanism of action is to inhibit T-cell activation and the release of its cytokines, which decreases the inflammatory response. Tacrolimus, the first TIM to become available, is both safe and effective in adults and children. It is formulated in a 0.03% and 0.1% ointment to be applied twice daily for up to seven days. Pimecrolimus, the latest TIM on the market, is a 1% cream for mild to moderate atopic dermatitis in adults and children. The most common adverse event associated with both agents is local burning and itching, which often resolves after the first few days of treatment. Unlike corticosteroids, TIMs do not cause skin atrophy, rebound inflammation, striae, hypopigmentation, suppression of the HPA axis, glaucoma, or cataracts; they may also be used on any area of the body including the face and around the eyes. The advantages of TIMs include safer long-term use, less local and systemic adverse events, maintenance of efficacy with prolonged use, and these products can be applied to the facial area. A big disadvantage is cost; tacrolimus is \$60-65 per 30g and pimecrolimus is \$50-55 per 30g. The high potency topical corticosteroids such as betamethasone dipropionate, augmented are similar, \$50-70 per 50g, but the low potency agents are much cheaper, eg, hydrocortisone at \$2-5 per 30g). Despite the cost, TIMs may replace corticosteroids as the mainstay of treatment for AD.^{2,4,7,8,9}



“...the cause... is unknown, however it appears to be a combination of genetic and environmental factors.”

Second line treatments include topical antihistamines that are of little value in alleviating symptoms. However, systemically they may be used to help aid in sleep. Commonly used antihistamines include hydroxyzine (e.g., *Atarax*) and diphenhydramine (e.g., *Benadryl*).^{2,4,6}

Antibiotics may be used when the skin is heavily colonized with *Staphylococcus aureus* and an infection is suspected. The lesions often appear crusted and weeping. Treatment usually consists of a topical antibiotic such as mupirocin (*Bactroban*). Systemic therapy is only used when superinfections are present.^{2,4}

Conclusion

Despite the fact that AD affects over 15 million Americans the cause of this chronic skin disorder is unknown, however, it appears to be a combination of genetic and environmental factors. The goals of treatment include maintaining skin hydration, relieving itching, and avoidance of trigger factors. Successful management should begin with lifestyle modifications followed by treatment with emollients, topical corticosteroids, and topical immunomodulators. Antihistamines and antibiotics may be of value in selected cases. Hopefully, scientists will soon find a cure for “the itch that rashes.” Until then, each individual will have to find the solution which best controls his or her symptoms.

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