Direct-to-Consumer Advertising: Implications for Patient Care

Biomedical Library Grand Rounds
December 2, 2008
Today’s Presenters

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DHMC/DMS
Conflicts of interest: none

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Research and Education Librarian
Dartmouth Biomedical Libraries
Conflicts of interest: none
Learning Objectives

- Understand direct-to-consumer advertising (DTCA) as a marketing device

- Help your patients find authoritative sources of consumer health information
“Direct to consumer” + drugs or pharmaceuticals = 252,000 hits (10/31/2008)
Outline

• Role of FDA
• DTCA today
• Asymmetric information
• Sources of consumer health information
Outline

- Role of FDA
- DTCA today
- Asymmetric information
- Sources of consumer health information
Federal Regulation (1)

• Biologics Act of 1902
  – First premarket control legislation.
  – Vaccines were the focus.

• Pure Food and Drugs Act of 1906
  – Adopted *U.S. Pharmacopoeia* and *National Formulary* as official standards for strength, quality and purity of drugs.
  – Federal Bureau of Chemistry assumed regulatory authority.
  – 1906 act included provision against “false and misleading” labeling, which did not cover advertising.
Federal Regulation (2)

• Food, Drug and Cosmetic Act of 1938
  – Expanded definition of misbranding and false advertising.
  – Required a doctor’s prescription for specified drugs.
  – Expanded FDA powers over medical devices.

• Prescription Drug User Fee Act (PDUFA) of 1992
  – Designed to speed up new drug approvals by requiring a fee payment used to hire additional FDA employees.
FDA Center for Drug Evaluation and Research Funding Sources

FIGURE 7-1 History of CDER funding.
FDA Resources on Drugs and Devices

http://www.clinicaltrials.gov/ct2/info/fdalinks

• Drug and Device Information from the US Food and Drug Administration
  – **CDER** - Center for Drug Evaluation and Research
  – **CDRH** - Center for Devices and Radiological Health
  – **CBER** - Center for Biologics Evaluation and Research
FDA Resources on Drugs and Devices
http://www.clinicaltrials.gov/ct2/info/fdalinks

• Drug Action Packages
  – Drugs@FDA - drug products approved by CDER
  – Approved Biologics - drug products approved by CBER
  – Licensed Product Approvals - products approved by CBER
FDA Resources on Drugs and Devices
http://www.clinicaltrials.gov/ct2/info/fdalinks

• Drug and Device Safety Information
  – MedWatch - safety information and adverse event reporting program
  – Public Health Advisories - drug-related warning statements
  – Drug Safety Initiative - information about drug safety issues
  – Medical Device Safety - device recalls, alerts, and other safety information
  – Device Public Health Notifications - risks associated with the use of medical devices
  – Biologics Safety Information - safety notifications by CBER
Outline

- Role of FDA
- **DTCA today**
- Asymmetric information
- Sources of consumer health information
DTCA of Prescription Drugs

• A First Amendment issue.
• FDA sanctioned DTCA in 1985.
• Guidance on Consumer-Directed Broadcast Advertisements issued in 1999.
• Permitted only by U.S. and New Zealand.
• Ads reviewed by Division of Drug Marketing, Advertising and Communications
FDA Guidance on DTCA

• Cannot omit material facts.
• Must present a “fair balance” between benefit and risk information.
• Most significant risks must be disclosed.
• Ads either contain a summary of side effects and contraindications or make adequate provision for dissemination of the product’s FDA-approved label.
• Drug advertisements are reviewed by FDA only after they have appeared.
Impact of DTCA: Assertions

Proponents of DTCA

• Provides educational information.
• Enhances doctor-patient relationship.
• Improves adherence to prescription drug regimens.
• Stimulates competition.
• Results in lower prices.

Opponents of DTCA

• Consumers lack expertise to evaluate content of ads.
• Drug risks are not communicated effectively.
• Encourages overuse of medications.
• Leads to increased prices.

Lyles, Ann Rev Public Health, 2002
Impact of DTCA: Facts

• Consumers who request an advertised medicine from their doctor very often receive a prescription for that product.

  Lyles, Ann Rev Public Health, 2002

• In 2000, every $1 spent on DTCA yielded an additional $4.20 in drug sales.

  Kaiser Family Foundation
  http://www.kff.org/rxdrugs/6084-index.cfm
Survey by USA Today
Kaiser Family Foundation
Harvard School of Public Health

Americans’ attitudes about pharmaceuticals
As drug ads surge, more get Rx’s filled

March 4, 2008
# Pharmaceutical Marketing Expenditures in the United States in 2004

<table>
<thead>
<tr>
<th>Type of Promotion</th>
<th>IMS (US$ Billions)</th>
<th>CAM (US$ Billions)</th>
<th>New Estimate (US$ Billions)</th>
<th>Percent of Total of New Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples</td>
<td>15.9</td>
<td>6.3</td>
<td>15.9 (IMS)</td>
<td>27.7</td>
</tr>
<tr>
<td>Detailing</td>
<td>7.3</td>
<td>20.4</td>
<td>20.4 (CAM)</td>
<td>35.5</td>
</tr>
<tr>
<td>DTCA (Data provided by CMR)</td>
<td>4</td>
<td>4</td>
<td>4 (CMR)</td>
<td>7</td>
</tr>
<tr>
<td>Meetings</td>
<td>nd</td>
<td>2</td>
<td>2 (CAM)</td>
<td>3.5</td>
</tr>
<tr>
<td>E-promotion, mailing, clinical trials</td>
<td>nd</td>
<td>0.3</td>
<td>0.3 (CAM)</td>
<td>0.5</td>
</tr>
<tr>
<td>Journal advertising</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5 (CAM/IMS)</td>
<td>0.9</td>
</tr>
<tr>
<td>Unmonitored promotion (estimate³)</td>
<td>nd</td>
<td>14.4</td>
<td>14.4 (CAM)</td>
<td>25</td>
</tr>
<tr>
<td>Total</td>
<td>27.7</td>
<td>47.9</td>
<td>57.5</td>
<td>100</td>
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</tbody>
</table>
## Table 1. Annual Spending on Direct-to-Consumer Advertising and Promotion to Health Professionals, 1996–2005.*

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Direct-to-consumer advertising</strong></td>
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<td></td>
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<tr>
<td>Total spending (millions of $)</td>
<td>985</td>
<td>1,301</td>
<td>1,578</td>
<td>2,166</td>
<td>2,798</td>
<td>2,954</td>
<td>2,864</td>
<td>3,478</td>
<td>4,160</td>
<td>4,237</td>
</tr>
<tr>
<td>Percentage of sales</td>
<td>1.2</td>
<td>1.5</td>
<td>1.6</td>
<td>1.8</td>
<td>2.1</td>
<td>2.0</td>
<td>1.9</td>
<td>2.2</td>
<td>2.5</td>
<td>2.6</td>
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<tr>
<td><strong>Professional promotion</strong></td>
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<tr>
<td>Total spending (millions of $)</td>
<td>3,747</td>
<td>4,093</td>
<td>4,861</td>
<td>5,064</td>
<td>5,447</td>
<td>6,055</td>
<td>6,731</td>
<td>7,364</td>
<td>7,585</td>
<td>6,777</td>
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<tr>
<td>Detailing</td>
<td>571</td>
<td>621</td>
<td>597</td>
<td>551</td>
<td>549</td>
<td>469</td>
<td>474</td>
<td>476</td>
<td>516</td>
<td>429</td>
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<td>Journal advertising</td>
<td>5.4</td>
<td>5.4</td>
<td>5.6</td>
<td>4.7</td>
<td>4.6</td>
<td>4.5</td>
<td>4.8</td>
<td>5.0</td>
<td>4.9</td>
<td>4.4</td>
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<tr>
<td>Percentage of sales</td>
<td>5.4</td>
<td>5.4</td>
<td>5.6</td>
<td>4.7</td>
<td>4.6</td>
<td>4.5</td>
<td>4.8</td>
<td>5.0</td>
<td>4.9</td>
<td>4.4</td>
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<tr>
<td><strong>Free samples</strong></td>
<td></td>
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<tr>
<td>Total retail value (millions of $)</td>
<td>6,104</td>
<td>7,358</td>
<td>7,910</td>
<td>8,476</td>
<td>9,021</td>
<td>11,539</td>
<td>12,928</td>
<td>14,362</td>
<td>16,404</td>
<td>18,438</td>
</tr>
<tr>
<td>Percentage of sales</td>
<td>7.6</td>
<td>8.4</td>
<td>8.1</td>
<td>7.1</td>
<td>6.9</td>
<td>8.0</td>
<td>8.6</td>
<td>9.1</td>
<td>9.9</td>
<td>11.2</td>
</tr>
<tr>
<td><strong>Total promotion</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total spending (millions of $)</td>
<td>11,407</td>
<td>13,373</td>
<td>14,946</td>
<td>16,257</td>
<td>17,815</td>
<td>21,018</td>
<td>22,997</td>
<td>25,680</td>
<td>28,664</td>
<td>29,881</td>
</tr>
<tr>
<td>Percentage of sales</td>
<td>14.2</td>
<td>15.3</td>
<td>15.3</td>
<td>13.7</td>
<td>13.6</td>
<td>14.6</td>
<td>15.2</td>
<td>16.3</td>
<td>17.2</td>
<td>18.2</td>
</tr>
</tbody>
</table>

* Data on promotional spending are from IMS Health (www.imshealth.com)

Annual Spending on DTCA and Professional Promotion ($ M)

Study: More using prescription drugs

By Julie Appleby, USA TODAY

The percentage of insured Americans taking prescription drugs for maladies ranging from high cholesterol and blood pressure to diabetes and depression rose sharply from 2000 to 2006, a study out today finds. The use of painkillers and estrogen declined following safety concerns about those drugs.

Where you live appears to affect what medications you take, according to the study, which offers a rare look at geographic differences in prescription drug use. Express Scripts, one of the USA's largest drug-benefit firms, surveyed drug-use data for 3 million adults with health insurance in 40 states.

PRESCRIPTION USAGE: State-by-state chart

Researchers described their findings as a wake-up call to states and employers, noting the 2000 to 2006 increase in the use of drugs for diabetes, high blood pressure, cholesterol, stomach problems and depression raised costs by 50%, or $12 billion.

Over time, the researchers note, the higher usage may save money by preventing heart attacks, strokes and other problems. But more prevention efforts might reduce the need for drugs. Express Scripts
Geographic Variation Trends in Prescription Use: 2000 to 2006

Executive Summary
In 2002, Express Scripts researchers added a new dimension — geographic location — to the list of factors influencing prescription-drug use. Since that time, major changes have taken place on the prescription-drug landscape. Increasing rates of obesity, drug recalls, reports of safety issues and changing treatment guidelines all affect prescription-drug use in important ways.

Using 2006 data from a random sample of 3 million commercially insured members, we explored, once again, patterns of use by state for seven major therapy classes: antihyperlipidemics, antidiabetics, antihypertensives, gastrointestinal (GI),

- The states with the greatest per capita increase in spending for these therapy classes were West Virginia, $196; Kentucky, $185; Alabama, $174; Mississippi, $162; Louisiana, $154; and Arkansas, $151.

Implications
Plan sponsors face numerous challenges in managing prescription-drug costs. Our key findings suggest that those challenges include the sociodemographic and market forces influencing the use of prescription medications. Total healthcare cost implications from increases or decreases in utilization are unclear. Encouraging use of the most cost-effective agents within a therapy class could help reduce overall prescription-drug costs.
# Trends in Prescription Use 2000 to 2006

Table 1: Age and Gender Adjusted Prevalence and Utilization by Therapy Class: 2000 and 2006

<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>Prevalence</th>
<th>PMPY Utilization</th>
<th>Coefficient of Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihyperlipidemics</td>
<td>6.1%</td>
<td>13.2%</td>
<td>116.4%</td>
</tr>
<tr>
<td>Antidiabetics</td>
<td>3.1%</td>
<td>5.5%</td>
<td>77.4%</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>8.0%</td>
<td>14.1%</td>
<td>76.3%</td>
</tr>
<tr>
<td>Gastrointestinal Medications</td>
<td>9.0%</td>
<td>10.8%</td>
<td>20.0%</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>10.7%</td>
<td>14.2%</td>
<td>32.7%</td>
</tr>
<tr>
<td>Analgesics/Anti-inflammatories</td>
<td>16.3%</td>
<td>15.4%</td>
<td>-5.5%</td>
</tr>
<tr>
<td>Estrogen</td>
<td>7.9%</td>
<td>3.7%</td>
<td>-53.2%</td>
</tr>
<tr>
<td>Overall</td>
<td>66.7%</td>
<td>74.4%</td>
<td>11.5%</td>
</tr>
</tbody>
</table>
Trends in Prescription Use 2000 to 2006

Antihyperlipidemics

Antidepressants

Express Scripts, Jan 2008
Trends in Prescription Use 2000 to 2006

Estrogens

Figure 15
Prevalence of Estrogen Use by State — 2000

Figure 16
Prevalence of Estrogen Use by State — 2006

Express Scripts, Jan 2008
Number of DTC Materials Submitted to FDA, 1999-2005

GAO-07-54, Nov 2006
“In late 2006 AstraZeneca launched a six-part podcast series with About.com as part of its ‘Living with Heartburn’ program in support of proton pump inhibitor Nexium. The company has also created a video for the effort, which educates consumers on coping with heartburn and acid reflux disease.”

MM&M June 2007
Outline

• Role of FDA
• DTCA today
• Asymmetric information
• Sources of consumer health information
Asymmetric Information
(Knowledge Is Power)

Agents on one side of a market have much better information than those on the other side.

2001 Nobel Prize in Economics

- Patients know their risks, insurance companies may not.
- Doctors understand the proper treatments, patients may not.
- Pharmaceutical companies know more about the benefits and risks of drugs than patients.
• November 21, 2008 - **Popular Radio Host Has Drug Company Ties.** Dr. Frederick Goodwin, host of NPR’s “The Infinite Mind” program, earned at least $1.3M from drug makers for marketing lectures.

• October 3, 2008 - **Top Psychiatrist Didn’t Report Drug Makers’ Pay.** Dr. Charles Nemeroff, chair of Emory Univ Department of Psychiatry, earned $2.8M consulting for drug makers.

• June 8, 2008 - **Researchers Fail to Reveal Full Drug Pay.** Dr. Joseph Biederman, child psychiatrist at Mass General Hospital, earned at least $1.6M in consulting fees from drug makers.
For Jarvik Heart Pioneer, Drug Ads Raise Profile and Questions

By STEPHANIE SAUL

Dr. Robert Jarvik is best known for the artificial heart he pioneered more than a quarter-century ago. Since then he has toiled in relative obscurity — until he began appearing in television ads two years ago for the Pfizer cholesterol drug Lipitor.

The ads have depicted him, among other outdoorsy pursuits, rowing a one-man racing shell swiftly across a mountain lake. “When diet and exercise aren’t enough, adding Lipitor significantly lowers cholesterol,” Dr. Jarvik says in the ad.

Celebrity advertising endorsements are nothing new, of course. But the Lipitor campaign is a rare instance of a well-known doctor’s endorsing a drug in advertising — and it has helped rekindle a smoldering debate over whether it is appropriate to aim ads for prescription drugs directly at consumers.

A Congressional committee, concerned that the Lipitor ads could be misleading, has said it wants to interview Dr. Jarvik about his role as the drug’s pitchman.

Some of the questions may involve his credentials. Even though Dr. Jarvik holds a medical degree, for example, he is not a cardiologist and is not licensed to practice medicine. So what, critics ask, qualifies him to recommend Lipitor on television — even if, as he says in some of the ads, he takes the drug himself?

And, for that matter, what qualifies him to pose as a rowing enthusiast? As it turns out, Dr. Jarvik, 61, does not actually practice the sport. The ad agency hired a stunt double for the sculling scenes.

“He’s about as much an outdoorsman as Woody Allen,” said a longtime collaborator, Dr. O. H. Frazier of the Texas Heart Institute.

An ad used a double for Dr. Robert Jarvik.

“He can’t row.”

The House Committee on Energy and Commerce is looking into when and why Dr. Jarvik began taking Lipitor and whether the advertisements give the public a false impression, according to John D. Dingell, the

Continued on Page A17
Dr. Robert Jarvik Lipitor Ad

The developer of an artificial heart becomes a lightning rod in debate over consumer drug advertising.

Common risk factors include: Family history, high blood pressure, smoking, low good cholesterol and age.

E-MAIL THIS VIDEO
PERMALINK:
http://video.on.nytimes.com/
Ask your doctor if LIPITOR is right for you.

In patients with multiple risk factors for heart disease, Lipitor reduces risk of heart attack by 36%*

If you have risk factors such as family history, high blood pressure, age, low HDL ('good' cholesterol) or smoking.

*That means in a large clinical study, 3% of patients taking a sugar pill or placebo had a heart attack compared to 2% of patients taking Lipitor.

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"Ask your doctor if LIPITOR is right for you."
Pfizer pulls Lipitor ads featuring Dr. Robert Jarvik

- February 26, 2008 - Pfizer announced that it is withdrawing the TV commercials featuring an endorsement of Lipitor by Dr Robert Jarvik.
- Dr. Jarvik and Pfizer were a target of a US House Committee on Energy and Commerce investigation into celebrity endorsements in direct-to-consumer advertisements.
- Pfizer spent $258 million on Lipitor advertisements between January 2006 and September 2007.

Direct-to-Consumer Advertising

Requip

What Is Restless Legs Syndrome?

Is Requip Right for Me?

When Should I See My Doctor?

Tips for Living with Restless Legs Syndrome

Requip is the first FDA-approved medication for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS)

Television Commercial for Requip

This video is available for viewing in QuickTime and Windows Media® Player. Please choose a format and speed:

http://www.requip.com/tv_commercial.html
Requip Ad Deconstructed
Consumer Reports, November 2007©

What the ad doesn’t tell you

**LIFE AS PATHOLOGY**
Music and lighting elevate a fairly uncommon condition, affecting fewer than 3 percent of adults, to something much bigger.

**BUYING CREDIBILITY**
Requip’s maker hyped the syndrome to promote press coverage of RLS, and now trumpets an article as “independent” proof.

**OMITTED FACTS**
You’d never know from this ad that RLS might be related to low blood iron, pregnancy, caffeine, alcohol, tobacco, or cold remedies.

**TURNAROUND**
The commercial exploits the doctor’s status as a trusted authority figure and pretends Requip is HIS idea. But the ad encourages the opposite reality: YOU are supposed to ask your doctor to prescribe Requip.

**HALF THE STORY**
Clinical trials show that Requip relieves symptoms in 53 to 73 percent of sufferers, compared to 47 to 57 percent on sugar pills. There’s also no mention of non-drug treatments such as iron pills or restricting caffeine and alcohol intake.

**WAKE-UP CALL**
If Requip lets you sleep at night, how come 12 percent of tested users were abnormally sleepy? Some users have fallen asleep so suddenly they crashed their cars.

**DON’T WORRY, BE HAPPY**
A calming voice-over, soothing music, and smiling faces help play down the side effects, while the parting words reinforce the upbeat promise of sleep.

“*It was so frustrating. Like a mystery I couldn’t solve. Night after night, strange sensations in my legs.*”

“*I had to get up and move when all I wanted to do was rest. I had Restless Leg Syndrome.*”

“*Two things. I didn’t want to go to the doctor. Then he said something else. Requip.*”

“*He said Requip would help relieve those RLS symptoms that were making nights so difficult.*”

“*He told me what to watch for; that Requip may cause you to fall asleep or feel very sleepy during normal activities such as driving, or to faint or feel dizzy when you stand up.*”

“*Tell your doctor if you experience these problems or if you drink alcohol or are taking medications that make you drowsy. Also tell your doctor if you experience new or increased gambling, sexual, or other intense urges while taking Requip.**

“*Side effects may include nausea, drowsiness, vomiting, and dizziness. Thanks to Requip, the RLS mystery is not keeping me up anymore. Ask your doctor about Requip.***
"It was so frustrating, like a mystery I couldn't solve. Night after night, strange sensations in my legs."

Consumer Reports, Nov 2007©
"I had to get up and move when all I wanted to do was rest. I had Restless Legs Syndrome."

Consumer Reports, Nov 2007©
"My doctor said symptoms usually get worse when it's time to relax."

Consumer Reports, Nov 2007©
"And then he said something else. Requip."
"He said Requip would help relieve those RLS symptoms that were making nights so difficult."

Consumer Reports, Nov 2007©
"He told me what to watch for, that Requip may cause you to fall asleep or feel very sleepy during normal activities such as driving, or to faint or feel dizzy when you stand up."

Consumer Reports, Nov 2007©
"Tell your doctor if you experience these problems or if you drink alcohol or are taking medicines that make you drowsy. Also tell your doctor if you experience new or increased gambling, sexual, or other intense urges while taking Requip."

"Side effects may include nausea, drowsiness, vomiting, and dizziness. Thanks to Requip, the RLS mystery is not keeping me up anymore. Ask your doctor about Requip."

"DON’T WORRY, BE HAPPY A calming voice-over, soothing music, and smiling faces help play down the side effects, while the parting words reinforce the upbeat promise of sleep."
Are your legs keeping you up at night®?

Do you have trouble falling asleep because of strange sensations in your legs? Do you dread long business meetings, going to the movies, or traveling on an airplane because you know your restless legs won't let you sit still?

If this sounds familiar, you may have Restless Legs Syndrome (RLS), a common medical condition characterized by an uncontrollable urge to move the legs when sitting or lying down. In its mild, moderate, and severe forms, RLS affects approximately 1 in 10 adults living in the United States.

You may have asked yourself if anything could be done about the symptoms of RLS. Talk to your doctor about Requip, a prescription medication, the first medication approved by the FDA for the treatment of moderate-to-severe primary RLS.

If you think you're experiencing the symptoms of RLS, see your doctor. If diagnosed, ask your doctor if Requip is right for you.

Important Safety Information:
Are your legs keeping you up at night?

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Important Safety Information:
Improvement in RLS Symptoms after 2 nights and 2 weeks

http://www.requip.com/hcp/treating_rls_with_requip клиничные данные.html
TREAT*RLS US CLINICAL TRIAL

Bogen, Mayo Clin Proc 2006
Ropinirole in the Treatment of Patients With Restless Legs Syndrome: A US-Based Randomized, Double-Blind, Placebo-Controlled Clinical Trial

RICHARD K. BOGAN, MD; JUNE M. FRY, MD, PHD; MARKUS H. SCHMIDT, MD, PHD; STANLEY W. CARSON, PHARM.D; AND SALLY Y. RITCHIE, MSC; FOR THE TREAT RLS US (THERAPY WITH ROPINIROLE EFFICACY AND TOLERABILITY IN RLS US) STUDY GROUP


Financial support for this study came from GlaxoSmithKline Research and Development.

Dr Bogan has acted as a consultant and is on the speakers’ bureau for GlaxoSmithKline; he does industry-funded research for GlaxoSmithKline, SCHWARZ PHARMA, Inc, and Boehringer Ingelheim. Dr Fry has research contracts with GlaxoSmithKline, Merck & Co, Inc, Boehringer Ingelheim, and Sanofi-Aventis. Dr Schmidt has research contracts with GlaxoSmithKline and is a member of GlaxoSmithKline’s RLS National Advisory Board. Dr Carson and Ms Ritchie are employees of GlaxoSmithKline.
Are your legs keeping you up at night?

Do you have trouble falling asleep because of strange sensations in your legs? Do you dread long business meetings, going to the movies, or traveling on an airplane because you know your restless legs won't let you sit still?

If this sounds familiar, you may have Restless Legs Syndrome (RLS), a common medical condition characterized by an uncontrollable urge to move the legs when sitting or lying down. In its mild, moderate, and severe forms, RLS affects approximately 1 in 10 adults living in the United States.

You may have asked yourself if anything could be done about the symptoms of RLS. Talk to your doctor about Requip, a prescription medication, the first medication approved by the FDA for the treatment of moderate-to-severe primary RLS.

If you think you're experiencing the symptoms of RLS, see your doctor. If diagnosed, ask your doctor if Requip is right for you.

Important Safety Information:
“Less than one in ten thousand—something like one in fourteen thousand—gets these side effects. Hardly anybody gets these side effects. They’re extremely rare. You should be very proud.”
Outline

• Role of FDA
• DTCA today
• Asymmetric information

• Sources of consumer health information
Who’s searching for health information on the web?

• 10 million Americans each day

• 80% American internet users, or some 113 million adults, have searched some time or other for info. about at least 1 of 17 health topics

August 2006 survey of internet users conducted by the Pew Internet & American Life Project
How are they searching?

- Two-thirds start with an internet search engine (like Google or Yahoo)

According to the August 2006 survey of internet users conducted by the Pew Internet & American Life Project
What’s the impact of their findings?

• 58% say the information they found affected a decision about how to treat an illness or condition.

• 55% say the information changed their overall approach to maintaining their health or the health of someone they help take care of.

• 54% say the information led them to ask a doctor new questions or to get a second opinion from another doctor.

August 2006 survey of internet users conducted by the Pew Internet & American Life Project
Concerns

- 25% say they felt overwhelmed by the amount of information they found online
- 22% say they felt frustrated by a lack of information or an inability to find what they were looking for online

August 2006 survey of internet users conducted by the Pew Internet & American Life Project
Quality of information

• Just 15% of health seekers say they "always" check quality indicators (e.g. source and date)
  – an additional 10% say they do so “most of the time”

• 85 million Americans gather health advice online daily without consistently examining the quality indicators

August 2006 survey of internet users conducted by the Pew Internet & American Life Project
How can you help?

Guide your patients toward reliable sources of health information

• Refer them to support at DHMC
  – Consumer Health Library in Matthews-Fuller Health Sciences Library
  – Health Education Center (HEC)

• Suggest web sites
  – MedlinePlus
  – Biomedical Libraries Consumer Health Information site
About the Consumer Health Library

- What is the Consumer Health Library?
- Where is the Consumer Health Library located?
- During what hours is the library available?
- Who can check out books from the Consumer Health Library?
- Can someone help me find information in the Consumer Health Library?
- Are there specific web sites that I can search for consumer health information?

What is the Consumer Health Library?
The Consumer Health Library contains books and videotapes on a wide variety of consumer health topics, such as heart disease, cancer, child health, prescription drugs, aging, and much more. Material in the Consumer Health Library is indexed in the Dartmouth College Library Catalog.

Where is the Consumer Health Library located?
The Consumer Health Library is located on the 5th floor of Dartmouth-Hitchcock Medical Center (2 floors up from the Main Entrance Information Desk) inside the Matthews-Fuller Health Sciences Library.

During what hours is the library available?
The Consumer Health Library is available during all hours that the Matthews-Fuller Health Sciences Library is open. See our posted hours for details.

Who can check out books from the Consumer Health Library?
Patients, family members, and members of the general public may check out up to two items from this Library for two weeks;
Google: consumer health DHMC
Consumer Health Information

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About the Consumer Health Library

Health Information Resources:

<table>
<thead>
<tr>
<th>Resource</th>
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<td>Children's Health</td>
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<td>Senior Health</td>
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<tr>
<td>Medical News</td>
<td>Healthy Lifestyle</td>
</tr>
</tbody>
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Disclaimer: The resources presented here are intended to provide public access to a wide range of health and disease information and should not be construed as medical advice or be used as a substitute for consultation with a health care professional.
Consumer Health Information: Drugs

**MEDLINEplus Drug Information**
Information on thousands of prescription and over-the-counter medications is provided through two drug resources -- MedMaster®, a product of the American Society of Health-System Pharmacists (ASHP), and the USP DI® Advice for the Patient®, a product of the United States Pharmacopeia (USP).

**CenterWatch Drug Directories**
Provides descriptions of FDA recently approved prescription drugs, as well as listings of drugs approved in previous years, back to 1995. The drugs are organized by therapeutic area.

**DrugDigest**
Provides easy-to-read reference materials on topics ranging from drugs, vitamins, and herbs to breakthrough medical research and state-of-the-art disease management. Offers a free eBulletin service, which includes the latest news and research on the health conditions. In addition, DrugDigest provides a Drug Interactions database, where you can check interactions between two or more drugs and get detailed information regarding potentially harmful drug interactions.

**Drug InfoNet**
Provides both information and links to areas on the web concerning healthcare and pharmaceutical-related topics. Includes links to drug information, government sites, healthcare news, health information, and pharmaceutical manufacturer information.

**FDA's Center for Drug Information and Research**
From the U.S. Food and Drug Administration; provides links to drug information sheets, drug approvals, drug shortages, inactive ingredient database, and news information.

**FDA Consumer Drug Information**
Offers summaries of drugs approved by the Food and Drug Administration since 1998. A searchable drug listing includes prescription and over-the-counter medications and discontinued drugs.

**Needy Meds**
Provides information about pharmaceutical manufacturers' special programs to assist people who can't afford to purchase medications they need.

**Prescription Drug Survival Guide**
Developed by Jon W. Wahrenberger, M.D., Section of Cardiology, Dartmouth-Hitchcock Medical Center. Includes information about ways to obtain medications in a safe and cost-effective manner. Intended to be used in conjunction with your doctor's recommendations.
Use MedlinePlus to find information on Restless Leg Syndrome
Current Health News

- Smokeout '09: The Perfect Time to Quit
- Cascade of Events Leads to Teen Violence
- Long-Term Antibiotic Use Affects 'Good' Gut Bacteria
- More news

Featured Site

November 20 is the Great American Smokeout. Learn more about quitting smoking.

In the Spotlight

November is Alzheimer's Disease Awareness Month. Learn more:
- Go to Alzheimer's Disease topic page
- NIH Senior Health: Alzheimer's Disease
- Latest News
Restless legs syndrome (RLS) causes a powerful urge to move your legs. Your legs become uncomfortable when you are lying down or sitting. Some people describe it as a creeping, crawling, tingling or burning sensation. Moving makes your legs feel better, but not for long.

In most cases, there is no known cause for RLS. In other cases, RLS is caused by a disease or condition, such as anemia or pregnancy. Some medicines can also cause temporary RLS. Caffeine, tobacco and alcohol may make symptoms worse. (Read more)
Restless Legs

Also called: RLS

Restless legs syndrome (RLS) causes a powerful urge to move your legs. Your legs become uncomfortable when you are lying down or sitting. Some people describe it as a creeping, crawling, tingling or burning sensation. Moving makes your legs feel better, but not for long.

In most cases, there is no known cause for RLS. In other cases, RLS is caused by a disease or condition, such as anemia or pregnancy. Some medicines can also cause temporary RLS. Caffeine, tobacco and alcohol may make symptoms worse.

Lifestyle changes, such as regular sleep habits, relaxation techniques and moderate exercise during the day can help. If those don’t work, medicines may reduce the symptoms of RLS.

Start Here

- Restless Legs Syndrome (American Academy of Family Physicians)
  Also available in Spanish
- Restless Legs Syndrome NIH (National Heart, Lung, and Blood Institute)
- Restless Legs Syndrome NIH (National Institute of Neurological Disorders and Stroke) - Short Summary

Basics

- Overviews
  - Latest News
  - Diagnosis/Symptoms
  - Treatment

Learn More

- Disease Management
  - Related Issues

Reference Shelf

- Clinical Trials
  - Journal Articles
- Dictionaries/Glossaries
  - Dictionaries
  - Organizations

Multimedia & Cool Tools

- No links available

Related Topics

- Leg Injuries and Disorders
- Movement Disorders
- Sleep Disorders
- Brain and Nerves

Go Local

Search and providers for Restless Legs in the U.S.

For You

- Women

Overviews

- Restless Leg Syndrome (Mayo Foundation for Medical Education and Research)
  Also available in Spanish
- Restless Legs Syndrome: Frequently Asked Questions (Restless Legs Syndrome Foundation)

Latest News

- Genetic Testing No Real Help in Predicting Type 2 Diabetes (11/19/2008, HealthDay)
- Spinal Anesthesia Doesn’t Cause Restless Leg Syndrome (11/19/2008, HealthDay)
Restless Legs Syndrome

What is restless legs syndrome (RLS)?

Restless legs syndrome (also called RLS) is a condition in which your legs feel very uncomfortable when you are sitting or lying down. It affects both men and women and can occur at any age, including during childhood, but often worsens with age and becomes a problem for older adults. RLS can make sleeping and traveling difficult and uncomfortable. Some cases of RLS are related to other conditions, such as pregnancy, iron-deficiency anemia or kidney failure. Other cases of RLS have no known cause. RLS may be hereditary, which means it can run in your family.

What does it feel like to have RLS?

People who have RLS say it’s difficult to describe their symptoms. If you have RLS, you may have a "creepy-crawly" feeling in your legs that makes you want to move around. You may experience achy, tingly or burning sensations in your legs, which can make it difficult to sleep or sit for long periods of time. Moving your legs makes the feeling go away for a few minutes, but it comes back after you sit or lie still again. Your legs may also twitch when you try and sleep (also called periodic limb movements of sleep or PLMS).

How does my doctor know I have RLS?

Tell your doctor about the restless sensations. He or she will ask you questions about your symptoms, such as when they start and whether you’re able to do anything to make them go away. He or she may also ask if any other people in your family have similar symptoms.

Tell your doctor about any medications (including over-the-counter medication) that you’re taking. Certain medications can make RLS symptoms worse. Your doctor can recommend another medicine if this seems to be happening to you.

What is the treatment for RLS?

Treatment for RLS includes medications and lifestyle changes. See the box below for a list of things that you can do at home to help relieve your symptoms.

Medications used to treat Parkinson’s disease can help reduce tremors and twitching in the legs. If your iron levels are low, your doctor may prescribe an iron supplement. Sleep aids, muscle relaxants (called benzodiazepines) and pain medications (called opioids) may also relieve symptoms. In some cases, an anticonvulsant medicine (usually used to stop seizures) can be helpful. For many cases of RLS, a combination of medications is usually needed to best treat the
Use **MedlinePlus** to find information on Lipitor
Drugs, Supplements, and Herbal Information

Drug Information: Browse by first letter of generic or brand name drug

Prescription and over-the-counter medication information is from AHFS® Consumer Medication Information™, a product of the American Society of Health-System Pharmacists (ASHP). For additional drug information, see the MedlinePlus Drug Therapy topic pages or FDA Approved Labels from DailyMed.

Herbs and Supplements: Browse by first letter of herb or supplement

Information on herbs and supplements is from Natural Standard®. For additional herb and supplement information, see the MedlinePlus Complementary and Alternative Therapies topics or the Dietary Supplements Labels Database from the National Library of Medicine.

Additional Information

See the following Food and Drug Administration pages, for more information:

- Drug Information Pathfinder
- Warnings, Recalls, and other Drug Information
- Medical Product Safety Information from MedWatch

For drugs in clinical research studies, see ClinicalTrials.gov

Search MEDLINE/PubMed for specific research articles on your drug

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*AHFS® Consumer Medication Information database provides information copyrighted by the American Society of Health-System Pharmacists, Inc., Bethesda, Maryland Copyright© 2009, All Rights Reserved.

*Natural Standard Monograph Copyright© 2008 Natural Standard. Commercial distribution or reproduction prohibited.
Other drug names: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z 0 9

Drugs beginning with "L"

- L-Carnitine see L-Carnitine Injection
- LPAM see Melphalan
- L-Triiodothyronine see Liothyronine
- Labetalol Oral
- LactiCare®-HC see Hydrocortisone Topical
- Lactulose
- Ladakmycin see Azacitidine Injection
- Lamictal® see Lamotrigine
- Lamictal® see Temazepam
- Lamictal® AT see Tegretol
- Lamivudine
- Lamivudine and Zidovudine
- Lamotrigine
- Lanacort® 10 see Hydrocortisone Topical
- Lanoxicaps® see Digoxin Oral
- Lanoxin® see Digoxin Oral
- Lanoxin® Orbit Pediatric see Digoxin Oral
- Lansoprazole
- Lansoprazole/clarithromycin/amoxicillin
- Lanthanum
- Lantus® see Insulin Glargine (rDNA origin) Injection
- Laropiprant
- Laronidase see Mefcozyme
- Lasix® see Furosemide
- Latanoprost
- Latanoprost-C® as a combination product containing Hydrocortisone, Neosporin Sulfate, and Polymyxin B Sulfate see Hydrocortisone Topical
- Ledercillin VK® see Penicillin V Potassium Oral
- Lefunomide
- Legatrin PM® Caplets® (as a combination product containing Diphenhydramine Hydrochloride and Acetaminophen) see Diphenhydramine
- Lenalidomide
- Lepargylic acid see Azelaic Acid Topical
- Lexapro see Escitalopram
Lidoderm® see Lidocaine Transdermal
Limbitrol® see Chlor Diazepoxide

Limbitrol® (as a combination product containing amitriptyline and chlordiazepoxide) see Amitriptyline
Limbitrol® DS see Chlor Diazepoxide
Limbitrol® DS (as a combination product containing amitriptyline and chlordiazepoxide) see Amitriptyline
Lindane
Linezolid

Lioresal® Intrathecal see Baclofen Oral
Liothyronine
Lotrix
Lipase see Pancrelipase
Liptor® see Atorvastatin

Liposomal doxorubicin see Doxorubicin
Liposyn® see Fat Emulsions for Injection
Lipram® 4500 see Pancrelipase
Lipram®-CR10 see Pancrelipase
Lipram®-CR20 see Pancrelipase

Lipram®-CR6 see Pancrelipase
Lipram®-PIN10 see Pancrelipase
Lipram®-PIN16 see Pancrelipase
Lipram®-PIN20 see Pancrelipase
Lipram®-UL12 see Pancrelipase

Lipram®-UL18 see Pancrelipase
Lipram®-UL20 see Pancrelipase
Liquid Pedax HIB see Haemophilus influenzae type b Vaccine
Liquidprin® Drops see Acetaminophen
Lisdexamfetamine

Losapril
Losapril and Hydrochlorothiazide
Lithium
Lithobid® see Lithium
Lo/Ovral® see Estrogen and Progestin (Oral Contraceptives)

Locholest® see Cholestyramine Resin
Locholest® Light see Cholestyramine Resin
Locoid® see Hydrocortisone Topical
Lodine® see Etodolac
Lodine® XL see Etodolac

Lodoxamide Ophthalmic
Lodrane® (as a combination product containing Brompheniramine Maleate and Pseudoephedrine Hydrochloride) see Brompheniramine
Lodrane® LD (as a combination product containing Brompheniramine Maleate and Pseudoephedrine Hydrochloride) see Brompheniramine
Loestrin® see Estrogen and Progestin (Oral Contraceptives)
Loestrin® Fe see Estrogen and Progestin (Oral Contraceptives)
Atorvastatin
(a tor’a va stat’in)

Contents of this page:
- Why is this medication prescribed?
- How should this medicine be used?
- Other uses for this medicine
- What special precautions should I follow?
- What special dietary instructions should I follow?
- What should I do if I forget a dose?
- What side effects can this medication cause?
- What storage conditions are needed for this medicine?
- In case of emergency/overdose
- What other information should I know?
- Brand names
- Brand names of combination products

IMPORTANT WARNING:  Return to top

[Posted 09/30/2008] An FDA analysis provides new evidence that the use of statins does not increase incidence of amyotrophic lateral sclerosis (ALS), a neurodegenerative disease often referred to as “Lou Gehrig’s Disease.” The FDA analysis, undertaken after the agency received a higher than expected number of reports of ALS in patients on statins, is based on data from 41 long-term controlled clinical trials. The results showed no increased incidence of the disease in patients treated with a statin compared with placebo.

The FDA is anticipating the completion of a case-control or epidemiological study of ALS and statin use. Results from this study should be available within 6-9 months. FDA is also examining the feasibility of conducting additional epidemiologic studies to examine the incidence and clinical course of ALS in patients taking statins.

Based on currently available information, health care professionals should not change their prescribing practices for statins and patients should not change their use of statins. For more information visit the FDA website at: http://www.fda.gov/medwatch/safety/2008/safety00.html#Statin and http://www.fda.gov/bbs/topics/NEWS/2008/NEWS01852.html

Why is this medication prescribed?  Return to top

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Atorvastatin is used along with diet, exercise, and weight-loss to reduce the risk of heart attack and stroke and to decrease the chance that heart surgery will be needed in people who have heart disease or who are at risk of developing heart disease. Atorvastatin is also used to decrease the amount of cholesterol (a fat-like substance) and other fatty substances in the blood. This will decrease the risk of stroke, heart attack, and other heart diseases because when there are high levels of cholesterol and other fats in the blood, these substances may build up along the walls of the blood vessels and decrease or block blood flow to the heart. Atorvastatin is in a class of medications called HMG-CoA reductase inhibitors (statins). It works by slowing the production of cholesterol in the body.

How should this medicine be used?  Return to top

Atorvastatin comes as a tablet to take by mouth. It is usually taken once a day with or without food. Take atorvastatin at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take atorvastatin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.
“Talking with Your Doctor”
Personal Health Issues

- Advance Directives
- Choosing a Doctor or Health Care Service
- Clinical Trials
- Communicating With Your Healthcare Provider see Talking With Your Doctor
- Confidentiality see Personal Medical Records

- Death and Dying see End of Life Issues
- Do Not Resuscitate Orders see Advance Directives
- Electronic Health Records see Personal Medical Records
- End of Life Issues
- Evaluating Health Information

- Health Literacy
- HIPAA see Personal Medical Records
- Informed Consent see Patient Rights
- Living Wills see Advance Directives
- Medical Research see Understanding Medical Research

- Ombudsman Programs see Patient Rights
- Palliative Care
- Patient Records see Personal Medical Records
- Patient Rights
- Patient Safety

- Personal Medical Records
- Privacy see Personal Medical Records
- Resuscitation Orders see Advance Directives
- Second Opinion see Patient Rights, Talking With Your Doctor
- Talking With Your Doctor

- Terminal Care see End of Life Issues
- Understanding Medical Research
Talking With Your Doctor

Visiting a doctor's office can make you nervous, impatient, or even scared. You may have only a few minutes with your health care provider. Later, you might remember something you forgot to ask. Or you may forget what the doctor or nurse said. Being prepared can help you get the information you need. Here are some things you can bring to make the most of your visit:

- Lists of your concerns, any allergies and all the medicines, herbs or vitamins you take
- A description of symptoms - when they started, what makes them better
- A notepad or tape recorder
- A trusted friend or relative

Make sure you understand your diagnosis and any treatments. Ask your health care provider to write down his or her instructions to you. If you still have trouble understanding, ask where you can go for more information.

Start Here

- Be an Active Member of Your Health Care Team (Center for Drug Evaluation and Research)
  Also available in Spanish
- How to Talk to Your Child's Doctor ( Nemours Foundation)
  Also available in Spanish
- Talking to Your Doctor: NIH (National Eye Institute)
  Also available in Spanish

Basics

- Overviews
- Latest News

Research

- Clinical Trials
- Research
- Journal Articles

Learn More

- Alternative Therapy
- Specific Conditions
- Related Issues

Reference Shelf

- Organizations

Multimedia & Cool Tools

- Tutorials
- Videos

For You

- Children
- Teenagers
- Seniors

Languages

- ASL (American Sign Language)
- Arabic (اللغة العربية)
- French (français)
- Hindi (हिंदी)
- Japanese (日本語)
- Korean (한국어)
- Russian (русский)
- Somali (soomaali)

Related Topics

- Patient Rights
- Patient Safety
- Health System
- Personal Health Issues
- Social/Family Issues

Go Local

Services and providers for Talking With Your Doctor in the U.S.
Select Location
Select from map

Overviews

- Getting the Most Out of a Visit with Your Doctor (American Academy of Orthopaedic Surgeons)
- Questions Are the Answer: Get More Involved with Your Health Care (Agency for Healthcare Research and Quality)
- Tips for Talking to Your Doctor (American Academy of Family Physicians)
  Also available in Spanish

Latest News

- Cancer Patients Often Forget Details of Doctor Visit (11/12/2008, Reuters Health)
- New Cancer Patients Retain Little Medical Information (10/22/2008, HealthDay)
Questions Are the Answer
Get More Involved With Your Health Care

Improve Your Health Care

Check Out Our Videos

Learn More

Do You Know the Right Questions to Ask

1. What is the test for?
2. How many times have you done this?
3. When will I get the results?
4. Why do I need this surgery?
5. Are there any alternatives to surgery?
6. What are the possible complications?
7. Which hospital is best for my needs?
8. How do you spell the name of that drug?
9. Are there any side effects?
10. Will this medicine interact with medicines that I’m already taking?
Build Your Question List

Are you visiting your health care clinician or pharmacist? It is important to be prepared. Create a personalized list of questions that you can take with you:

- Did your clinician give you a prescription?
- Are you scheduled to have medical tests?
- Did you recently receive a diagnosis?
- Are you considering treatment for an illness or condition?
- Did your clinician recently recommend surgery?
- Are you choosing a health plan?
- Are you choosing a clinician?
- Are you choosing a hospital?
- Are you choosing long-term care?

Check the boxes below that apply to you, and then select "Create a List." You will be able to print a custom list of questions with space for answers.
Are you considering treatment for an illness or condition?

Ask:

☐ What are my treatment options?
☐ What do you recommend?
☐ Is the treatment painful?
☐ How can the pain be controlled?
☐ What are the benefits and risks of this treatment?
☐ How much does this treatment cost?
☐ Will my health insurance cover the treatment?
☐ What are the expected results?
☐ When will I see results from the treatment?
☐ What are the chances the treatment will work?
☐ Are there any side effects?
☐ What can be done about them?
☐ How soon do I need to make a decision about treatment?
☐ What happens if I choose to have no treatment at all?

Create a List, Continue, or go Back to Top

Did your clinician recently recommend surgery?

Ask:
By Name  By Category NEW!

LIPITOR

- Show examples. NEW!
- Show drug category descriptions. NEW!
- Show list of resources searched.
Drug Information Portal
Quick Access to over 12,000 Selected Drugs

Home  Search Results

By Name  By Category
LIPITOR  Go

Go back to previous page.

Search Results

Drug Name: Atorvastatin calcium [USAN]  [show more names]
Search Term: LIPITOR
Description: Hydroxymethylglutaryl-CoA reductase inhibitor.
Categories: Anticholesterolmic Agents  [show more categories]

Summary

- Summary of drug information (MedlinePlusDrug)
- Summary of consumer health information (MedlinePlusTopics)
- Manufacturers drug label (DailyMed)
- Clinical trials (ClinicalTrials.gov)

Detailed Summary

- Summary of reviewed biological and physical data (HSDB)
- References from scientific journals (Medline/PubMed)
- References from toxicological journals (TOXLINE)
- Biological activities and chemical structures (PubChem)
- Biological activities against HIV/AIDS and other viruses (NIAID ChemDB)
- Toxicological and chemical resources (ChemIDplus)

Additional Resources

- Information from the US Food & Drug Administration (Drugs@FDA)
- Search engine for other government resources (USA.gov)

Go back to previous page.
Search Results

Drug Name: Atorvastatin calcium [USAN] [show more names]
Search Term: LIPICTOR
Description: Hydroxymethylglutaryl-CoA reductase inhibitor.
Categories: [I] Anticholesterolmic Agents [hide more categories]
  [I] Antiinflammatory Agents
  [I] Antimetabolites
  [I] Enzyme Inhibitors
  [I] Hydroxymethylglutaryl-CoA Reductase Inhibitors

Summary
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Go back to previous page.
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Quick Access to over 12,000 Selected Drugs

Search Results

Search

Search Term: LIITOR
Description: Hydroxymethylglutaryl-CoA reductase inhibitor.
Categories: Anticholesterolmic Agents

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References from toxicology
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Toxicological and chemical resources (ChemIDplus)

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