

Getting the message across: Effective Communications and Pharmacovigilance

a presentation

by **Bruce Hugman**

Communications consultant to
Uppsala Monitoring Centre



Communications failures in everyday life

- Friends
- Family
- Shopping
- Driving
- Safety
- Health
- ...more...





Why do communications matter in drug safety?

- Welfare of hundreds of millions of people worldwide
- Extreme dangers of failure

and

- Communications are commonly poorly-executed, second-rate and ineffective



i love typography

MAR 17 2009 [34 COMMENTS]

Malabar type family released

BY DAN REYNOLDS

Last week, Linotype released my newest typeface family, *Malabar*. With six fonts for the Latin script, *Malabar* is a sturdy oldstyle serif. Designed for extensive reading, *Malabar* was originally part of a larger design project conceived for Indian newspapers, and a Devanagari addition will be released at a later date. After that, who knows?

Es tut mir Leid

aber von DEINER ARBEIT bekomme ich manchmal

»echt Bauchweh«

Popular articles

How to make a font

Best 'font

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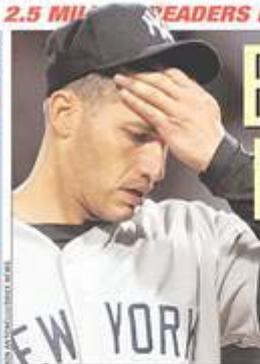


Weather: Sunny and warm, 54/64 SPORTS + FINAL Monday, April 27, 2009

DAILY NEWS

50¢ 2.5 MILLION READERS EVERY DAY NYDailyNews.com

CITIZENSHIP NOW!
OUR HELP PHONE LINES ARE OPEN TODAY
SEE PAGE 10



BEANTOWN BEATDOWN
LOST WEEKEND AT FENWAY AS SOX SWEEP YANKS
SEE SPORTS

SWINE FLU SPREADS!

- Feds fear virus could turn deadly in U.S.
- Mayor says don't panic as cases confirmed

EVERYTHING YOU NEED TO KNOW — SEE PAGES 4-6





Background is an A4 sheet

- Too many words
 - Font too small
 - Little white space
 - No structure
 - No priorities
- Pretty much useless for most people*





**The January 2011 posting includes 43 drug products with safety labeling changes to the following sections:
BOXED WARNING, CONTRAINDICATIONS,
WARNINGS, PRECAUTIONS, ADVERSE REACTIONS,
PATIENT PACKAGE INSERT, and MEDICATION
GUIDE.**



Communication challenges!

- The importance of ADRs and reporting them
- Information about benefit – harm and effectiveness – risk
- Encouraging rational drug use/adherence
- Communicating uncertainty
- Dealing with traditional beliefs and practices
- Involving patients; reaching informed consent
- Preventing or resolving crises



Problematic issues in drug safety: *all reliant on communications for safety*

- Adverse effects: 'no drug 100% safe'
- Risk as a concept in medicine
- Safety and medicines (prescribing, dispensing)
- Benefit-harm
- Effectiveness-risk
- Public health and commercial goals
- Public health and individual welfare
- Access to medicines
- Uncertainty

continued...





More problematic issues in drug safety:

- Individual patient variation and susceptibility
- Polypharmacy/polytherapy
- Interactions
- Relationship of allopathic and traditional medicines
- Resistance
- Diagnostic, prescribing and dispensing errors
- Correct use and compliance/adherence issues
- Labelling and storage



Medicines - a major part of everyday life

- In the US approx 3 billion prescriptions annually: 10 for every person in the population (pop. 300m)
- In the UK approx 750 million community prescriptions annually (pop. 61m)
- ADRs and adverse interactions increase exponentially with 4 or more medications
- Tens of millions of patients are self-medicating: OTCs, trad meds, internet



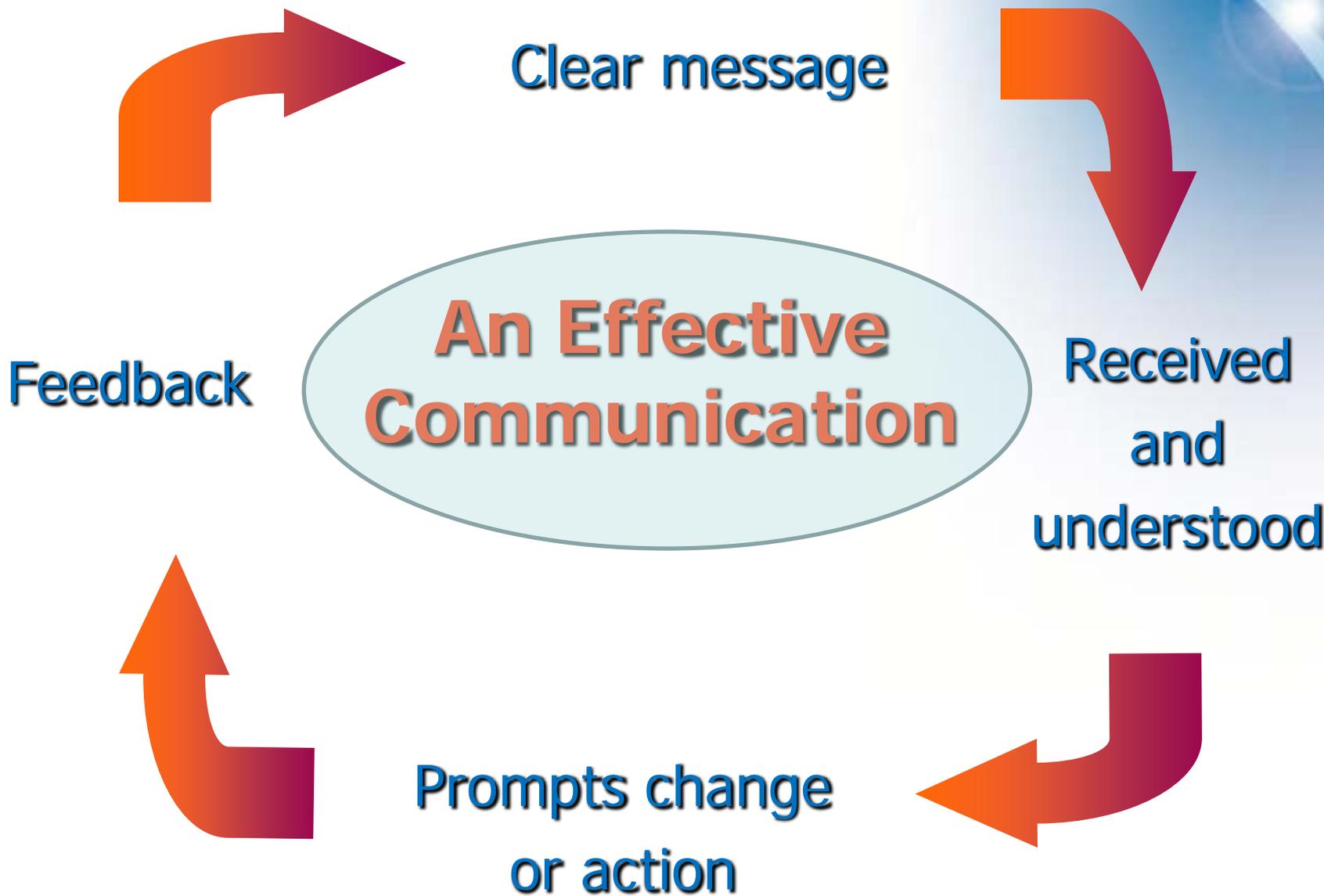
What is an effective communication?

**' But I sent her
an email...'**



**An effective communication
is a message which has been
sent, with evidence that it
has been received,
understood and has
prompted appropriate
change or action**





Principles of Effective Communications

- Be clear about your message and purpose
- Know your audience(s): empathy; tailor the message
- Choose appropriate methods/media
- Present message with impact
- Make benefits clear
- Pre-test and revise message
- Repeat message
- Repeat message
- Seek feedback, monitor effects, start again



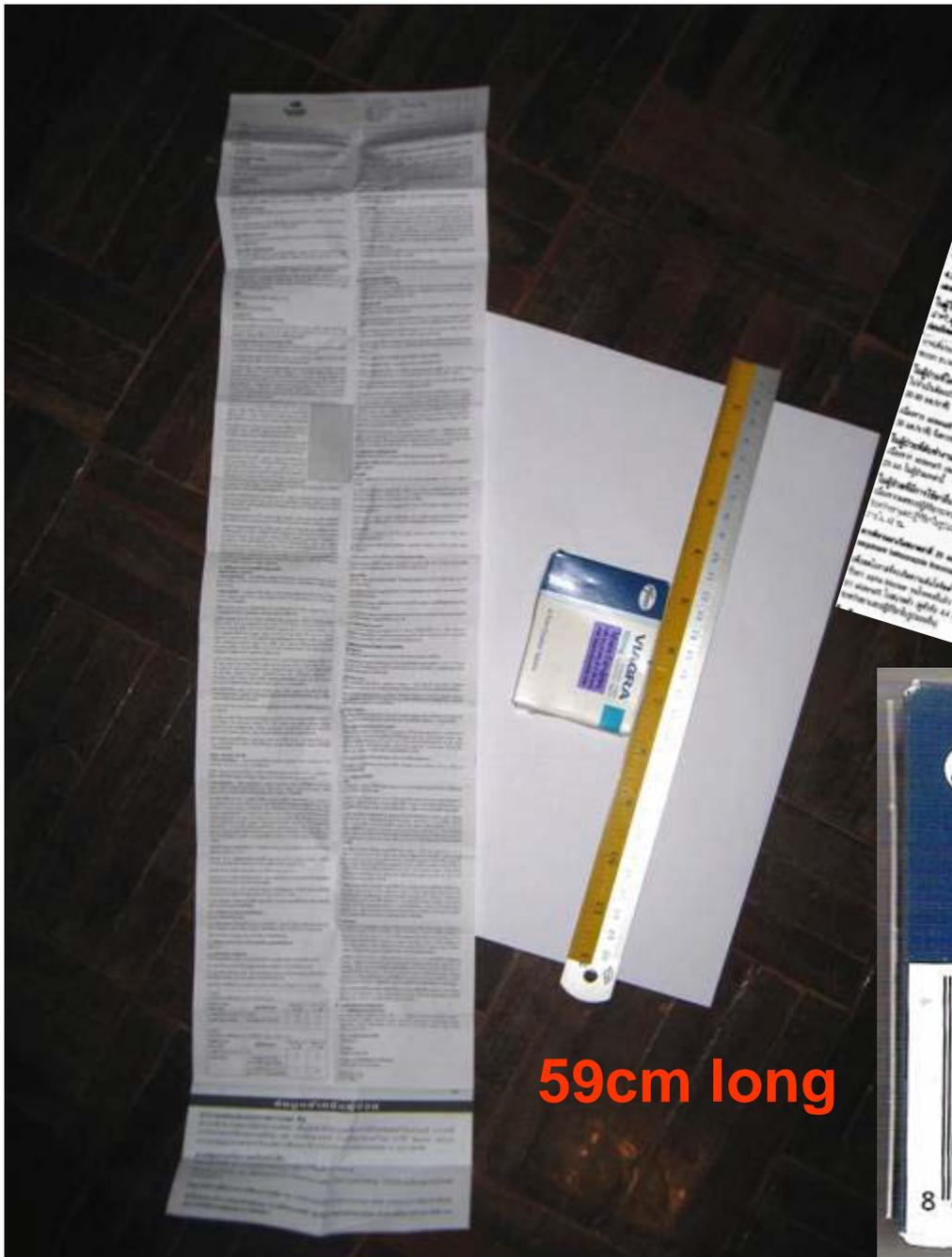




Thinkstock







59cm long

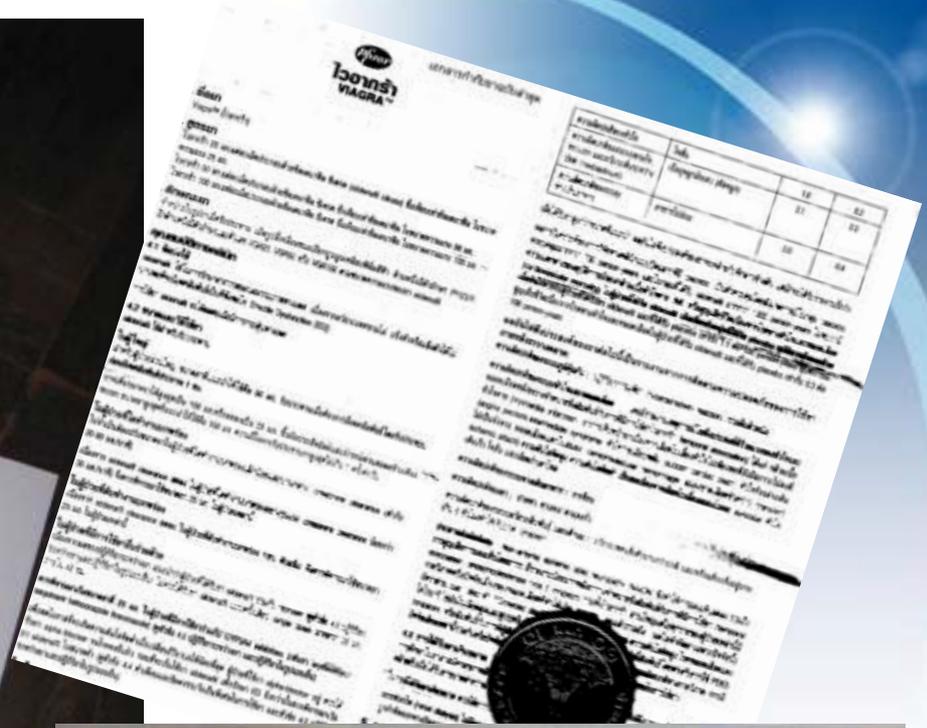






Photo credit: www.longines.com - Dr. Fred by Charles & Ray

Elegance is an attitude



exquisite polished diamonds
all steel with diamond bezel
£1250

LONGINES

L'ÉLEGANCE DU TEMPS DEPUIS 1852

LONGINES WATCHES ARE AVAILABLE FROM LEADING RETAIL JEWELLERS.
FOR A CATALOGUE PLEASE TELEPHONE 0481 624 3977



Targeting

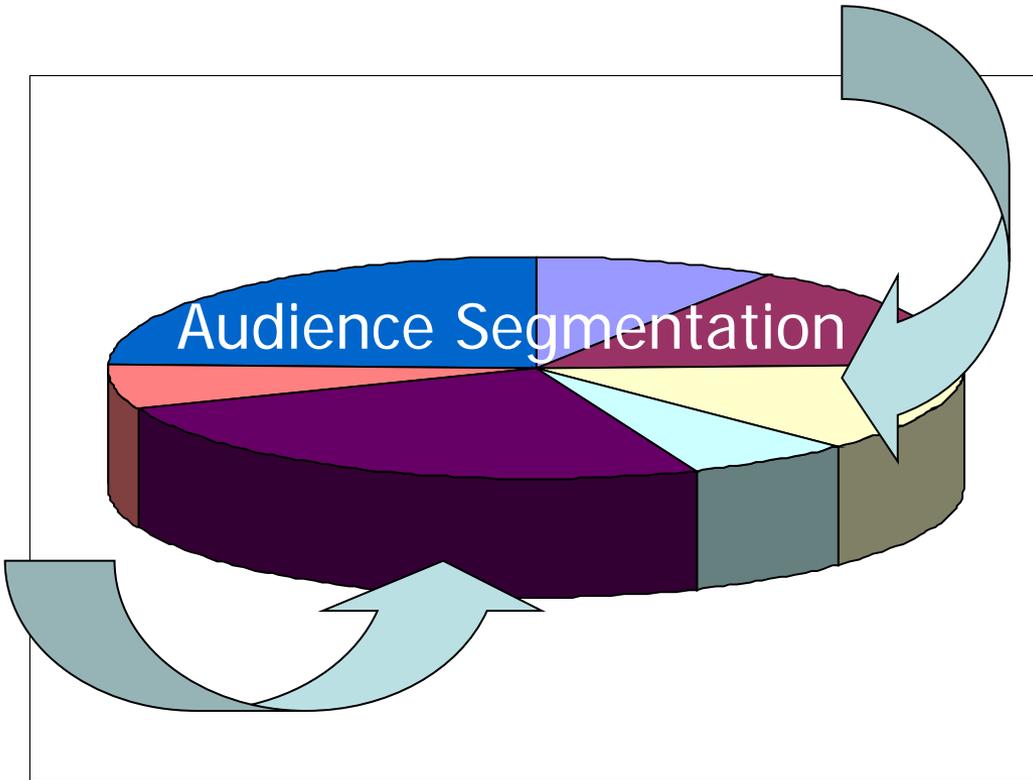
Audience segmentation



**Doctors and nurses are all
different**

Pharmacists are all different

Patients are all different



- Age, gender
- Education, ability
- Intelligence
- Role, job
- Location, lifestyle
- Income, debt
- Attitudes, values
- ...more





Partners and audiences in drug safety

- Manufacturers
- Regulators
- Politicians
- Employees
- **Health professionals**
- Academics
- Bosses/managers
- **The public**
- **Patients**
- Consumer and lobby groups
- Lawyers
- The media
- International community



Literacy and health literacy

- Percentage of population at or below basic literacy (US 20-30%)
- Percentage of population with poor health literacy (US maybe 50%+)
- Percentage of population with poor numeracy and health numeracy skills – measurement, risk - (at least 50%+)





Empathy

What's it like for them?



Know your audience

- Watch
- Listen
- Research
- Ask
- Test





昌眼鏡公司

翔時裝公司

上海第一食品商店

上海第一食品商店

上海時裝有限公司

皇冠娛樂

上海市第一食品商店

麥當勞

江蘇陽光集



Communicate competitively

MAOCHANG

茂昌

公司



樂



**Getting attention,
changing beliefs,
values, feelings and
behaviour is very
difficult**





STOP!

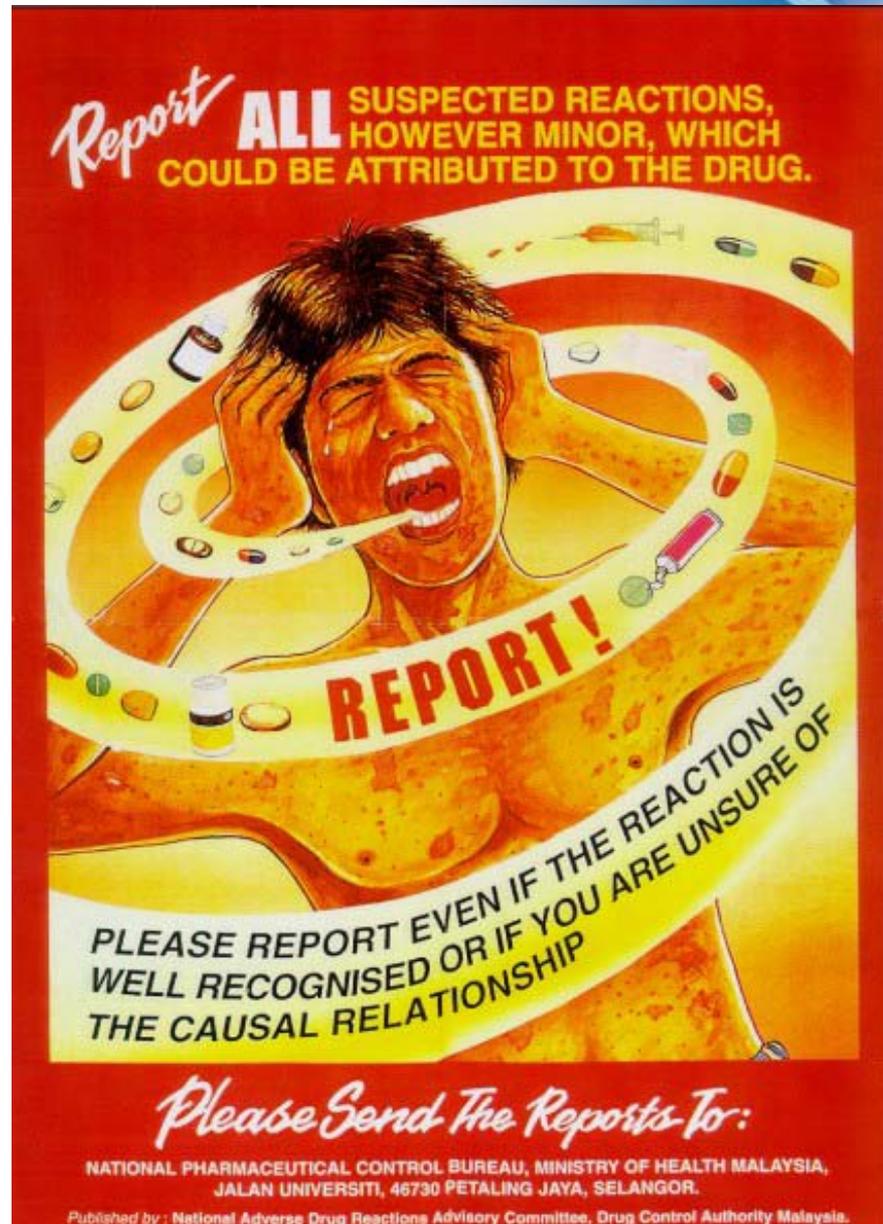
PAY ATTENTION!

REMEMBER!

ACT!



Malaysian ADR poster



COUNTERFEIT DRUGS KILL!



WORKING TOGETHER FOR SAFE DRUGS:

- World Health Organization (WHO)
- International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
- International Generic Pharmaceuticals Alliance (IGPA)
- World Self-Medication Industry (WSMI)
- CHMP/Pharmaciens Sans Frontières

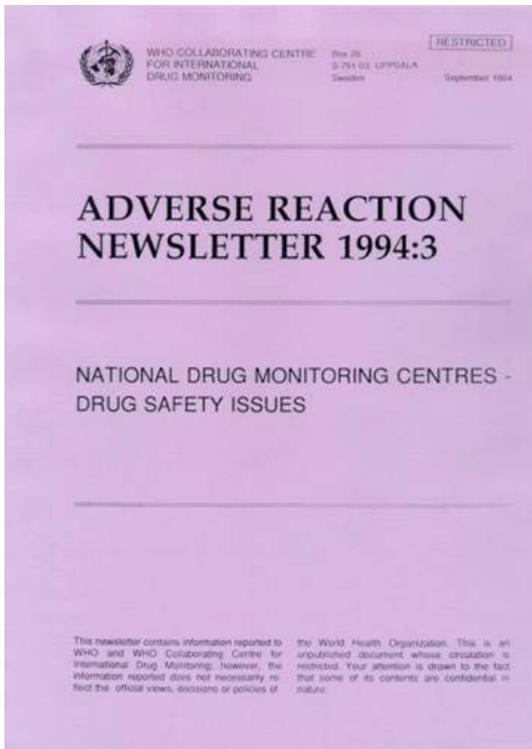


I HAVE AIDS
Please hug me



I can't make you sick







Evidence based medicine: does it make a difference?



30 g



Elocon[®] Ointment

0.1 % w/w MOMETASONE FUROATE

Schering-Plough

PATIENT INFORMATION LEAFLET

Elocon[®] Ointment

Mometasone Furoate



Please Read This Leaflet Carefully

This leaflet will tell you about ELOCON, a medicine your doctor has prescribed. It should give you all the information you need, but if there is anything you do not understand, please ask your doctor or pharmacist.

What is ELOCON?

The ointment contains mometasone furoate 0.1% w/w, as well as the following inactive ingredients : hexylene glycol USP, purified water Ph.Eur, phosphoric acid Ph.Eur, propylene glycolstearate, white wax, white petrolatum. The ointment is available in tubes containing 30g or 100g.

What Type of Medicine is ELOCON?

ELOCON Ointment is one of a group of medicines called topical corticosteroids. It is classified as a "potent corticosteroid". These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

Who Makes it?

The holder of the Marketing Authorisation is : Schering-Plough Ltd, Welwyn Garden City, Herts, AL7 1TW, England. The manufacturer is : Schering-Plough Labo NV, Heist-op-den-Berg, Belgium.

What is ELOCON for?

In adults and children, ELOCON Ointment is used to reduce redness and itchiness caused by certain skin problems called psoriasis or dermatitis.

Is there any reason why you should not use ELOCON?

- If you, or your child, have ever had an allergic reaction to ELOCON or any other similar medicines, you should not use it. You should tell your doctor so that he can give you, or your child, another medicine.
- Do not put it on any other skin problems as it could make them worse especially rosacea (a skin condition affecting the face), acne, dermatitis around the mouth, genital itching, nappy rash, cold sores, chickenpox, shingles or other skin infections. Ask your doctor or pharmacist if you are not sure.
- You should tell your doctor if you are pregnant or breast-feeding, before you start using ELOCON.
- If your skin becomes irritated or sensitive after using ELOCON, you should stop using it and tell your doctor.

PATIENT INFORMATION LEAFLET (PIL)

ACICLOVIR 800MG TABLETS

WHAT YOU SHOULD KNOW ABOUT ACICLOVIR 800MG TABLETS
Please read this leaflet carefully before you start to take Aciclovir 800mg Tablets. It provides some information about your medicine and how to take it. If you have any questions or are in any doubt about anything, please ask your doctor or pharmacist.

YOUR MEDICINE

The name of your medicine is Aciclovir 800mg Tablets. The carton contains 30 tablets.
WHAT IS IN YOUR MEDICINE
● Each tablet contains 800mg Aciclovir Ph. Eur.
● The tablet also contains microcrystalline cellulose, sodium starch glycolate, polyethylene glycol, magnesium stearate and colloidal anhydrous silica. If you are allergic to any of these ingredients you must tell your pharmacist or doctor.

MANUFACTURER AND PRODUCT LICENSE HOLDER: Ethical Generics, 140, Hermannstrasse, 40474 Düsseldorf, Germany.

WHAT IS YOUR MEDICINE FOR

Aciclovir 800mg Tablets belong to a group of medicines called antivirals. They are used for herpes such as:

BEFORE YOU TAKE YOUR MEDICINE

- Have you ever had a bad reaction to this medicine or to any other medicines containing aciclovir?
- Are you pregnant, trying to become pregnant or breast feeding?
- Do you suffer from any kidney disease?
- Are you taking probenecid or any other medicines for gout?

If the answer to any or all of the above questions is YES, DO NOT TAKE Aciclovir 800mg Tablets without asking your doctor's advice.

HOW DO YOU TAKE YOUR MEDICINE

You must take your medicine as the doctor tells you to. It is important to take Aciclovir 800mg Tablets at the right time. The label on the box will tell you how much to take and how often. If it does not or you are not sure, ask your doctor or pharmacist.

- The usual dose for adults is 800mg every 4 hours. The tablets should be taken 3 times a day leaving out the night time dose. But this may be changed by your doctor.
- You should take the tablets as soon as you notice the symptoms.
- You should swallow Aciclovir 800mg Tablets with some water after food.
- If you forget to take a tablet, take it as soon as you remember. Then continue to take the tablets as before.
- If you, or anyone else, accidentally swallow more tablets than the recommended dose, contact a doctor immediately.
- Always take Aciclovir 800mg Tablets and the carton with you so that the doctor knows what the product is.

AFTER YOU HAVE TAKEN YOUR MEDICINE

Normally this medicine is well tolerated but occasionally some people may get side effects.

- Some people may get a skin rash, feel sick, get diarrhoea, or dizziness and confusion, or other effects after taking Aciclovir 800mg Tablets.
- Very occasionally, some people may get a headache or feel tired after using Aciclovir 800mg Tablets.

If you are one of these people, stop the reaction stage or becomes troublesome, stop using the medicine. If you get any other unusual or unexpected symptoms, you should tell your doctor or pharmacist.

HOW YOU SHOULD LOOK AFTER YOUR MEDICINE

- Keep this and all medicines in a cool, dark place below 25°C where children cannot get them. Your medicine could harm them.
- Do not use this medicine after the expiry date which is printed on the carton. If you have any Aciclovir 800mg Tablets left after that, return them to your pharmacist.
- If your doctor decides to stop treatment, take only left over tablets to your pharmacist. Only keep those if your doctor tells you to.

Product Licence Number: PL 24884-0006
Date: December 1996

DISTRIBUTED BY: Ethical Generics Ltd, West Point, 40-42 West Street, Hove, Brighton BN1 1RD.
Mkx 1996 31





KENACOMB® CREAM

DESCRIPTION

Kenacomb Cream for topical use contains the synthetic corticosteroid triamcinolone acetonide, the antibiotic neomycin sulphate, emollients, glycerol, petrolatum and lanolin.

Each gram of Kenacomb Cream provides triamcinolone acetonide 1 mg, Neomycin 2.5 mg, Glycerol 0.25 mg, Methyl 100,000 units.

CLINICAL PHARMACOLOGY

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive actions. The mechanism of anti-inflammatory activity of topical corticosteroids is unclear. Various laboratory models, including vasoconstrictor assays, are used to compare and predict potassium ion channel effects of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption (see TOPICAL AND ADMINISTRATION). Once absorbed through the skin, topical corticosteroids can traverse through the same pharmacokinetic pathways as systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into bile.

Neomycin and glycerol are not absorbed from intact skin or mucous membranes. Neomycin can be absorbed through inflamed skin. Once absorbed, it is equally excreted unchanged through the kidneys. The half-life is approximately 2 to 3 hours.

Microbiology

Neomycin acts by binding to sterols in the cell membrane of susceptible species resulting in a change in membrane permeability and the subsequent leakage of intracellular components. It is active against a broad range of Gram positive and Gram negative bacteria, including staphylococci, streptococci, bacilli, and certain strains of gram negative bacilli such as *Pseudomonas aeruginosa*, and *Proteus mirabilis*. Gramicidin exerts its antibacterial activity against many gram positive organisms by altering cell membrane permeability.

INDICATIONS AND USAGE

Kenacomb Cream is indicated for the relief of the inflammatory and pruritic manifestations of dermatoses likely to become or are already itched.

CONTRAINDICATIONS

Hypersensitivity to any of the components of the preparation, not indicated in those patients with tuberculous lesions, topical or systemic viral infections (i.e., varicella, zoster, herpes simplex).

PRECAUTIONS

General

If sensitivity or irritation develops, topical use of the medication should be discontinued and appropriate therapy instituted. Hypersensitivity reactions to the anti-infective components may be masked by the presence of a corticosteroid. The medication is not for oral use only. Because of the potential hazard of nephrotoxicity and ototoxicity, this medication should not be used

in patients with extensive skin damage or other conditions where absorption of neomycin is possible. The use of occlusive dressings should be avoided because of the increased risk of sensitivity reactions and increased percutaneous absorption potential of neomycin and corticosteroid.

As with any antibiotic preparation, prolonged use may result in overgrowth of non-susceptible organisms, including fungi other than *Candida*. Corticosteroids, such as prednisone, can enhance microbial infection. Therefore, constant observation of the patient is essential. Should superinfection due to fungus, bacteria, or parasites occur, suitable antimicrobial therapy must be administered. A flare-up response does not occur promptly, application should be discontinued if further infection is adequately controlled by other anti-infective measures.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use of hot, moist, occlusive, and prolonged use. Therefore, patients receiving a large dose of any potent topical steroid and/or any condition which may enhance systemic absorption, should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation test, and for symptoms of adrenal insufficiency. If any of these conditions occur, an attempt should be made to withdraw the drug to reduce the frequency of application, or substitute a less potent steroid.

Frequently, signs and symptoms of steroids with adrenal insufficiency, requiring supplemental systemic corticosteroids. Information for Patients Patients using this medication should receive the following information and instructions. This medication is to be used as directed by the physician. It is for skin use only. Avoid contact with the eyes. Patients should be advised not to use this medication for any disorder other than that for which it was prescribed. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt or discontinue therapy until the prescribed course of treatment is completed. Patients should report any signs of adverse reactions. The treated skin area should not be bandaged, covered or wrapped unless directed by the physician. Do not use long-term plastic barriers or emollient preparations on patients being treated, as these preparations may contribute to occlusive dressing. When using this medication in the genital area, patients should be advised to apply the preparation sparingly and to wear loosely fitting clothing. Patients should be advised to use preventive measures to avoid reinfections.

Information for Patients

The following local adverse reactions are reported infrequently with topical corticosteroids (reaction to the steroid is an approximate decreasing order of frequency): burning, itching, irritation, dryness, folliculitis, hyperkeratosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, mucositis of the skin, secondary infection, skin atrophy, striae, and miliaria.

Neomycin is not labeled even with prolonged therapy initiation and cases of contact dermatitis have been reported. Delayed type hypersensitivity reactions have been reported during use of neomycin. Neomycin has been reported to be toxic to the eye. Ocular toxicity and iridodiolysis have been reported when applied to large surfaces of damaged skin. Sensitivity reactions to petrolatum have been reported.

Adverse Reaction-Pediatric Patients Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of hypoadrenalism (hypocorticism) include vomiting, diarrhea, hypotension, dehydration, weight loss, and loss of appetite.

Laboratory Tests

If there is a lack of therapeutic response, KCl, sodium, sulfate, or other diagnostic methods should be repeated. A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating hypothalamic-pituitary-adrenal (HPA) axis suppression due to corticosteroids.

Contraception, Mutagenesis and Impairment of Fertility

Long-term animal studies have not been performed to evaluate reproductive or mutagenic potential, or possible impairment of fertility in males or females.

Pregnancy, Teratogenic Effects Corticosteroids are generally known to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The most potent corticosteroids have been shown to be teratogenic in

laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topical applied corticosteroids to treat dermatoses. Therefore, this medication should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The medication should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers

It is not known whether topical administration of this medication could result in sufficient systemic absorption of the components to produce detectable quantities in breast milk. Systemically administered corticosteroids are excreted into breast milk and are likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when the medication is administered to a nursing woman.

Pediatric Use

Use of this medication over large surface areas or for prolonged periods in pediatric patients could result in sufficient systemic absorption to produce systemic effects. Pediatric patients may demonstrate greater susceptibility to HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight.

HPA axis suppression, Cushing's syndrome, and glucocorticoid hypersecretion have been reported in children receiving topical corticosteroids (see ADVERSE REACTIONS-Pediatric Patients). When applied to pediatric patients, the medication should be limited to the least amount for the shortest duration compatible with an effective therapeutic regimen. These patients should be closely monitored for signs and symptoms of systemic effects.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids (reaction to the steroid is an approximate decreasing order of frequency): burning, itching, irritation, dryness, folliculitis, hyperkeratosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, mucositis of the skin, secondary infection, skin atrophy, striae, and miliaria. Neomycin is not labeled even with prolonged therapy initiation and cases of contact dermatitis have been reported. Delayed type hypersensitivity reactions have been reported during use of neomycin. Neomycin has been reported to be toxic to the eye. Ocular toxicity and iridodiolysis have been reported when applied to large surfaces of damaged skin. Sensitivity reactions to petrolatum have been reported.

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OVERDOSAGE

Topically applied corticosteroids and neomycin can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS, General). Treatment: No specific antidote is available and treatment should be symptomatic.

DOSEAGE AND ADMINISTRATION

Apply to the affected area 2 to 3 times daily.

Storage

Store at room temperature. Avoid excessive heat.

Made by:

Dixell-Myers Squibb Australia Pty Ltd, 555 Princes Highway, Noble Park, Victoria, Australia, 3174.

SK142





Qualities of modern communications:

- Intimacy
- Immediacy and high impact
- Peer-to-peer
- Addressing competition and low attention levels
- Benefits





Planning communications:

- Today's modern standards and methods
- Simple, clear message
- Stimulating motivation and offering benefits (including rewards and feedback)
- The use of specialist skills and creative imagination





Monitor, measure and evaluate effects

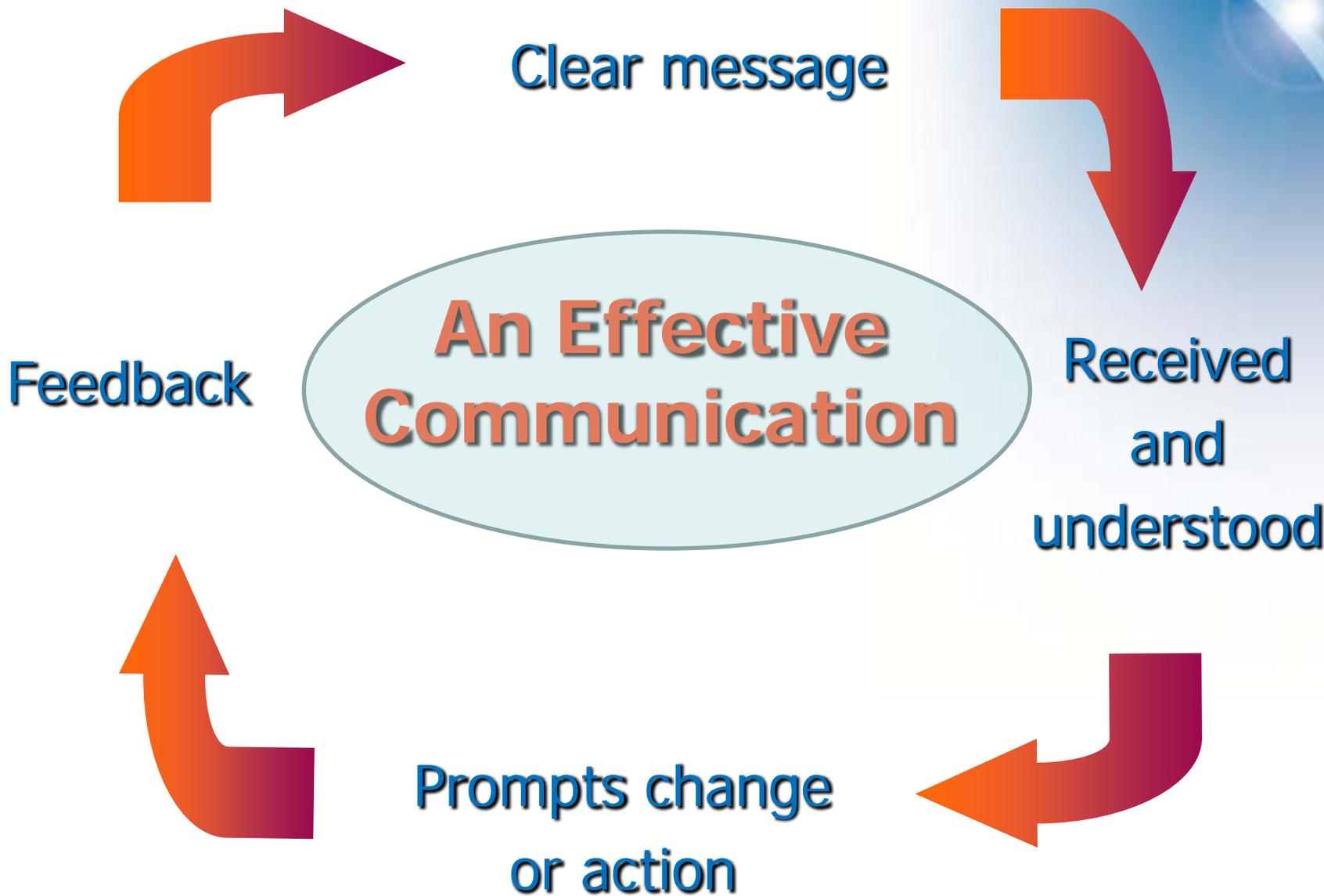
Does it work?

If so, why?

If not, why not?

If not, change it







Dear Friend

As your personal representative, I am writing to you regarding the interest in your account. It is my duty to ensure that you should be able to access your funds as soon as possible with courtesy and efficiency.

However, I have been advised that your account may be subject to some restrictions. I will do my best to resolve this as quickly as possible for you.

For that reason, I do understand that you may have some difficulties. I will do my best to assist you in any way possible.

I hope to see you soon and will be glad to discuss this matter with you. Please contact me if you have any questions.

Yours faithfully,
[Signature]

BANK
BYOK

**The heart of good
communications is
understanding all your
audiences and tailoring
messages precisely to them**

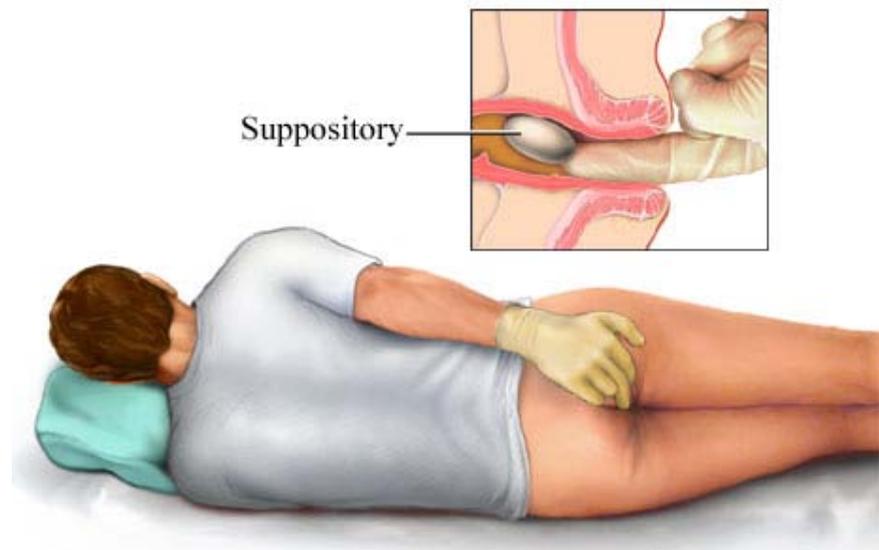
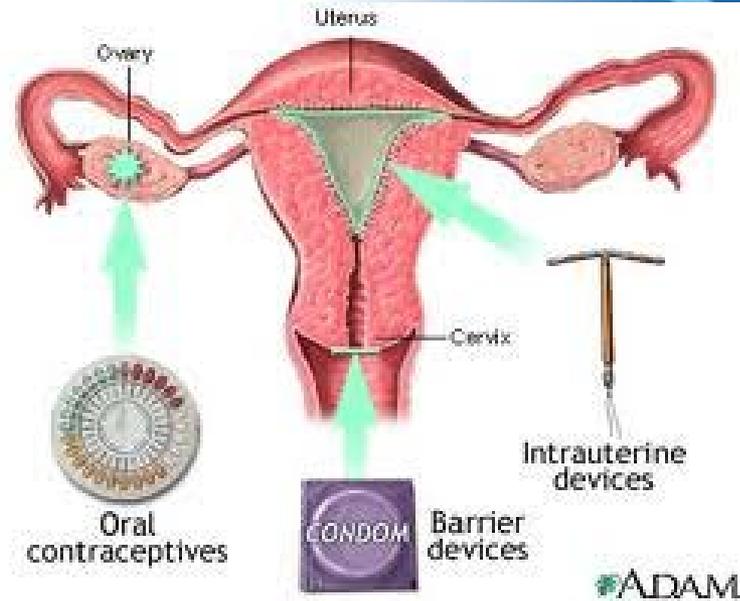
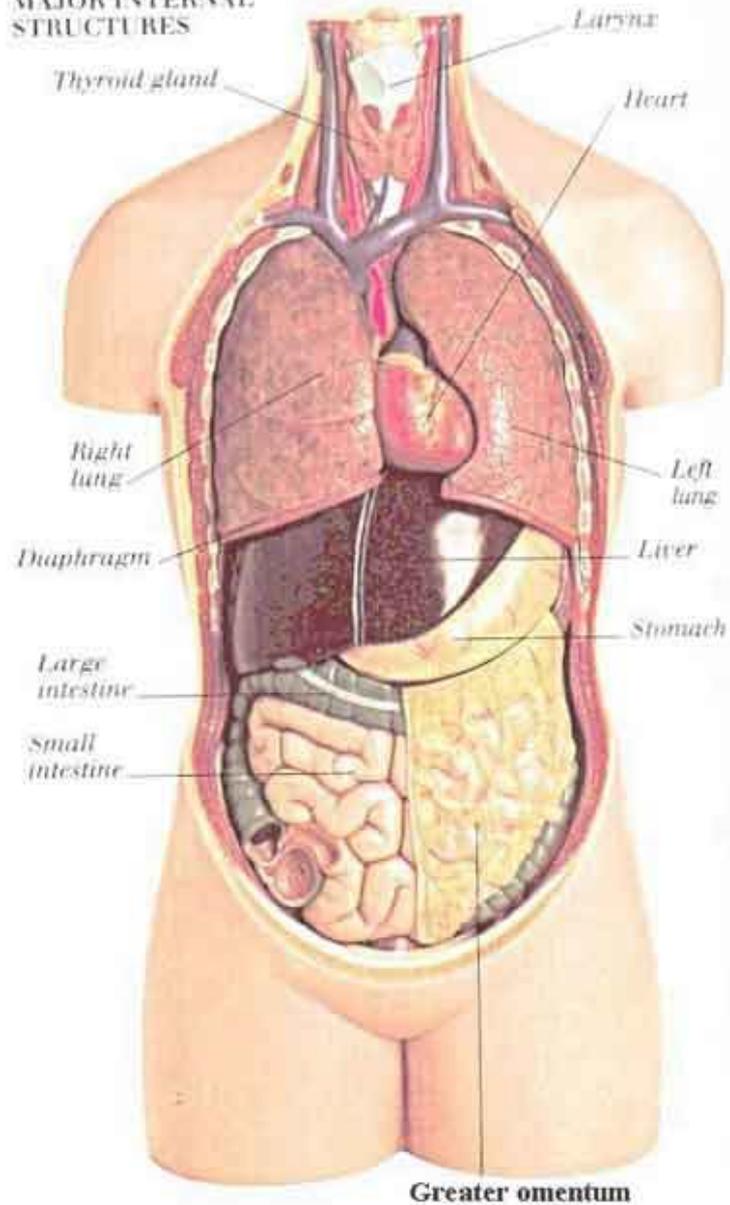




Branding
Repetition
Location



MAJOR INTERNAL STRUCTURES



Stop the spread of flu germs

Cover your mouth and nose with a tissue when you cough or sneeze



Put your used tissue in the rubbish bin or in a plastic bag

Wash and dry your hands often, especially after coughing or sneezing – use soap

Stay away from others if you're sick



www.moh.govt.nz/pandemicinfluenza

Protect your family/whānau from influenza

Symptoms of Swine flu

Systemic
- Fever

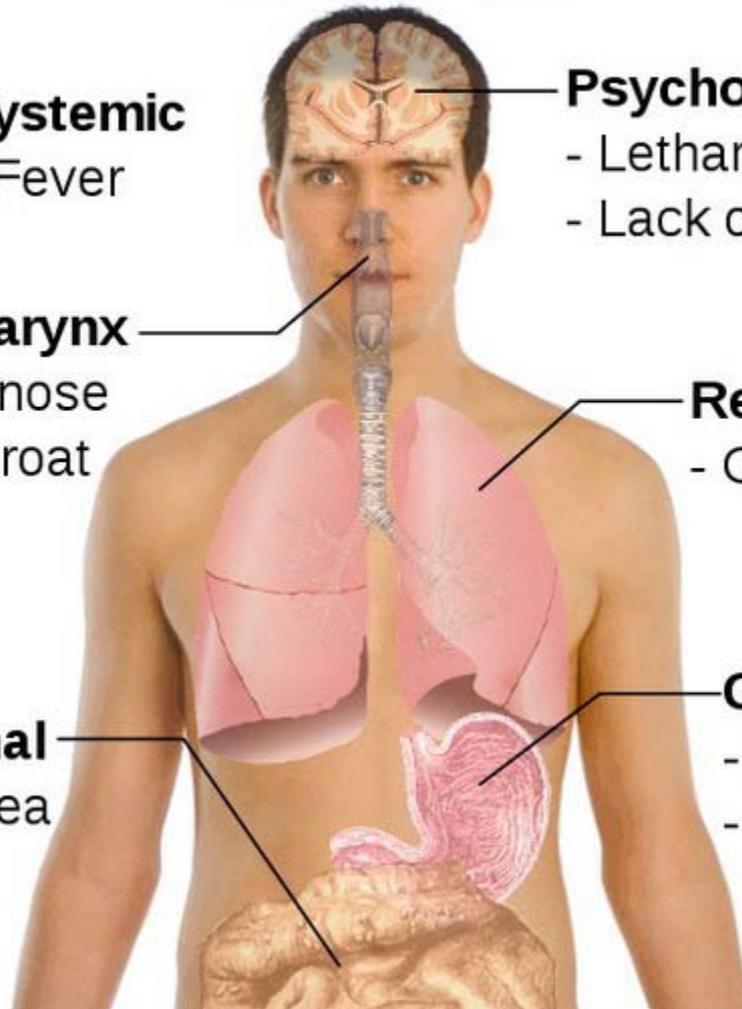
Psychological
- Lethargy
- Lack of appetite

Nasopharynx
- Runny nose
- Sore throat

Respiratory
- Coughing

Intestinal
- Diarrhea

Gastric
- Nausea
- Vomiting



Principles of Effective Communications

- Be clear about your message and purpose
- Know your audience(s): empathy; tailor the message
- Choose appropriate methods/media
- Present message with impact
- Make benefits clear
- Pre-test and revise message
- Repeat message
- Repeat message
- Seek feedback, monitor effects, start again



Summary

- Our communications must:
 - Be strong and visible
 - Be precisely targeted and tested
 - Change attitudes, values, behaviour
 - Be followed up and revised
 - Embrace modern standards and skills



almost

The End

of this presentation...

and the beginning

of the challenges for you.



Crisis management and communication

- Crises will happen (fire, death, ADRs...)
- Assess risks
- Anticipate and plan for all likely and unlikely events
- Create, rehearse and revise crisis plans
- In crisis, communicate
 - Quickly
 - Openly and honestly
 - Express regret, apologise
 - Explain what is being done to solve the crisis and prevent repetition



Read

Expecting the Worst

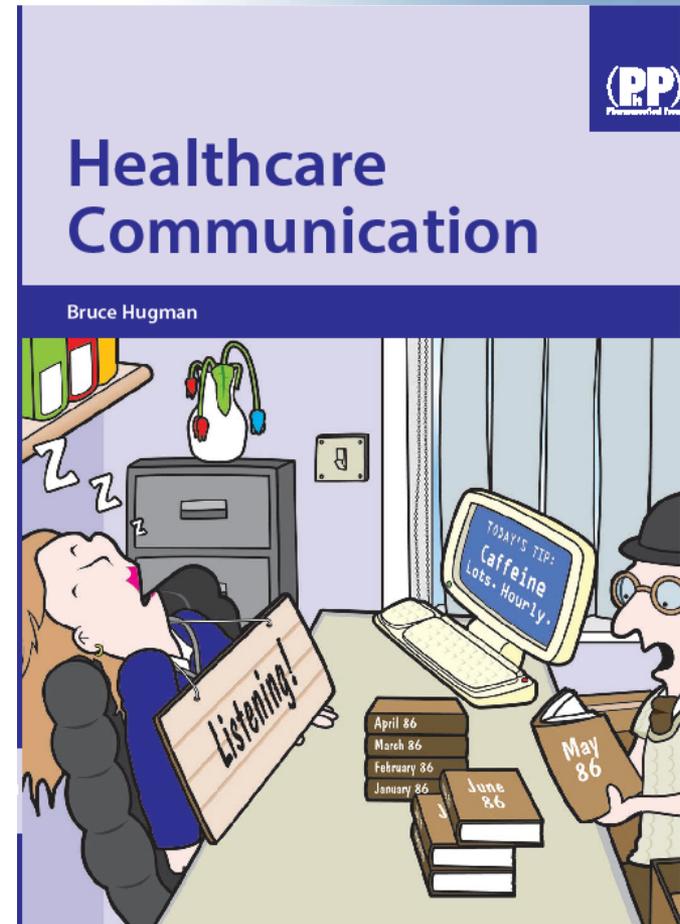
The UMC's crisis management and
communication manual

If you think
I have something
useful to say,
you might like
to read...

www.pharmpress.com

www.amazon.com

www.brucehugman.com





The end

ACKNOWLEDGEMENT: This presentation was created by Bruce Hugman for the *pro bono* purpose of training representatives of member countries of the WHO Programme for International Drug Monitoring, under the auspices of Uppsala Monitoring Centre (UMC), a Swedish not-for-profit foundation, authorised by WHO for such purposes. The presentation is entirely original but draws on a wide range of material; Creative Commons, royalty-free or public sources have been used wherever possible, but the author regrets and accepts sole responsibility for any copyright infringement that may inadvertently have occurred.