ENGELBERG CENTER for Health Care Reform at BROOKINGS

July 2010

DISCUSSION GUIDE

Expert Workshop: The Science of Communicating Medication Information to Consumers

Background

In order to use prescription medications safely, consumers need to receive clear, actionable information. This medication information must be accurate, balanced, and delivered in a consistent and easily understood format. In 2008, an evaluation of Consumer Medication Information (CMI) showed that while 94 percent of consumers received CMI with new prescriptions, only 75 percent of information met the minimum criteria for usefulness, demonstrating that this need is not being met.[1] At present, the written prescription communications patients receive are numerous, uncoordinated, and sometimes inaccurate or conflicting. At the point of dispensing, a consumer may receive any or all of the following:

- Patient Package Inserts (PPI) – Prescription information for oral contraceptives, other estrogen-containing products, and some additional drugs, which are developed by the manufacturer, approved by the Food and Drug Administration (FDA), and dispensed with specific products.
- Consumer Medication Information (CMI) – Prescription information written by the pharmacy or an outside company, which is not FDA-reviewed and is voluntarily distributed by pharmacies to consumers.
- Medication Guides – Prescription information for certain medications "that pose a serious and significant public health concern," are developed by the manufacturer, approved by FDA, and required to be given to consumers each time the medication is dispensed. [2]

For the purpose of this workshop, we will use the term CMI to refer to any written prescription drug information.

Historical Context

The issue of ensuring effective CMI has a long history, marked by great interest and effort on the parts of the federal government and stakeholder groups. Appendix A provides a timeline of important events, the most relevant of which are described below.

In August 1996, Congress mandated that the Secretary of the Department of Health and Human Services (HHS) convene a committee to devise a long-term action plan for improving oral and written prescription drug information.[3] In December 1996, that committee delivered what has come to be called the Keystone action plan, which outlined specific criteria for evaluating the usefulness of CMI for patients.[4]

Over the next decade, FDA held several important meetings, commissioned studies, and considered public input on the issue of effective CMI. In June 2008, the Agency received a citizen petition from a large group representing pharmacy practice, medical consumers, and medical communications companies, requesting that FDA adopt a "one-document solution" to replace PPI, CMI, and Medication Guides.[5]

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[1] Kimberlin CL, Winterstein AG. Expert and Consumer Evaluation of Consumer Medication Information-2008. US Food and Drug Administration. November 4, 2008. Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM117149.pdf. Accessed June 10, 2010.

[2] 21 CFR 208

[3] Public Law 104-180 (August 6, 1996). Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997.

[4] Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information. Action Plan for the Provision of Useful Prescription Medicine Information. December 1996. Available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ReportsBudgets/UCM163793.pdf.

[5] Citizen Petition Requesting FDA Action on a "One Document Solution" for All Pharmacy-Based Communications. June 30, 2008.

In February 2009, the FDA Risk Communication Advisory Committee recommended FDA adopt a single standard document for communicating essential information about prescription drugs, which would replace PPI, CMI, and Medication Guides.[6]

In September 2009, FDA held a public workshop to discuss optimal content and format of written prescription drug information, during which they sought input on four draft patient information prototypes developed through review of the scientific literature and current labeling practices and guidance.[7] In response to the feedback provided during both the February and September 2009 meetings, FDA has developed three draft patient information prototypes (see Appendix B).

On May 4, 2010, FDA announced the design of an evaluation strategy in the Federal Register (FR) and solicited comments by July 6, 2010. Following approval by the Office of Management and Budget, FDA will evaluate the three prototypes using an experimental consumer testing study.[8]

Expert Workshop: The Science of Communicating Medication Information to Consumers

Through a cooperative agreement, the Engelberg Center for Health Care Reform at Brookings is working in collaboration with FDA to convene three workshops to discuss optimizing, implementing, and evaluating adoption of a single standard medication information document.[9] The first meeting is a small expert meeting for the purpose of gathering expert feedback on three prototype documents and on the evaluation plan for these prototypes. The second meeting will be a large public workshop on October 12, 2010. The goals of this workshop will be to identify key challenges facing adoption and dissemination of the new standardized document, including but not limited to distribution, technology, and patient access considerations. The final meeting will be a small expert workshop to consider how to design a pilot for the implementation, distribution, and evaluation of standardized CMI.

Workshop Objectives

The objectives of the July 21 workshop are to discuss: (1) the overarching principles for communicating prescription information effectively; (2) metrics for evaluating CMI; (3) the most useful content and format of a single medication information paper document, as represented in FDA's three prototypes and the proposed strategy for evaluating them; and (4) how patients will receive medication information in the future and whether that has implications for near-term initiatives centered around a single document solution. These objectives will be accomplished through presentations and thoughtful discussion by a small group of experts representing academia, medical professional groups, and various stakeholders from the private sector, including manufacturers, consumer organizations, and publishers of CMI.

Session I: Principles and Approaches for Communicating Medication Information and Understanding its Effect on Patients

Session I of the workshop will identify guiding principles for CMI based on current evidence of how patients learn most effectively, and discuss strategies for measuring the effectiveness of CMI. Participants should be prepared to address the following questions:

- What are some primary guiding principles for developing effective patient-centered, written communication about prescription medications?
- How do we ensure readability, comprehensibility, and usability regardless of the medium used?
- What types of performance measures can be used to determine whether CMI is effective?

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[6] US Food and Drug Administration. Minutes of the Risk Communication Advisory Committee, FDA. February 26-27, 2009. Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM152593.pdf. Accessed June 10, 2010.

[7] US Food and Drug Administration. Workshop Summary. September 24-25, 2009. Available at: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM190419.pdf.

8 Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Patient Information Prototypes. Docket No. FDA-2010-N-0184. Federal Register Vol. 75, No. 85 (May 4, 2010). pp. 23775-23777.

[9] Convener of Active Medical Product Surveillance Discussion (U13). Docket No. FDA-2009-N-0275. Federal Register Vol. 74, No. 120 (June 24, 2009). pp. 30097-30098

Session II: Optimal Content, Format, and Evaluation Strategy for a Single, Paper-Based Medication Leaflet

During Session II, FDA officials will present three CMI prototypes (Appendix B). Workshop participants will offer specific suggestions to optimize the content and format of the documents. To inform this discussion, selected real-world examples will be used to illustrate important, evidence-based concepts.

Open discussion of the prototypes will focus on three elements: content, format, and evaluation strategy. Potential discussion topics for each of these segments are provided below:

Content

- What should patients know about their medications to achieve the greatest benefit?
- Do the prototypes include sufficient information (e.g., is any content lacking or unnecessary)?
- Is there an appropriate balance of risk and benefit information?
- What are the pros and cons of including certain standard statements such as "Your doctor may prescribe this medication for other uses than those approved by FDA"?
- What are the pros and cons of including broader disease awareness information in the leaflets along with medication-specific information?
- What are the pros and cons of including additional clinical rationale with serious side effects listed under the "When Should I Call My Doctor?" section? (see Draft Prototype #2)

Format

- What order is optimal for displaying the information (e.g., is there an optimal location for "Important Warnings")?
- How should new information be highlighted?
- How should icons, pictograms, or other formatting techniques (e.g., bold, italics, underline) be used to achieve emphasis?
- How should headers be utilized? Should they be action-oriented (e.g., "ask your doctor before using if…"), question-and-answer-oriented (e.g., "what should I tell my doctor?"), or descriptive (e.g., "important things to tell your doctor")?
- Should other headers be considered (e.g., "who should not use", "warnings for suddenly stopping the drug", "serious drug interactions")?

Evaluation Strategy

FDA's proposed evaluation strategy is summarized in the bullet points below:

- **Study objective:** To evaluate different ways of presenting information about prescription drugs to patients who have obtained a prescription. Prototypes tested will display information for a fictitious drug that treats rheumatoid arthritis, ankylosing spondylitis, and plaque psoriasis.
- **Study participants:** 900 adults who have been diagnosed with one of the conditions the fictitious drug treats. Participants will be prescreened to obtain a reasonable representation of health literacy, ensuring that at least 30 percent of the sample reads at or below 8th grade level. 540 additional participants will be involved in pre-testing the materials and stimuli to ensure the stimuli meet minimum communication requirements and are delivering expected messages.
- **Independent variables:** Two independent variables in a 3 x 2 design. The independent variables are Format (Drug Facts [Draft Prototype #3], Minimal Column [Draft Prototype #1], and Column Plus [Draft Prototype #2]) and Order (Warning first and Indication first).

Order	**Format**		
	Drug Facts (Draft Prototype #3)	Minimal Column (Draft Prototype #1)	Column Plus (Draft Prototype #2)
Warning first			
Indication first			

The Order manipulation will vary the primacy of the boxed warning information and the paragraph about uses of the drug. In terms of Format, the Drug Facts format will follow the conventions of the existing over the counter (OTC) labeling. The Minimal Column condition will contain information in two columns with only basic information in the sections regarding information patients should tell their doctors. The Column Plus condition will also present information in two columns, but will include additional contextual information in the sections about what information patients should report to their doctors.

- **Dependent variables:** The study will assess whether consumers: (1) are able to locate the risk information; (2) gain an accurate understanding of the risks and benefits of the medication; and (3) accurately understand and apply the information. The study will also measure consumer perceptions and attitudes toward the medication**.**
- **Assignment:** Participants with relevant medical conditions will be randomly assigned to one of the six experimental conditions and each participant will see only one version of the patient information.
- **Data collection:** Data collection will occur via Internet with materials pre-mailed to participants. Questionnaire measures will include open- and closed-ended questions.
- **Follow-up study on electronic prototype presentation:** An additional smaller study (n=200 consumers with rheumatoid arthritis) will be conducted via the Internet with prototypes embedded within the web program to determine whether electronic prototype presentation alters the processing of the information in any way. Two hundred individuals with the same characteristics as the original sample (e.g., medical condition, literacy levels) will complete the same questionnaire as original participants.

With regard to this evaluation strategy, FDA is particularly interested in discussing the following topics:

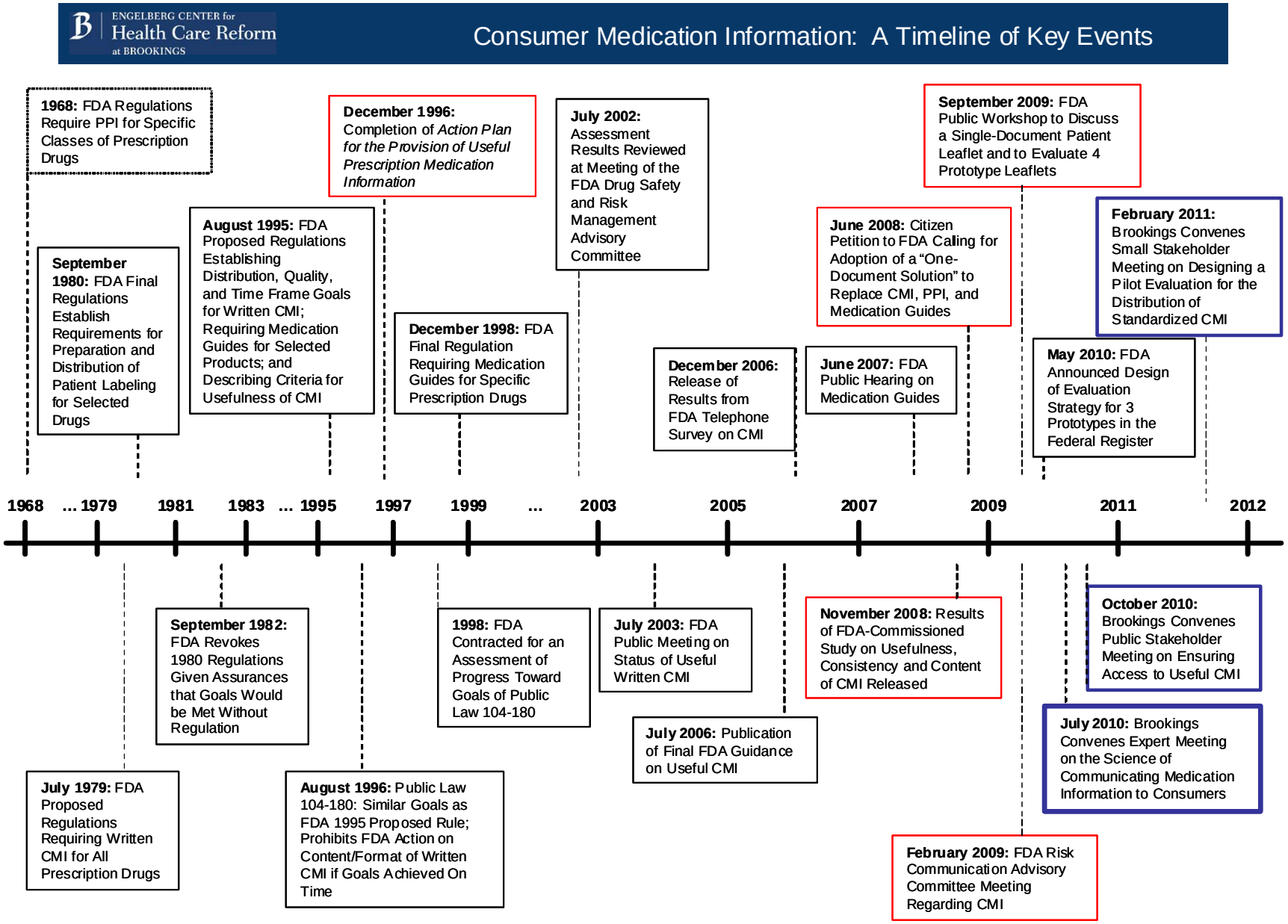
- Is the proposed study appropriate to evaluate the prototypes, and will the results have practical utility?
- Are the study design and assumptions valid?
- What modifications will enhance the quality, utility, and clarity of the information to be collected?

Session III: Alternatives to Paper-Based CMI

Consumers receive health information from a growing myriad of sources, including health care providers, manufacturers, insurance companies, employers, the Internet, and mobile devices. It is therefore essential that future steps to improve the content and format of CMI be flexible and consider media types and channels of distribution beyond paper leaflets. In the third session, participants will be asked to address the following types of questions:

- What are the most likely channels through which patients will receive CMI in the next 10-20 years and how do these vary by demographic group?
- What opportunities do new channels of distribution offer for improving the effectiveness of CMI?
- What are the implications of these channels for content and format?
- Are there strategies to ensure patients have access to the most important messages without loss of content or clarity?
- Do these trends have implications for near-term initiatives?

Appendix A: Timeline of Key Events



Drug Approved by FDA: 2005
Date of Leaflet: May 2009

DRAFT PROTOTYPE 1

PATIENT INFORMATION

Rheutopia™ [Roo-toh-pee-ah] (also known as arixalate)

Important Warning: Serious Infections

- Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection.
- People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

What Does Rheutopia Treat?

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis (JRA) in people older than 4 years of age who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

What Should I Tell My Doctor?

Before using Rheutopia, tell your doctor if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB.
- lived in or traveled to other countries.
- have any nervous system or heart problems.
- are taking the medicine Kineret (anakinra).
- are scheduled to receive a vaccination. (including a flu shot). You should not get a vaccination while taking Rheutopia.

When Should I Call My Doctor?

Stop using Rheutopia and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores).
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

What Are Some Common Side Effects?

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Tell your doctor about any side effect that does not go away in a few days or gets worse.

How Do I Use Rheutopia?

- Rheutopia is an injection (shot). Do not use Rheutopia until you have been shown how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Where Can I Get More Information?

- Visit www.fda.more-information.gov
- Call 1-800-(manufacturer).

You may report side effects to (manufacturer) at (phone # and web address) or FDA at 1-800-332-1088.

Drug Approved by FDA: 2005
Date of Leaflet: May 2009

DRAFT PROTOTYPE 2

PATIENT INFORMATION

Rheutopia™ [Roo-toh-pee-ah] (also known as arixalate)

Important Warning: Serious Infections

- Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection.
- People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

What Does Rheutopia Treat?

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis (JRA) in people older than 4 years of age who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

What Should I Tell My Doctor?

Before using Rheutopia, tell your doctor if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB. You may be tested and treated for TB.
- lived in or traveled to other countries. There is more risk for getting TB or other infections in certain countries.
- have any nervous system or heart problems.
- are taking the medicine Kineret (anakinra). The risk of serious infections increased when used with Rheutopia.
- are scheduled to receive a vaccination (including a flu shot). You should not get a vaccination while taking Rheutopia.

When Should I Call My Doctor?

Stop using Rheutopia and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness. Symptoms of nervous system diseases, like multiple sclerosis, may develop or get worse.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss. You may have a higher chance of getting lymph node cancer.
- Bruising, bleeding, and pale skin. Your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain. These are symptoms of heart failure that may develop or get worse.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be symptoms of an immune reaction with lupus-like syndrome.

What Are Some Common Side Effects?

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Tell your doctor about any side effect that does not go away in a few days or gets worse.

How Do I Use Rheutopia?

- Rheutopia is an injection (shot). Do not use Rheutopia until you have been shown how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Where Can I Get More Information?

- Visit www.fda.more-information.gov
- Call 1-800-(manufacturer).

You may report side effects to (manufacturer) at (phone # and web address) or FDA at 1-800-332-1088.

DRAFT PROTOTYPE 3

Drug Approved by FDA: 2005
Date of Leaflet: May 2009

Rheutopia [Roo-toh-pee-ah]

Active ingredient: arixalate

Uses

- Rheumatoid arthritis (adults and children older than 4): reduces painful swollen joints, slows joint damage and improves mobility
- Ankylosing spondylitis: reduces back pain, swelling, and improves mobility
- Plaque psoriasis in adults: clears up areas of the skin with psoriasis

Warnings

Important Warning: Serious Infections

Do not use Rheutopia if you have an active infection. Rheutopia affects the immune system and can lower your ability to fight infection. Some people have died from an infection such as tuberculosis (TB) when taking Rheutopia.

Ask your doctor before using if you

- have any signs of infection (fever, cough, flu-like symptoms)
- have a skin infection (warm, red, painful skin or open sores)
- have tested positive for tuberculosis (TB) or have been near someone who has TB
- have a problem with your nervous system
- have recently been vaccinated or are scheduled to be vaccinated
- have lived or traveled outside the country
- have a problem with your heart
- are taking Kineret (anakinra)

Stop use and call your doctor right away if you

- have an infection (fever, chills, cough, flu-like symptoms)
- have a skin infection (warm, red, painful skin or open sores)
- have a skin rash
- have numbness (can't feel your skin) or tingling skin
- have changes in your vision
- have swollen lymph nodes, night sweats
- took more Rheutopia then you were told to take
- have weakness in your arms or legs
- feel faint or light headed
- easily bruise or bleed
- get short of breath
- get swollen (fat) ankles
- have chest pain
- have sudden weight loss or gain

Report side effects to FDA at 1-800-FDA-1088.

Common side effects

- redness, rash, swelling, itching, or bruising where the shot was given
- headaches
- runny nose

Tell your doctor about any side effect that does not go away in a few days or gets worse.

Directions

- Rheutopia is given by injection (shot). Do not use Rheutopia before you receive instructions for giving a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- Do not miss any doses. If you do forget to take your Rheutopia, give yourself a shot as soon as you remember. Then give your next shot at your regularly scheduled time.

For More Information

- Visit **www.fda.more-informatio.gov**
- Call [manufacturer] toll-free 1-800-_____ from ___ a.m. to __p.m. (ET) Monday to Friday