

Northwestern University Feinberg School of Medicine

A Consumer-Led Process for Improving FDA Medication Guides

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- Co-Investigators: Allison L Russell, BA; Cammeo R Medici, BA; Elizabeth A H Wilson, PhD; Jennifer P King, MPH; Bruce L Lambert, PhD



Funded by an unrestricted research grant from Abbott Laboratories



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Background – Medication Guides

- FDA required; issued to consumers for prescription medications that possess "serious and significant public health concerns"
- Industry-developed; no standard format
- Wolf et al.
 - 2006 study Too complex and written at too high a reading grade level
 - 2010 study 53% correct in an open book, untimed assessment
- FDA and Brookings Institution actively working to create improved, more readable documents

Objective

Obtain consumer feedback and refinement on proposed, one-page Med Guide prototypes, which will then be incorporated in developing and field-testing an improved, patient-centered Med Guide.



Methods - Materials

Piloted 7 one-page prototypes

4 FDA proposed 1 European

Rheutopia	
Active ingredient arixalate 	
User • rheumatoid arthritis (adults and children older than 4) • plaque pioriasis	
Warnings	Rheutopia [Roo-TOH-pee-
Important warnings about Rheutopia • You can have serious side effects, including an infection that can cause death. Ask your doctor before use if you • have any signs of infection (fever, cough, flu-like symptoms) • have a skin infection (warn, red. pinihli skin or open sores) • have tested pointive for thereculosis (TB) or know someone who has TB	Uses • Rheumatoid arthritis in adults damage, and improves mobil • Polyarticular juvenile rheuma have good results from other decreases the number of pail • Ankylosing spondviltis. Rheut
 are taking Kineret (anakinra) have recently been vaccinated or are scheduled to be vaccinated have any heart problems 	Plaque psoriasis in adults wh (using ultraviolet light). Rheut
Step use and call your dector right away if you 	Important Warning: Serious Rheutopia affects the immun not use Rheutopia if you have serious infections including to by viruses, fungi, or bacteria.
When using this medicine you may get • redness where the shot is given • a shuffy or runny nose • headaches These can be side effects of Rheutopia. Tell your doctor about any side effect that does not go away or gets worke.	Tell your doctor before us • have an infection, are being tre- infection, or think you have an i- as a cold, flu or skin infection), • have TB or have been near sor TB. • have any nervous system or he
Direction: Benetopia is taken as an injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not freeze Rhentopia. Do not use Rhentopia that has been frozen. Store Rhentopia in the refrigerator, between 36°F to 46°F.	 Stop use and call your do Fever, cough, flu-like symptom infection (red, warm, painful ski sores). Numbness, tingling, weakness, problems, or dizziness. Chills, swollen lymph nodes, ni fever, or weight loss.
Questions • For more information on Rheutopia visit <u>www.fda.more-information.gov</u> • Call Abbott Laboratories toll-free 1-800-448-6472.	Common side effects • redness, rash, swelling, itch • headache
Inactive ingredients Single-use prefilled syringe: sucrose, sodium chloride, L-arginine hydrochloride 	runny nose Call your doctor for medical adv 1-800-FDA-1088 or www.fda.ge
	Directions for use Rheutopia is an injection (sho how to give a shot, Store Bhautopia is the refrige

n	Rheutopia (arixalate) solutio	PROTOTYPE 2 Rheutopia (arixalate) solution and powder for solution for subcutaneous injection		
	Important Warning ab You can develop a serious infe death, including: • tuberculosis (TB), • infections caused by viruse	ction that can cause		
	Uses Rheutopia is a prescription me Tumor Necrosis Factor (TNP) • moderate to severe rheum	blocker used to treat:		
	adults moderate to severe juvenil URAN to severe juvenil OrugApprovid by FDA: 2005	e rheumatoid arthritis Her mbo have not ients		
pia [Roo-TOH-pee-ah] (also knov	Last Revised May 2009	nic) adult ay benefit with		
e, and improves mobility and the abiliticular juvenile rheumatoid arthritis in cod results from other medicines. Rhe ses the number of painful joints, sing spondylitis. Rheutopia reduces ba psoriasis in adults who may benefit fr	uces painful and swollen joints, slows joint yt do chysical activities. hildren at least 4 years od who did not utlopia reduces pain, improves mobility, and ck pain, swelling, and improves mobility. om taking medicine or reaciving phototherapy or clears up areas of skin with psoriasis.	vour doctor (shot) off a shot Using ige than your r at 36 to 46°F		
	lower your ability to fight infections. Do ction. People taking Rheutopia have gotten and infections caused have died from these infections.	inge stant Warning Symptoms of like irm, painful		
ur doctor before using if you				
n infection, are being treated for an in, or think you have an infection (such ld, flu or skin infection). B or have been near someone who has	 have lived in or traveled to other countries. have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). 	u have a get new or ude ion problems,		
ny nervous system or heart problems.	are taking the medicine Kineret (anakinra).			
se and call your doctor right awa	ay if you develop			
cough, flu-like symptoms, a skin en (red, warm, painful skin or open ness, tingling, weakness, vision ms, or dizziness. swollen lymph nodes, night sweats, 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.			
n side effects				
ss, rash, swelling, itching, or bruising ache nose	where the shot was given.			
r doctor for medical advice about side e DA-1088 or www.fda.gov/medwatch.	effects. You may report side effects to FDA at			
ns for use				
ipia is an injection (shot). Do not use I give a shot. Rheutopia in the refrigerator. Do not sf	Rheutopia until your doctor has shown you ake or freeze.			

 Lymph node cancer: You may have a higher chance of getting cancer of the lymph nodes.
 Blood problems: Your body may not make enough blood cells to fight infection or to help topia an cause

enough blood cells to fight infection or to he stop bleeding. Symptoms include bruising, fatigue, and pale skin. Heart failure: You may get heart failure or worsening heart failure. Symptoms include shortness of breath, swelling of ankles or feet, shortness of breath, swelling of ankles or feet, or sudden weight gain. Immune reactions with a lupus-like syndrome: Symptoms include chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common side effects Injection site reactions (redness, rash, swelling, bruising), infections, headache, and runny

Tell your doctor about any side effect that does not go away or gets worse

Taking other medicines with Rheutopia Do not take the medicine Kineret (anakinra) while you take Rheutopia. You are more likely to develop a serious infection · Do not get a vaccination while you are taking Rheutopia. Tell your doctor that you take Rheutopia before you get any vaccine.

utopia reduces pain, improves mobilit decreases the number of painful joint Specific Groups vlosing spondylitis. Rheutopia reduces · Rheutopia has not been studied in children pain, swelling, and improves mobility younger than 4 years old que psoriasis in adults who may

More Information · Talk to your doctor or pharmacist Visit www.fda.more-information.gov Call [manufacturer] at 1-800-123-4567 To report any side effects contact (manufacturer) at phone # and Web address) or FDA at 1-800-FDA-1088

Rheutopia was approved by the FDA in 2002. Revised: 5/2009

in lower your ability to fight infections. not use Rheutopia if you have an activ ple taking Rheutopia have gotten pus infections including tuberculosis (TB) infections caused by viruses, fungi, or teria. Some people have died from ie infections.

matoid arthritis in adults. Rheutopia ices painful and swollen joints, slows i

rarticular iuvenile rheumatoid arthritis

nildren at least 4 years old who did no a good results from other medicines.

efit from taking medicine or receiving

utopia improves or clears up areas of

rtant Warning: Serious Infections

utopia affects the immune system

totherapy (using ultraviolet light).

with psoriasis.

hage, and improves mobility and ability to do physical activities.

en Your Doctor

Before using Rheutopia, tell your doctor if 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 · have any nervous system or heart problems have lived in or traveled to other countries · have been recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). are taking the medicine Kineret (anakinra).

Information for the Patient: Rheutopia [Roo-toh-pee-ah] (also known as arisalate

What does Rheatopia treat?

Rhasesahold arthritis in adulta. It reduces pointel & wellen joints. Nows joint datwags, and improve obility and the shiller to do physical activitie · Polyanizatio inconsite chaumanid anthentis (10A) in

people older than 4 years of age who did not have wood country there enhanced interes. Educationia reduces pain, inspanses mubility, and detenates the number of paints isints

- Ankylosing spoedylitis. Shrubopia reducer back pain, swelling, and improves mobility. Plaque provisis in adults who may brough from es or having photo theyaoy (using ultraviole
- light). Rhoutopla improves or clears up steas of skin Important Warning: Serious intections

have an infection at the moment. People taking

Rhoutopta have gotten serious infections auloding alculo (TB) and indecisions obtaced by virtue

fungi, or bacteria, Some people have deal from these

Check with your doctor before using Electropia if:

infection, or think you have an infection (##47) AR A

You may be tested and treated for TR Also tell voor

doctor if you have lived in or travelled to other

You have any nervous system or heart problems

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

countries. You are more likely to get TB or other

· You have an indection, are being throad for an

What should I tell my doctor?

cold fly or skin infection).

You have TB or have been near st

nfections in certain countries

pia attects the in-

stop blending. Shoetareto of breath, s readdon weight gain. These are signs of heart tellore has sony develop or get work-· Chest disconfort or pain, shortness of breath, idea bility to fight indections. Do not use Rheutonie if you

of a serious infection. Fooling numbers, work, distry, tingling or si

which node cancer

When should I call my doctor?

Record Analy Builder provotions, skin infection land.

problems. Sizes of persons ovders diseases. The

itiple sclerosis, may develop or get worse

· Chills, swollen lumph nodes, night events, fever, or ecight loss. You may have a higher chance of getting

Bruising, bleeding, and pale skin. Your body may wit

make enough blood cells to light indection or to help

wares, painful skin or oper sores). These can be signs

if you get:

pain or a rish on your checks or arms. These may be signs of a sections instrume machine.

What are some common side effects?

Redmess, zash, seedling, itching or bruising where th shot was given. Headache or runny nor 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 until yo uve been shown how to give a shot. Your doctor will tell you how often to have it.
- Store in the refrigerator. Do not shake or freez · If you forget to take a dose, take it as soon as you emember. Take your next dose at your regularly scheduled time
- Drug Approved by FDA: 2005 Last Revised: May 2009 e often than prescribed ormation?

tion.gov or call 1-800 t side effects to 0-332-1088

	Call Your Doctor
joint	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).
t	 Numbness, tingling, weakness, vision problems, or dizziness.
y, s.	 Chills, swollen lymph nodes, night sweats, fever, or weight loss.
s /	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.
Ξ	
	Common Side Effects
/e	 Redness, rash, swelling, itching or bruising where the shot was given.
	Headache

ising · Runny nose Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

- · Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- shake or freeze If you forget to take a dose, take it as soon

Rheutopia. Do not use Rheutopia more ofter than prescribed

Draft Prototype 2A Warning

Directions for Use Store Rheutopia in the refrigerator. Do not as you remember. Take your next dose at your regularly scheduled time. Your doctor will tell you how often to use

Δ

 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. have any nervous system or heart problems. 	 have lived in or traveled to other cour have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). are taking the medicine Kineret (anaki
Stop use and call your doctor right aw	ay if you develop
 Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores). Numbness, tingling, weakness, vision 	Bruising, bleeding, and pale skin. Shortness of breath, swelling of ankle or feet, or sudden weight gain.
Control ess, angung, weatness, vision problems, or dizziness, Chills, swollen lymph nodes, night sweats, fever, or weight loss.	 Chest discomfort or pain, shortness of breath, joint pain or a rash on your or arms.

. 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

Draft Prototype 3A_Warnings

PROTOTYPE 2

Methods – Materials, cont.

2 Northwestern proposed

Generic name	Arixalate
Brand name	Rheutopia
Purpose	This medicine helps treat rheumatoid arthritis (RA), ankylosing spondylitis (AS), ongoing (chronic) adult plaque psoriasis, and Crohn's Disease.
lenefit	Rheutopia is a tumor necrosis factor (TNF) blocker. Rheutopia helps to prevent the negative side effects of RA, AS, and Crohn's Disease.
low to take	 Take Rheutopia as prescribed by your doctor Rheutopia is taken as an injection (shot) Store Rheutopia in the refrigerator, between 36 to 46°F Do not drop or crust the glass syringe
or how long	Your doctor will tell you how long you should be on this medication. Refill this medicine until your doctor tells you to stop.
mportant!	Ask your doctor before use 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 know someone who has TB • are taking Kineret (anakinra) • have recently been vaccinated or are scheduled to be vaccinated • have any heart problems
top taking nd call us	Stop taking this medicine and call your doctor right away if you: • have an infection (fever, cough, flu-like symptoms) • have a skin rash • have a skin rash • have unwhness (can't feel your skin) or tingling skin • have shortness of breath or joint pain • have weakness in your arms or legs • feel faint or light headed
all us	Call us if these side effects are severe, last longer than one week, or if you feel concerned: • redness where the shot was given • a stuffy or runny nose • headaches
emember	Talk to your doctor about any questions or concerns you may have regarding this medicine. • Follow up is important to see how well the medicine is working. • Remember the date of your next appointment.

RHEUTOPIA® (ARIXALATE)

This medication helps treat rheumatoid arthritis (RA), ankylosing spondylitis (AS), ongoing (chronic) adult plaque psoriasis, and Crohn's Disease.

Purpose This medi adult plaq Benefit

People with these diseases have too much of a protein called tumor necrosis factor (TNF) in their body. This medicine can block pain and other bad effects of TNF.

Length of Treatment

You may need to be on this medication for the rest of your life.

Instructions

Rheutopia is taken as an injection (shot). Take Rheutopia as prescribed by your doctor and store it in the refrigerator at 36 to 46°F. Do not drop or crush the glass syringe.

Safe Use

To avoid unwanted interactions, it is very important that you tell us: - About all your medications (especially Kineret), vitamins, herbal products, and supplements. - If you are allergic to medications or foods.

To use this medicine safely, tell us if you:

- Have any signs of infection, or a problem with your heart.
- Have tested positive or been around someone with tuberculosis (TB)
- Have gone outside the country.
- Have recently been vaccinated or are scheduled to be vaccinated.

Side Effects

Some patients have redness where the shot was given, headaches, or a stuffy or runny nose when using this medicine. Call us if these last longer than one week or get worse (312-695-8630).

Risks and Warnings

All medicines have risks. This medicine affects your immune system and can lower the ability of your immune system to fight infections. Signs of infection include fever, cough, flu-like symptoms skin problems (red, warm, painful iskin), or open sores. If any of these happen, stop taking this medicine and call us right wave (312-659-630).



Discussion Points

Be sure to review your ability to take the medication, to pay for it, and any concerns or questions.

Follow Up You should follow up with your doctor to see how Rheutopia is working for you.

This sheet provides brief information to help you and your doctor make a decision about the medication. You will get more detailed information from your pharmacy. You may find the following websites useful: <u>www.ahrg.gov/consumer</u> and <u>www.nhm.ih.gov/medilenglus/druginformation.html</u>

Study – Methods

- 6 in-person focus groups; 47 English-speaking adults
- Recruited from 2 primary care clinics and 1 adult basic education center

Individual Interview

- Demographic and socioeconomic information
- Prescription use and behaviors
- Health literacy assessment Newest Vital Sign (NVS)

Study – Methods

Group Discussion

- Brief overview
- Pairwise comparison
- Group discussion

RHEUTOPIA" (ARIXALATE)

This medication helps treat rheumatoid arthres (RA), ankylosing spondyles (AS), ongoing (chronic)

adult plaque psonasis, and Crohn's Disease.

People with these diseases have too much of a protein called tumor necrosis factor (TNF) in their body. This medicine can block pain and other bad effects of TNF

Length of Treatment You may need to be on this medication for the rest of your life.

Instructions

Rheutopia is taken as an injection (shot) Take Rheutopia as prescribed by your doctor and store it in the refrigerator at 36 to 46"F. Do not drop or crush the glass syringe.

Safe Use

To avoid unwanted interactions, it is very important that you tell us: - About all your medications (especially Kineret), vitamins, herbal products, and supplements. If you are allergic to medications or foods.

- To use this medicine safely, tell us if you: Have any signs of infection, or a problem with your heart.
- Have tested positive or been around someone with tuberculosis (TB).
- Have gone outside the country Have recently been vaccinated or are scheduled to be vaccinated.

Side Effects

Some patients have redness where the shot was given, headaches, or a stuffy or runny nose when using this medicine. Call us if these last longer than one week or get worse (312-695-8630).

Risks and Warnings

All medicines have risks. This medicine affects your immune system and can lower the ability of your immune system to fight infections. Signs of infection include fever, cough, flu-like symptoms skin problems (red, warm, painful skin), or open sores. If any of these happen, stop taking this medicine and call us right away (312-695-8630).

For women of child bearing age. Talk to your doctor before use if you are pregnant, think you are pregnant, or breastfeeding.

Discussion Points

Be sure to review your ability to take the medication, to pay for it, and any concerns or questions Follow Up

You should follow up with your doctor to see how Rheutopia is working for you.

This sheet provides brief information to help you and your doctor make a decision about the medication. You will get more detailed information from your pharmacy. You may find the following websites useful: www.ahrg.gov/consumer

and www.nim.nih.gov/medlineplus/druginformation.html

Rheutopia (arixalate) solution and powder for solution for subcutaneous injection

- Important Warning about Rheutopla You can develop death, including: xus infection that can cause
- tuberculosis (TB). infections caused by viruses, fungi, or bacteria

Uses

- Rheutopia is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker used to treat. moderate to severe rheumatoid arthritis (RA) in medicine
- adults
- adults moderate to severe juvenile repumoted arthritis (JRA) in people age 4 or older who have not had good results with other treatments: a anityloning spondytist (AS) moderate to severe organic (chronic) adult plaque psortiasia in people who may benefit from baking medicine or treatment with uttraviolet spits (phototherapy)

How to take Rheutopia

- Take Rheutopia as prescribed by your doctor
 Rheutopia is taken as an injection (shot)
- You must learn how to give yourself a shot before you can use Rheutopia
 Read the detailed "Instructions for Using
- Rheutopia" that come in the package
- Do not use Rheutopia more often than your
- Store Rheutopia in the refrigerator at 36 to 46°F · Do not drop or crush the glass syringe.

Serious side effects

- · Serious Infections: See the Important Warning in the box at the top of the page. Symptoms of infection include fever, cough, flu-like
- symptoms, skin problems (red, warm, painful skin) or open sores
- skn) or open sores. Nervous system problems: If you have a nervous system disease, you may get new or worse symptoms. Symptoms include numbness, tingling, weakness, vision problems, or dirziness

Lymph node cancer. You may have a higher chance of getting cancer of the lymph nodes. Blood problems. You body may not make enough blood cells to fight infection or to help stop bleeding. Symptoms include bruising.

- fatigue, and pale skin. Heart failure: You may get heart failure or worsening heart failure. Symptoms include
- shortness of breath, swelling of ankles or feet, sudden weight gair · Immune reactions with a lupus-like
- syndrome. Symptoms include chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common side effects

 Injection site reactions (redness, rash, swelling, bruising), infections, headache, and runny 1056.

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

Taking other medicines with Rheutopia

- · Do not take the medicine Kinerel (anakinra) while you take Rheutopia. You are more likely to develop a serious infection.
- Do not get a vaccination while you are taking Rheutopia. Tell your doctor that you take Rheutopia before you get any vaccine.

Specific Groups · Rheutopia has not been stud

younger than 4 years old.

More Information

- · Talk to your doctor or pharmacist Visit www.fda.more-information.cov
 Call (manufacturer) at 1-800-123-4567
 - · To report any side effects contact
 - (manufacturer) at phone # and Web address) or FDA at 1-800-FDA-1058

Rheutopia was approved by the FDA in 2002.

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Revised: 5/2009
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Results – Sample Characteristics (N=47)

- Age 54% between 18-45 years old
- Female 60%
- 69% NH-Black, 69% ≤ High School, and 64% ≤ \$20,000

Health Litera	cy, %	Read Info	New Rx, %	Refill, %
Limited	49	Always/often	58	33
Marginal	24	Sometimes	18	24
Adequate	27	Rarely/never	24	42

Results – Pairwise Comparison

Winners:

Kneuto	opia
Active ingredient arixalate 	
Uses • rheumatoid arthritis (adults and children olde • plaque psoriasis	er than 4)
Warnings	
mportant warnings about Rheutopia	
 You can have serious side effects, including 	an infection that can cause death.
Ask your doctor before use if you	
 have any signs of infection (fever, cough, fl 	
 have a skin infection (warm, red, painful sk 	
 have tested positive for tuberculosis (TB) or are taking Kineret (anakinra) 	r know someone who has TB
 are taking Kineret (anakinra) have recently been vaccinated or are schedu 	iled to be vaccinated
 have any heart problems 	ned to be vite miled
Stop use and call your doctor right away if you	
 have an infection (fever, cough) 	 have shortness of breath or joint pain
 have a skin rash 	 have weakness in your arms or legs
 have numbness (can't feel your skin) 	 feel faint or light headed
You may report side effects to FDA at 1-800-FDA	-1088.
When using this medicine you may get	
 redness where the shot is given 	
 a stuffy or runny nose headaches 	
 neadacnes These can be side effects of Rheutopia. Tell your of 	doctor about any side effect that does not so
way or gets worse.	doctor about any side effect that does not go
Directions	
 Rheutopia is taken as an injection (shot). Do 	o not use until your doctor tells you when and
how to take this drug.	2 d d a a a
 Do not freeze Rheutopia. Do not use Rheuto Store Rheutopia in the refrigerator, between 	
 Do not drop or crush the glass syringe. 	50 1 10 40 1.
Duestions	
 For more information on Rheutopia visit www. 	w.fda.more-information.gov
 Call Abbott Laboratories toll-free 1-800-448 	

Generic name	Arixalate				
Brand name	Rheutopia				
Purpose	This medicine helps treat rheumatoid arthritis (RA), ankylosing spondylitis (AS), ongoing (chronic) adult plaque psoriasis, and Crohn's Disease.				
Benefit	Rheutopia is a tumor necrosis factor (TNF) blocker. Rheutopia helps to prevent the negative side effects of RA, AS, and Crohn's Disease.				
How to take	 Take Rheutopia as prescribed by your doctor Rheutopia is taken as an injection (shot) Store Rheutopia in the refrigerator, between 36 to 46*F Do not drop or crush the glass syringe 				
For how long	Your doctor will tell you how long you should be on this medication. Refill this medicine until your doctor tells you to stop.				
Important!	Ask your doctor before use 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 know someone who has TB • are taking Kineret (anakinra) • have recently been vaccinated or are scheduled to be vaccinated • have any heart problems				
Stop taking and call us	Stop taking this medicine and call your doctor right away if you: • have an infection (fever, cough, flu-like symptoms) • have a skin rash • have numbness (can't feel your skin) or tingling skin • have shortness of breath or joint pain • have weakness in your arms or legs • feel faint or light headed				
Call us	Call us if these side effects are severe, last longer than one week, or if you feel concerned: • redness where the shot was given • a stuffy or runny nose • headaches				
Remember	Talk to your doctor about any questions or concerns you may have regarding this medicine. • Follow up is important to see how well the medicine is working. • Remember the date of your next appointment.				

Chosen 54.5% (138/235)

Chosen 54.0% (127/235)

Results - Formatting

Break up text, white space

- "It's too hectic; the words are too back-to-back."
- "It looks like a textbook, or a homework assignment I'd throw in my bag and never take out again."

Headings

"I can find the information based on the heading. It helps me to decide what information I want to read."

Bolding, bullets, and boxes

"I like that the warning is shaded because side effects are important to me and the box means that is important information."

Results – Sequence and More Information

Sequence of topic areas

- "I want the directions at the top I won't have adverse reactions to the medicine if I take it correctly."
- "The information in the box seems a little bit more important, but everything is important on here."

Icons

"I like the symbol of a pregnant woman because it makes me read the information very closely."

More Information

"If I can't read this paper or don't understand something, I want a phone number up at the top, real big, for me to call and talk to someone."

Limitations

- Small sample size (N=47)
- Hypothetical situation
- Pharmacy limitations of color

Conclusion and Next Steps

- Patient-centered approach can confirm viable improvements to current Med Guide formats and support the need for a standardized template
- Found very popular to have a one page, 'top hits', document
- Merge findings with evidence-based guidelines for content
- Next steps to finalize optimal final format(s), confirm via clinical trial
- Recognize there may be multiple 'winners' in the end

Questions?

Contact Information

Allison L. Russell Research Project Coordinator Health Literacy and Learning Program Division of General Internal Medicine Northwestern University 750 N. Lake Shore Drive, 10th Floor Chicago, IL 60611 Phone: 312.503.5531 Email: allison-russell@northwestern.edu

