

What is Wrong with Current SmPCs?

DK Theo Raynor

*Professor of Pharmacy Practice, University of Leeds
and Director, Luto Research Ltd
d.k.raynor@leeds.ac.uk*

DIA Product Information Forum, London, June 2011

What is Wrong with Current SmPCs? or *What is Posology?*

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A Tale of Two Documents

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SUMMARY OF PRODUCT CHARACTERISTICS

PL 14894/040/1

1 NAME OF THE MEDICINAL PRODUCT

Vancomycin 500mg Powder for Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains Vancomycin 500mg (equivalent to 500,000 IU) as Vancomycin hydrochloride

For full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Powder for solution for infusion

Powder for solution for oral use

A white/powder cake

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Vancomycin is indicated in potentially life-threatening infections which cannot be treated with other effective, less toxic antimicrobial drugs, and the penicillins and cephalosporins.

Vancomycin is useful in the therapy of severe staphylococcal infections, patients who cannot recover or who have failed to respond to the penicillins and cephalosporins, or who have infections with staphylococci resistant to other antibiotics.

Vancomycin is used in the treatment of endocarditis and as prophylaxis against endocarditis in patients at risk from dental or surgical procedures.

Its effectiveness has been documented in other infections due to staphylococci, streptococci, pneumonia, septicemia and soft tissue infections.

Vancomycin may be used orally for the treatment of Clostridium difficile. Parenteral administration of vancomycin is not effective for these infections. Intravenous administration may be used concomitantly if required.

PATIENT INFORMATION LEAFLET

This leaflet contains important information about your medicine, read it carefully.

Keep this leaflet, you may want to read it again.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Vancomycin Hydrochloride 500 mg and 1 g Powder for Concentrate for Infusion

The active substance is vancomycin hydrochloride. The manufacturer is Wissner-Grohmann GmbH, Wissnerstrasse 10, 8051 Zürich, Switzerland. The distributor is AstraZeneca UK Limited, Quayhouse, Royal Leamington Spa, Warwickshire, CV32 4SE, United Kingdom.

The manufacturer of the 500 mg and 1 g presentation is Wissner-Grohmann GmbH, 8051 Zürich, Switzerland.

Vancomycin is used to treat serious infections such as MRSA (methicillin resistant Staphylococcus aureus).

It is a bacteria which is resistant to many antibiotics. Vancomycin can be used to treat infections or sepsis if the infection is caused by MRSA. It can also be used to prevent infections if the timing of the need in dental and surgical procedures.

1. What Vancomycin Hydrochloride Powder for Concentrate for Infusion is and what it is used for

Vancomycin Hydrochloride Powder for Concentrate for Infusion is an antibiotic or medicine used to treat infections caused by bacteria in the body. It is given via infusion (a powder which is made into a solution by adding water) or as a single injection via a drip into a vein.

This medicine is presented in glass containers called vials. Each 500 mg vial contains 500 mg of vancomycin hydrochloride and each 1 g vial contains 1 g of vancomycin hydrochloride.

This medicine is presented in glass containers called vials. Each 500 mg vial contains 500 mg of vancomycin hydrochloride (an equivalent to 1,000,000 IU vancomycin activity). It is made into a solution by adding water.

Vancomycin is used to treat serious infections such as MRSA (methicillin resistant Staphylococcus aureus).

It is a bacteria which is resistant to many antibiotics. Vancomycin can be used to treat infections or sepsis if the infection is caused by MRSA. It can also be used to prevent infections if the timing of the need in dental and surgical procedures.

2. Before Vancomycin Hydrochloride Powder for Concentrate for Infusion is used

Vancomycin Hydrochloride should not be used:

- if you have shown signs of hypersensitivity (allergy) to vancomycin on previous occasions
- if you are allergic to other antibiotics

Special care will be taken:

- if you have kidney problems
 - if you have a kidney transplant
 - if you are taking a general anaesthetic
 - if you are taking other medicines, such as:
 - other antibiotics that can affect your kidneys e.g. amikacin, neomycin, gentamicin, kanamycin, amphotericin B, streptomycin, tobramycin
 - water tablets e.g. ethacrynic acid and furosemide
 - cholesterol降e.g. a medicine used to treat high levels of fat in the blood or diabetes in inflammatory bowel disease

Please tell your doctor if you are taking, or have recently taken, any other medicines, including ones that do not need a prescription.

Do not drive or use machines:

- if you experience any effect which may impair your ability to drive or use machines

3. How Vancomycin Hydrochloride Powder for Concentrate for Infusion is used

The dose of medicine given to you will depend on your age, the infection you have, how well your kidneys are working and how you tolerate the medicine.

The usual adult dose is 500 mg every 8 hours or 1 g every twelve hours. Before it is given to you, this medicine will be dissolved in water and given to you as an injection or infusion in a drip into a vein. It will then be given as a slow infusion via a drip into a vein. Each injection will be given over 20-60 minutes depending on the dose, but it may also be given continuously over 24 hours. The total dose may be changed depending on the results of blood tests.

Summary of Product Characteristics – for Professionals

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Using an SmPC

- *What is an SPC?*
- *I can't remember looking at one*

How easy to use?

- *It seems a little bit muddled - not terribly user friendly*
- *It's very wordy, not very easy because you are flicking from one part to another*
- *I don't really understand why it repeats itself*
- *I'm not sure what 'posology' means.*

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3 PHARMACEUTICAL FORM

Powder for solution for infusion

Powder for solution for oral use

Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Vancomycin is indicated in potentially life threatening infections which cannot be treated with other effective, less toxic antimicrobial drugs, and the penicillins and cephalosporins.

Its effectiveness has been documented in other infections due to methicillin resistant Staphylococcus aureus (MRSA).

Vancomycin may be used orally for the treatment of Clostridium difficile.

Parenteral administration of vancomycin is not effective for these infections.

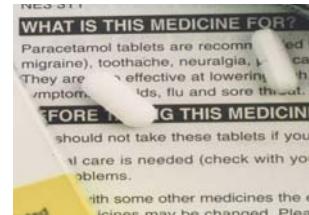
Parenteral administration may be used concomitantly if required.

Package Leaflets – for Patients



What do you think about medicine leaflets?

- *They don't inspire you*
- *Priorities are those who wrote it, not patients*
- *People who suffer should help write leaflets*
- Concern about complex language & poor visual presentation
- Patients value information that contains a balance of benefit & harm information



□ Raynor et al. *Patient Education & Counseling* 2004

□ Raynor et al, *Health Technol Assess* 2007

In this presentation



1. Summary of Product Characteristics

- What is it for?

2. SmPC

- How does it perform?

3. SmPC

- Impact on Package Leaflet

Background – University of Leeds & Luto Research



Consumer medicines information research group:

- Impact of EU legislation & User Testing
- Expressing risks and benefits to patients
- US & Australian medicine leaflets
- Collaborate with **Sydney, Wisconsin, Utrecht & Aarhus**
- Expert advice to policy-makers including European Parliament & FDA

Luto Research - University Spin Out

- Patient information testing service for pharma companies
- Spin outs promoted by University – putting research into practice
- **EPAR Summaries**, clinical trial PIS, IFUs, RMP materials

Principal role remains as an academic

School of Healthcare
FACULTY OF MEDICINE AND HEALTH



1. Summaries of Product Characteristics - What are they for?

What is Wrong with Current SmPCs?

d.k.raynor@leeds.ac.uk

What is the SmPC for?



Serves three masters:

1. Represents the agreed position ...as *distilled through the course of the assessment process*
2. *“Basis of information for healthcare professionals on how to use the product safely and effectively”*
3. *“The Package Leaflet shall be drawn up in accordance with the SmPC”*

Too many masters?

2. Summary of Product Characteristics - How do they perform?

What is Wrong with Current SmPCs?

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How useful for health professionals?



We tested two SmPCs with doctors in the UK

- Generalist SmPC: 'Lariam'; mefloquine
 - anti-malarial
- Specialist SmPC: 'CellCept'; mycophenolate
 - prophylaxis of transplant organ rejection

Using the process of 'user testing'

- Performance based testing
- Legal requirement for the package leaflet – process the same

Collaboration with Roche

- Roche contracted with Luto Research for testing of the 2 SmPCs
- Project led by
 - Prof Theo Raynor (University of Leeds)
 - Dr Peter de Veene (Roche)

User Testing in Brief



Select 15 key points

- Relevant to safe and effective use

(a) Quantitative aspect

- Design & pilot a questionnaire which tests:
 - Finding each piece of information
 - Understanding (express in own words)
- Recruit 10 people from target group
 - Interviewed individually
 - Can they find and understand the information?

(b) Qualitative aspect

- Interview concludes with qualitative questions
 - What did they like and not like about the document?

User Testing is an iterative process

- **Test material**
- **Identify problems**
 - the points people struggled with and their general comments
- **Remedy problems**
 - using research evidence & good practice in writing & design
- **Test again**



 Raynor DK. *Testing, Testing: The Benefits of User-testing Package Leaflets*
Regulatory Affairs Focus 2008

Roche Products Limited

Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire, AL7 1TW

Telephone: +44 (0)1707 366 000

Fax: +44 (0)1707 338 297

WWW: <http://www.rocheuk.com/>

Medical Information Direct Line: +44 (0)800 328 1629

Medical Information e-mail: medinfo.uk@roche.com

Customer Care direct line: +44 (0)800 731 5711

Medical Information Fax: +44 (0)1707 384555

Before you contact this company: often several companies will market medicines with the same active ingredient. Please check that this is the correct company before contacting them. [Why?](#)

Summary of Product Characteristics last updated on the eMC: 16/09/2009

Lariam



1. NAME OF THE MEDICINAL PRODUCT

Lariam 250mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 250mg mefloquine (as 274.09mg mefloquine hydrochloride).

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet. White to off-white cylindrical biplanar tablets, cross scored and imprinted with Roche on one face.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Therapy and prophylaxis of malaria.

Therapy: Lariam is especially indicated for therapy of *P. falciparum* malaria in which the pathogen has become resistant to other antimalarial agents.

Following treatment of *P. vivax* malaria with Lariam, relapse prophylaxis with an 8-amino-quinoline derivative, for example primaquine, should be considered in order to eliminate parasites in the hepatic phase.

Prophylaxis: Malaria prophylaxis with Lariam is particularly recommended for travellers to malarious areas in which multiple resistant *P. falciparum* strains occur.

For current advice on geographical resistance patterns and appropriate chemoprophylaxis, current guidelines or the Malaria Reference Laboratory should be consulted, details of which can be found in the British National Formulary (BNF).

Lariam SmPC Testing 1: - the original



15 Key points tested with General Practitioners

Finding the information

- Doctors' ability to navigate around the document was poor
- 9/15 points not found, or found with difficulty, by 2 or more doctors

Understanding

- 5/15 points were not understood by 2 or more doctors

Qualitative comments

- Comments included that the SmPC was '*muddled*'
- *Information buried*
- *Search backwards and forwards*

Revising the Lariam SmPC:



Problem points of information

• Pregnancy	• Identifying side effects
• Driving and using machines	• Reducing side effects with food
• Lactose intolerance	

Common themes

- Information not where expected; headings not useful
- Repetition - a problem with the sections on interactions, pregnancy, and driving
- Who is it addressing?



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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Therapy and prophylaxis of malaria.

Therapy: Lariam is especially indicated for therapy of *P. falciparum* malaria in which the pathogen has become resistant to other antimalarial agents.

Following treatment of *P. vivax* malaria with Lariam, relapse prophylaxis with an 8-amino-quinoline derivative, for example primaquine, should be considered in order to eliminate parasites in the hepatic phase.

Prophylaxis: Malaria prophylaxis in areas in which multiple resistance to other antimalarial agents has been seen.

For current advice on geographical resistance patterns or the Malaria Reference Laboratory, see the British National Formulary.

2. What Lariam is used for

2.1 Indications

Lariam is used to treat or prevent malaria.

To treat malaria

- Lariam is particularly recommended to treat *P. falciparum* which has become resistant to other anti-malarial agents.
- It can also be used for treatment of *P. vivax* malaria. However, you need to also consider relapse prophylaxis with an 8-amino-quinoline derivative e.g. primaquine. This is to eliminate parasites in the hepatic phase of malaria.

Cross-resistance between mefloquine and halofantrine has been seen.

If there is no improvement 48 to 72 hours after a full treatment course, consider alternative treatments.

Tell patients that re-infection or re-appearance of malaria is possible after effective anti-malarial therapy.

For prophylaxis of malaria

- Malaria prophylaxis with Lariam is particularly recommended for travellers to areas with malaria where there are multiple resistant *P. falciparum* strains.
- Check current guidelines in the British National Formulary (BNF) or from the malaria reference laboratory for current advice on:
 - geographical resistance patterns
 - appropriate chemoprophylaxis



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4.7 Effects on ability to drive and use machines

Mefloquine can cause dizziness or disturbed sense of balance. It is consequently recommended not to drive or carry out tasks demanding fine co-ordination and spatial discrimination during treatment with mefloquine. Patients should avoid such tasks for at least 3 weeks following therapeutic use, as dizziness, a disturbed sense of balance or neuropsychiatric reactions have been reported up to three weeks after the use of Lariam.

Prophylactic use

Caution should be exercised with regard to driving, piloting aircraft and operating machines, as dizziness, a disturbed sense of balance or neuropsychiatric reactions have been reported during and up to three weeks after use of Lariam.

In a small number of patients it has been reported that dizziness or vertigo and loss of balance may continue for months after discontinuation of the drug (see section 4.8 Undesirable Effects).



4.5 Effects on ability to drive and use machines

While taking Lariam

Mefloquine can cause dizziness or a disturbed sense of balance. It is recommended not to drive or carry out tasks demanding fine co-ordination and spatial discrimination during treatment or prophylaxis. This includes driving, piloting aircraft and operating machines.

After taking Lariam

Patients should not undertake such tasks for at least 3 weeks following therapeutic use. This is because dizziness, a disturbed sense of balance or neuro-psychiatric reactions have been reported up to three weeks after the use of Lariam.

In a small number of patients it has been reported that dizziness, vertigo or loss of balance may continue for several months after stopping the drug.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Microcrystalline cellulose
 lactose
 crospovidone
 maize starch
 ammonium-calcium alginate
 poloxamer (polyoxyethylene-polyoxypropylene copolymer)
 talc
 magnesium stearate

4. Contra-indications and precautions**4.1 Contra-indications**

Do not use **Lariam** if the patient has:

- known hypersensitivity to **mefloquine** or related compounds e.g. quinine
- severe liver function impairment and needs malaria prophylaxis - there is no experience in such patients
- history of psychiatric problems (including depression) and needs malaria prophylaxis - **Lariam** may precipitate these conditions
- history of epilepsy and needs malaria prophylaxis - **Lariam** may precipitate convulsions. May be used for treatment if there are very good reasons (see also Section 4.2 Special warnings)
- rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption - this is because **Lariam** contains lactose

Do not use **halofantrine** (for prophylaxis or treatment) at the same time, or after, **Lariam**. (See Section 4.3: Interactions)

4.8 Undesirable effects

At the doses given for acute m symptoms of the disease itself prophylaxis is comparable to **mefloquine**. Adverse events is

Because of the long half-life of than several weeks after discontinuation, adverse events is

Patients should be advised to concerning or neuropsychiatric particularly if neuropsychiatric prophylaxis can then be evaluated.

The following adverse events (cannot be estimated from the

Blood and Lymphatic System

Psychiatric Disorders: Sleep disturbance, depression, mood swings, panic attacks, paranoid reactions.

There have been rare reports of suicidal thoughts and suicide, but no relationship to **Lariam** administration has been established.

Nervous System Disorders: Disorientation, memory impairment, sensory neuropathies. Isolated cases of encephalopathy have been reported.

Hepatobiliary disorders: Transient elevation of transaminases.

Skin and Subcutaneous Tissue

hyperhidrosis. Isolated cases have been reported.

Musculoskeletal and Connective

5.2 List of adverse events

The following adverse events have been reported, although their absolute frequencies are not known:

Psychiatric:

- panic attacks
- depression, mood swings
- agitation, restlessness, anxiety
- confusional state, hallucinations
- sleep disorders (insomnia, abnormal dreams)
- aggression, psychotic or paranoid reactions.

There have been rare reports of suicidal thoughts and suicide, but no relationship to **Lariam** administration has been established.

Blood and lymphatic system:

- leucopenia or leucocytosis and thrombocytopenia.

Nervous system:

- headache
- drowsiness
- memory impairment
- syncope, convulsions
- dizziness and loss of balance
- isolated cases of encephalopathy have been reported.
- sensory and motor neuropathies (including paraesthesia, tremor and ataxia)

Liver and biliary:

- transient elevation of transaminases.

Skin and subcutaneous tissue:

- alopecia

4.2 Posology and method of administration
Curative treatment

The recommended total therapeutic dose of **mefloquine** for non-immune patients is 20 – 25mg/kg. A lower total dose of 15mg/kg may suffice for partially immune individuals.

The recommended total therapeutic dosages of **Lariam** tablets relative to body weight and immune status are presented in the following table.*

5. Side effects

5.1 Overview of undesirable effects

At the doses given for acute malaria, adverse reactions to **Lariam** may not be distinguishable from symptoms of the disease itself. The overall incidence of adverse events reported during **mefloquine** prophylaxis is comparable to that reported for other **chemoprophylactic** regimens.

Tell patients taking **Lariam** for prophylaxis to talk to a doctor if any concerning symptoms develop. They should do this before they take the next weekly dose.

Neuro-psychological adverse events

Most **mefloquine** adverse events are **neuro-psychological**.

- Because of the long half-life, adverse reactions may happen or persist for more than several weeks after stopping the drug.
- If psychiatric disturbances occur, **Lariam** should be stopped and an alternative prophylactic or treatment agent recommended.

Minimising side effects

Splitting the total daily dose into 2 or 3 parts may reduce the chance of side effects or make them less severe.

- For example 3+1, 3+2 or 3+2+1 tablets taken 6 to 8 hours apart.

Lariam SmPC Testing 2:
- Revised wording in original layout 

10 more General Practitioners

Finding the information

- Doctors' ability to navigate around the document was again poor
- 7/15 points not found, or found with difficulty, by 2 or more doctors

Understanding

- 4/15 points were not understood by 2 or more doctors

Qualitative comments

- Its not particularly easy to use but its very, very necessary, the information that's in there*
- [Pregnancy] mentioned in 2 totally different sections, might be worthwhile combining the two*
- Important points should perhaps be aggregated on front page*



Lariam 250mg Tablets

Summary of Product Characteristics



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Key information

- Lariam is used to treat or prevent malaria, particularly:
 - treating *P. falciparum* resistant to other anti-malarials
 - prophylaxis in areas with multiple resistant *P. falciparum*

See Section 2 below for more information. Always check guidelines before prescribing anti-malarials.

- See the tables in Section 3 for the dose regimes.
 - For treatment: spread doses through the day, after a meal.
 - For prophylaxis: once a week on the same day; 1 to 3 weeks before and 4 weeks after leaving the affected country.
- Do not use for prophylaxis in severe liver problems, a history of psychiatric problems or epilepsy (see Section 4.1).
- When treating malaria, use with caution in people with epilepsy or cardiac conduction disorders (see Section 4.2).
- Lariam interacts with some other medicines including quinine and similar drugs, ketoconazole and anti-convulsants. Also, do not use halofantrine at the same time or after Lariam. (See Section 4.3 for more information)
- Do not use in pregnancy (particularly the first trimester) unless the benefits outweigh the risks. Contraception should be used during treatment and 3 months after treatment. Women should not breast-feed while taking Lariam. (See Section 4.4 for more information)
- In acute malaria, side effects may be very similar to the disease itself.
- The most common side effects are neuro-psychological – if psychiatric problems happen, stop Lariam. When taken for prophylaxis, patients who get side effects should see a doctor, before taking the next weekly dose. (See Section 5 for more information on side effects)
- Lariam can cause dizziness or balance problems which can last up to 3 weeks after stopping. Sometimes they may last for months after.

See over for the full information about Lariam.



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1. NAME OF THE MEDICINAL PRODUCT
 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
 3. PHARMACEUTICAL FORM
 4. CLINICAL PARTICULARS
 4.1 Therapeutic indications
 4.2 Posology and method of administration
 4.3 Contraindications
 4.4 Special warnings and precautions for use
 4.5 Interaction with other medicinal products and other substances
 4.6 Pregnancy and lactation
 4.7 Effects on ability to drive and use machines
 4.8 Undesirable effects
 4.9 Overdose
 5. PHARMACOLOGICAL PROPERTIES
 5.1 Pharmacodynamic properties
 5.2 Pharmacokinetic properties
 5.3 Preclinical safety data
 6. PHARMACEUTICAL PARTICULARS
 6.1 List of excipients
 6.2 Incompatibilities
 6.3 Shelf life
 6.4 Special precautions for storage
 6.5 Nature and contents of container
 6.6 Special precautions for disposal and other handling
 7. MARKETING AUTHORISATION HOLDER
 8. MARKETING AUTHORISATION NUMBER(S)
 9. DATE OF FIRST AUTHORISATION/RENEWAL
 10. DATE OF REVISION OF THE TEXT
 LEGAL STATUS

In this SPC

1. General information
2. What Lariam is used for
3. Dose and how to use
4. Contra-indications and precautions
5. Side effects
6. Overdose
7. Pharmacological properties
8. Formulation and storage
9. Marketing authorisation holder

Larium SmPC Testing 3:

- Revised wording & revised layout

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10 more General Practitioners

Finding the information

- Doctors' ability to navigate around the document was poor
- 8/15 points not found, or found with difficulty, by 2 or more doctors

Understanding

- 7/15 points were not understood by 2 or more doctors

Qualitative comments

- *Its probably taught me something. I didn't know that information would have been there*

CellCept SmPC Testing 1:

- the original

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15 Key points tested with Specialist Hospital Doctors

Finding the information

- Doctors' ability to navigate around the document was poor
- 11/15 points not found, or found with difficulty, by 2 or more doctors

Understanding

- 1/15 points were not understood by 2 or more doctors

Qualitative comments

- *Haven't ever looked at CellCept SPC although have prescribed for years*
- *I can't confidently tell you I have ever looked at an SPC*
- *There's actually lot more information in here than we tend to give credit for*

3. Package Leaflets and Impact of SmPC

What is Wrong with Current SmPCs?

d.k.raynor@leeds.ac.uk

Impact of SmPC on PL

SmPC is comfort blanket for some regulators and regulatory affairs staff. Resistance to moving information points to where patients will look on the PL

- **Duplication of contra-indications**
 - Interactions
 - Pregnancy
- **Side effect information in Section 2 'Before taking...'**
 - Serious side effects deemed needing to be stated up front
- **No benefit information in SmPC**
 - Prime desire of patients

Key points



- **SmPCs serve 3 purposes**
 - Do we need a bespoke version for health professionals?
- **Two SmPCs tested performed poorly**
 - Particularly for doctors finding relevant information
- **User Testing identified where there were problems**
 - Solutions could be applied, as for PLs
- **Key solutions relate to headings, sub-headings**
 - Placement of information where doctors expect it
- **Revised versions showed some improvements**
 - Qualitative results particularly informative
 - Key information section widely liked
 - Could be used more if easier to use and doctors knew of value
- **Improving the SmPC could improve the PL**

School of Healthcare
FACULTY OF MEDICINE AND HEALTH



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*Professor of Pharmacy Practice, University of Leeds
and Director, Luto Research Ltd
d.k.raynor@leeds.ac.uk*

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