

# Medical packaging for people:

*Using information about medicines*

Dr Karel van der Waarde

Sheffield, July 3-5, 2013

Sheffield Hallam University: Design for Health Conference 2013

**1 Examples: what is the problem?**

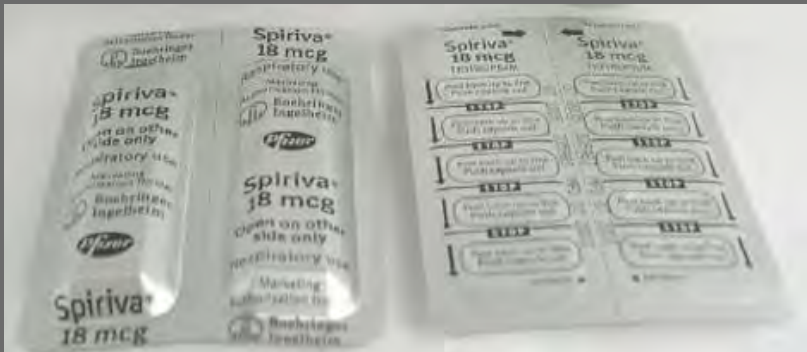
2 What are the causes?

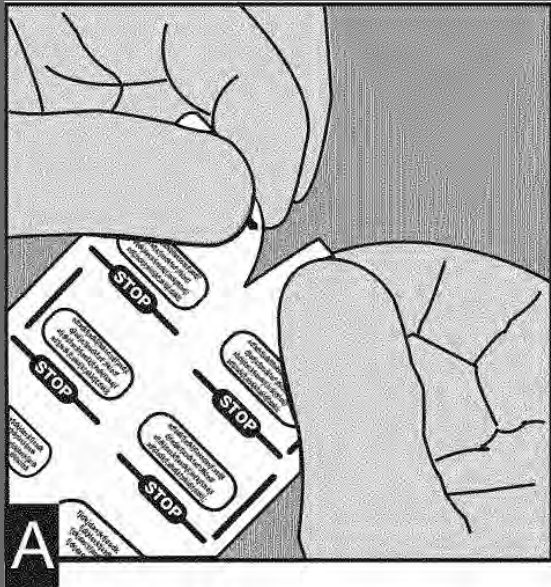
3 What's stopping us?

4 Why is that difficult?

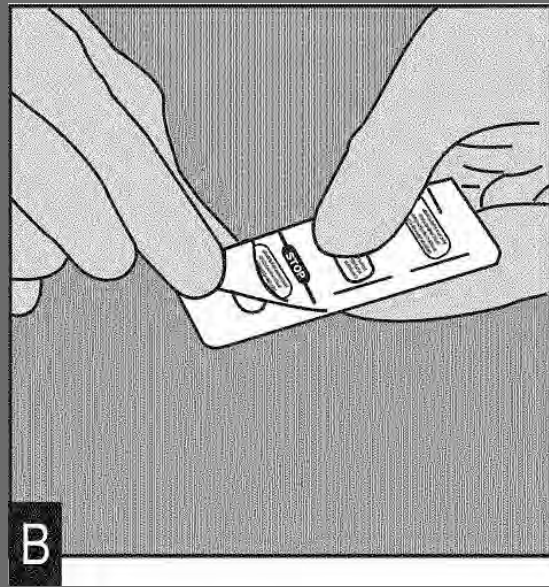
5 What's next?

1

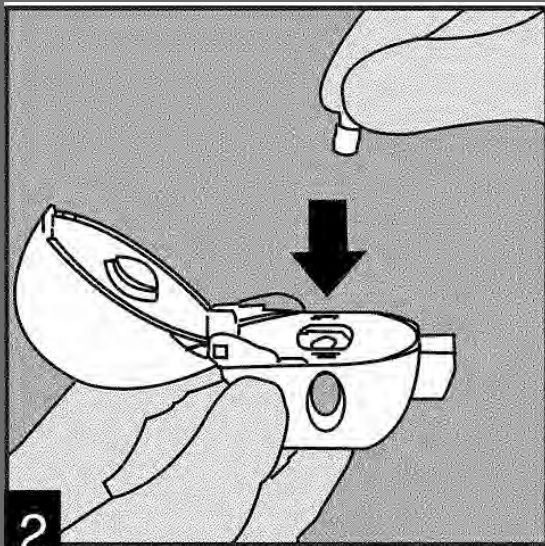




A



B



2



**CRESTOR 5 mg, 10 mg, 20 mg and 40 mg tablets (rosuvastatin)**

Read all of this leaflet carefully before you start taking CRESTOR

- **Keep this leaflet.** You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **This medicine has been prescribed for you.** Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

- 1) What is CRESTOR and what is it used for?
- 2) Before you take CRESTOR
- 3) How to take CRESTOR
- 4) Possible side effects
- 5) How to store CRESTOR
- 6) Further information

**1) WHAT IS CRESTOR AND WHAT IS IT USED FOR?**

CRESTOR belongs to a group of medicines called statins. It is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol.

There are different types of cholesterol found in the blood – 'bad' cholesterol (LDL-C) and 'good' cholesterol (HDL-C). CRESTOR can reduce the 'bad' cholesterol and increase the 'good' cholesterol.

You have been prescribed CRESTOR because you have a high cholesterol level. This means you are at risk from a heart attack or stroke.

You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels.

CRESTOR works by helping to block your body's production of 'bad' cholesterol and improves your body's ability to remove it from your blood.

**Why is it important to keep taking CRESTOR?** You need to keep taking CRESTOR, even if it has got your cholesterol to the right level, because it prevents your cholesterol levels from creeping up again. However, you should stop if your doctor tells you to do so, or you have become pregnant.

You should continue with your cholesterol-lowering diet and exercise while you are taking CRESTOR. For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. If you correct your cholesterol levels, you can reduce your risk of having a heart attack or stroke.

**2) BEFORE YOU TAKE CRESTOR**

**Do not take CRESTOR:**

- if you have ever had an allergic reaction to CRESTOR, or to any of its ingredients.
- if you are pregnant or breast-feeding. If you become pregnant while taking CRESTOR stop taking it immediately and tell your doctor.
- Women should avoid becoming pregnant while taking CRESTOR by using suitable contraception.
- if you have liver disease.
- if you have severe kidney problems.
- if you have repeated or unexplained muscle aches or pains.
- if you take a drug called clozapine (used, for example, after organ transplants)

If any of the above applies to you, please go back and see your doctor.

In addition, do not take CRESTOR 40 mg (the highest dose):

- if you have moderate kidney problems (if in doubt, please ask your doctor).
- if your thyroid gland is not working properly.
- if you have had any repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- if you regularly drink large amounts of alcohol.
- if you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).

• if you take other medicines called fibrates to lower your cholesterol

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

**Take special care with CRESTOR:**

- If you have problems with your kidneys.
- If you have problems with your liver.
- If you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- If you regularly drink large amounts of alcohol.
- If your thyroid gland is not working properly.
- If you take other medicines called fibrates to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- If the patient is a child: CRESTOR should not be given to children
- If you are over 70 (as your doctor needs to choose the right start dose of CRESTOR to suit you)
- If you are of Asian origin – that is, Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of CRESTOR to suit you.

If any of the above applies to you (or if you are not sure):

- Do not take CRESTOR 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of CRESTOR.

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will usually carry out this blood test (liver function test) before and during treatment with CRESTOR.

**Taking other medicines**

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

Tell your doctor if you are taking any of the following: clozapine (used for example, after organ transplants), warfarin (for any other drug used for thinning the blood), fibrates (such as gemfibrozil, fenofibrate) or any other medicines used to lower cholesterol (such as ezetimibe), indigestion remedies (used to neutralise acid in your stomach), erythromycin (an antibiotic) or oral contraceptive (the pill) or hormone replacement therapy. The effects of these medicines could be changed by CRESTOR or they could change the effects of CRESTOR.

**Taking CRESTOR with food and drink**  
You can take CRESTOR with or without food.

**Pregnancy and breast-feeding**

Do not take CRESTOR if you are pregnant or breast-feeding. If you become pregnant while taking CRESTOR stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking CRESTOR by using suitable contraception.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**  
Most people can drive a car and operate machinery while using CRESTOR – it will not affect their ability. However, some people feel dizzy during treatment with CRESTOR. If you feel dizzy, consult your doctor before attempting to drive or use machines.

**Important information about some of the ingredients of CRESTOR**

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking CRESTOR.

For a full list of ingredients please see Further information below.

**3) HOW TO TAKE CRESTOR**

Always take CRESTOR as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Starting dose**  
Your treatment with CRESTOR must start with the 5 mg or the 10 mg dose, even if you have taken a higher dose of a different statin before. The choice of your start dose will depend upon:

- Your cholesterol level.
- The level of risk you have of experiencing a heart attack or stroke.

- Whether you have a factor that may make you more sensitive to possible side effects.
- Please check with your doctor or pharmacist which start dose of CRESTOR will best suit you.
- Your doctor may decide to give you the lowest dose (5 mg) if:
- You are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
  - You are over 70 years of age.
  - You have moderate kidney problems.
  - You are at risk of muscle aches and pains (myopathy).

**Increasing the dose and maximum daily dose**  
Your doctor may decide to increase your dose. This is so that you are taking the amount of CRESTOR that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of CRESTOR is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

**Taking your tablets**  
Swallow each tablet whole with a drink of water. Take CRESTOR once daily. You can take it at any time of the day.

Try to take your tablet at the same time every day to help you to remember it.

**Regular cholesterol checks**  
It is important to go back to your doctor for regular cholesterol checks to make sure your cholesterol has reached and is staying at the correct level. Your doctor may decide to increase your dose so that you are taking the amount of CRESTOR that is right for you.

If you take more CRESTOR than you should Contact your doctor or nearest hospital for advice. If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking CRESTOR.

**If you forget to take a dose**  
Don't worry. Just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

**If you stop taking CRESTOR**  
Talk to your doctor if you want to stop taking CRESTOR. Your cholesterol levels might increase again if you stop taking CRESTOR.

**4) POSSIBLE SIDE EFFECTS**

Like all medicines, CRESTOR can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

**Stop taking CRESTOR and seek medical help immediately** if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- Severe itching of the skin (with raised lumps).

**Also, stop taking CRESTOR and talk to your doctor immediately** if you have any unusual aches or pains in your muscles which go on for longer than you might expect. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as rhabdomyolysis.

**Common possible side effects (these may affect between 1 in 10 and 1 in 100 patients):**

- Headache
- Stomach pain
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your CRESTOR tablets (only CRESTOR 40 mg).

**Uncommon possible side effects (these may affect between 1 in 100 and 1 in 1,000 patients):**

- Rash, itching or other skin reactions
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your CRESTOR tablets (only CRESTOR 5 mg, 10 mg and 20 mg).

**Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):**

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking CRESTOR and seek medical help immediately

- Muscle damage – as a precaution, stop taking CRESTOR and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected
- A severe stomach pain (inflamed pancreas)
- Joint pain
- Increase in liver enzymes in the blood.

**Very rare possible side effects (these may affect less than 1 in 10,000 patients):**

- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Traces of blood in your urine
- Damage to the nerves of your legs and arms (such as numbness)

If any of the side effects become troublesome, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5) HOW TO STORE CRESTOR**

- Keep out of the reach and sight of children.
- Do not use CRESTOR after the expiry date which is shown on the box/tablet label. The expiry date refers to the last day of the month.
- Tablets should not be thrown in your bin or put down the drain. If they are out of date, or no longer suitable for you, return them to your pharmacist.
- Store your tablets below 30°C.
- If your tablets come in a plastic bottle, keep the lid tightly closed.
- Keep your tablets in the container you received them in.

**6) FURTHER INFORMATION**

**What CRESTOR contains:**  
The active substance in CRESTOR is rosuvastatin. CRESTOR film-coated tablets contain rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin. The other ingredients are: lactose monohydrate, microcrystalline cellulose, calcium phosphate, croscopollose, magnesium stearate, hypromellose, glycerol triacetate, titanium dioxide (E171), CRESTOR 10 mg, 20 mg and 40 mg film-coated tablets also contain red iron oxide (E172), CRESTOR 5 mg film-coated tablets also contain yellow iron oxide (E172).

**What CRESTOR looks like and contents of the pack**  
CRESTOR comes in blister packs containing 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 tablets and plastic bottles containing 30 and 100 tablets (Not all packs are available in every country).

CRESTOR comes in four tablet strengths:  
CRESTOR 5 mg film-coated tablets are yellow, round and marked with ZD4522 and 5.  
CRESTOR 10 mg film-coated tablets are pink, round and marked with ZD4822 and 10.  
CRESTOR 20 mg film-coated tablets are pink, round and marked with ZD4522 and 20.  
CRESTOR 40 mg film-coated tablets are pink, oval and marked with ZD4522 and 40.

**Marketing Authorisation Holder and Manufacturer**  
The Marketing Authorisations for CRESTOR are held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.  
Manufacturers responsible for batch release:  
AstraZeneca UK Ltd, Macclesfield, Cheshire, UK  
Telephone: +44 1625 582628  
AstraZeneca GmbH, Plinkhofstraße, Germany  
Telephone: +49 6202 9300  
AstraZeneca GmbH, Wedel, Germany  
Telephone: +49 41 037 080  
AstraZeneca Reims, France  
Telephone: +33 3286 18688  
NV AstraZeneca SA, Destelbergen, Belgium  
Telephone: +32 935 94211  
AstraZeneca Farmacobieltica Spain SA, Porriño, Spain  
Telephone: +34 988 345 200  
AstraZeneca AB, Södertälje, Sweden  
Telephone: +46 8 553 280 00

This product is authorised in the Member States of the EEA under the following name(s):

CRESTOR 5 mg, 10 mg, 20 mg and 40 mg (NL, AT, BE, DK, GR, FI, IE, IT, LU, PT, SE, UK), and 5 mg, 10 mg and 20 mg (FR).

This leaflet was last approved in 10/2006.

CV 05 0225b P018162



**CRESTOR 5 mg, 10 mg, 20 mg and 40 mg tablets (rosuvastatin)**

Read all of this leaflet carefully before you start taking CRESTOR

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- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
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There are different types of cholesterol found in the blood – 'bad' cholesterol (LDL-C) and 'good' cholesterol (HDL-C). CRESTOR can reduce the 'bad' cholesterol and increase the 'good' cholesterol.

You have been prescribed CRESTOR because you have a high cholesterol level. This means you are at risk from a heart attack or stroke.

You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels.

CRESTOR works by helping to block your body's production of 'bad' cholesterol and improves your body's ability to remove it from your blood.

**Why is it important to keep taking CRESTOR?**  
You need to keep taking CRESTOR, even if it has got your cholesterol to the right level, because it prevents your cholesterol levels from creeping up again. However, you should stop if your doctor tells you to do so, or you have become pregnant.

You should continue with your cholesterol-lowering diet and exercise while you are taking CRESTOR. For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. If you correct your cholesterol levels, you can reduce your risk of having a heart attack or stroke.

**2) BEFORE YOU TAKE CRESTOR**

**Do not take CRESTOR:**

- if you have ever had an allergic reaction to CRESTOR, or to any of its ingredients.
- if you are pregnant or breast-feeding. If you become pregnant while taking CRESTOR stop taking it immediately and tell your doctor.
- Women should avoid becoming pregnant while taking CRESTOR by using suitable contraception.
- if you have liver disease.
- if you have severe kidney problems.
- if you have repeated or unexplained muscle aches or pains.
- if you take a drug called clopidogrel (used, for example, after organ transplants)

If any of the above applies to you, please go back and see your doctor.

In addition, do not take CRESTOR 40 mg (the highest dose):

- if you have moderate kidney problems (if in doubt, please ask your doctor).
- if your thyroid gland is not working properly.
- if you have had any repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- if you regularly drink large amounts of alcohol.
- if you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).

- if you take other medicines called fibrates to lower your cholesterol.
- If any of the above applies to you (or you are in doubt),

**Take special care with CRESTOR:**

- if you have problems with your kidneys.
- if you have problems with your liver.
- if you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- if you regularly drink large amounts of alcohol.
- if your thyroid gland is not working properly.
- if you take other medicines called fibrates to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- if the patient is a child: CRESTOR should not be given to children
- if you are over 70 (as your doctor needs to choose the right start dose of CRESTOR to suit you)
- if you are of Asian origin – that is, Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of CRESTOR to suit you.

If any of the above applies to you (or if you are not sure):

- Do not take CRESTOR 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of CRESTOR.

**Warning: liver damage**  
CRESTOR can cause liver damage. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will usually carry out this blood test (liver function test) before and during treatment with CRESTOR.

**Taking other medicines**

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

Tell your doctor if you are taking any of the following: clopidogrel (used for example, after organ transplants), warfarin (for any other drug used for thinning the blood), fibrates (such as gemfibrozil, fenofibrate) or any other medicines used to lower cholesterol (such as ezetimibe), indigestion remedies (used to neutralise acid in your stomach), erythromycin (an antibiotic) or oral contraceptive (the pill) or hormone replacement therapy. The effects of these medicines could be changed by CRESTOR or they could change the effects of CRESTOR.

**Taking CRESTOR with food and drink**

You can take CRESTOR with or without food.

**Pregnancy and breast-feeding**

Do not take CRESTOR if you are pregnant or breast-feeding. If you become pregnant while taking CRESTOR stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking CRESTOR by using suitable contraception.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Most people can drive a car and operate machinery while using CRESTOR – it will not affect their ability. However, some people feel dizzy during treatment with CRESTOR. If you feel dizzy, consult your doctor before attempting to drive or use machines.

**Important information about some of the ingredients of CRESTOR**

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking CRESTOR.

For a full list of ingredients please see Further information below.

**3) HOW TO TAKE CRESTOR**

Always take CRESTOR as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Starting dose**

Your treatment with CRESTOR must start with the 5 mg or the 10 mg dose, even if you have taken a higher dose of a different statin before. The choice of your start dose will depend upon:

- Your cholesterol level.
- The level of risk you have of experiencing a heart attack or stroke.

- Whether you have a factor that may make you more sensitive to possible side effects.
- Please check with your doctor or pharmacist which start dose of CRESTOR will best suit you.
- Your doctor may decide to give you the lowest dose (5 mg) if:
- You are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
  - You are over 70 years of age.
  - You have moderate kidney problems.
  - You are at risk of muscle aches and pains (myopathy).

**Increasing the dose and maximum daily dose**  
Your doctor may decide to increase your dose. This is so that you are taking the amount of CRESTOR that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of CRESTOR is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

**Taking your tablets**

Swallow each tablet whole with a drink of water. Take CRESTOR once daily. You can take it at any time of the day.

Try to take your tablet at the same time every day to help you to remember it.

**Regular cholesterol checks**

It is important to go back to your doctor for regular cholesterol checks to make sure your cholesterol has reached and is staying at the correct level. Your doctor may decide to increase your dose so that you are taking the amount of CRESTOR that is right for you.

If you take more CRESTOR than you should Contact your doctor or nearest hospital for advice.

If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking CRESTOR.

**If you forget to take a dose**

Don't worry. Just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

**If you stop taking CRESTOR**

Talk to your doctor if you want to stop taking CRESTOR. Your cholesterol levels might increase again if you stop taking CRESTOR.

**4) POSSIBLE SIDE EFFECTS**

Like all medicines, CRESTOR can cause side effects, although not everybody gets them.

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

**Stop taking CRESTOR and seek medical help immediately** if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- Severe itching of the skin (with raised lumps).

**Also, stop taking CRESTOR and talk to your doctor immediately** if you have any unusual aches or pains in your muscles which go on for longer than you might expect. As with other statins, a very small number of people have experienced unexplained muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as rhabdomyolysis.

**Common possible side effects (these may affect between 1 in 10 and 1 in 100 patients):**

- Headache
- Stomach pain
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness

- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your CRESTOR tablets (only CRESTOR 40 mg)

**Uncommon possible side effects (these may affect between 1 in 100 and 1 in 1,000 patients):**

- Rash, itching or other skin reactions
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your CRESTOR tablets (only CRESTOR 5 mg, 10 mg and 20 mg).

**Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):**

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking CRESTOR and seek medical help immediately

- Muscle damage – as a precaution, stop taking CRESTOR and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected
  - A severe stomach pain (inflamed pancreas)
  - Joint pain
  - Increase in liver enzymes in the blood.
- Very rare possible side effects (these may affect less than 1 in 10,000 patients):**
- Jaundice (yellowing of the skin and eyes)
  - Hepatitis (an inflamed liver)
  - Traces of blood in your urine
  - Damage to the nerves of your legs and arms (such as numbness)

If any of the side effects become troublesome, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5) HOW TO STORE CRESTOR**

- Keep out of the reach and sight of children.
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- Tablets should not be thrown in your bin or put down the drain. If they are out of date, or no longer suitable for you, return them to your pharmacist.
- Store your tablets below 30°C.
- If your tablets come in a plastic bottle, keep the lid tightly closed.
- Keep your tablets in the container you received them in.

**6) FURTHER INFORMATION**

**What CRESTOR contains:**

The active substance in CRESTOR is rosuvastatin. CRESTOR film-coated tablets contain rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin. The other ingredients are: lactose monohydrate, microcrystalline cellulose, calcium phosphate, croscopollose, magnesium stearate, hypromellose, glycerol triacetate, titanium dioxide (E171), CRESTOR 10 mg, 20 mg and 40 mg film-coated tablets also contain red iron oxide (E172), CRESTOR 5 mg film-coated tablets also contain yellow iron oxide (E172).

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CRESTOR comes in four tablet strengths:

- CRESTOR 5 mg film-coated tablets are yellow, round and marked with ZD4522 and 5.
- CRESTOR 10 mg film-coated tablets are pink, round and marked with ZD4822 and 10.
- CRESTOR 20 mg film-coated tablets are pink, round and marked with ZD4522 and 20.
- CRESTOR 40 mg film-coated tablets are pink, oval and marked with ZD4522 and 40.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisations for CRESTOR are held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.

Manufacturers responsible for batch release: AstraZeneca UK Ltd, Macclesfield, Cheshire, UK

Telephone: +44 1625 582628  
AstraZeneca GmbH, Plattenstraße, Germany  
Telephone: +49 6202 9300

AstraZeneca GmbH, Wedel, Germany  
Telephone: +49 41 037 080

AstraZeneca Reims, France  
Telephone: +33 3286 18688

NV AstraZeneca SA, Destelbergen, Belgium  
Telephone: +32 935 94211

AstraZeneca Farmacubética Spain SA, Porriño, Spain  
Telephone: +34 988 345 200

AstraZeneca AB, Södertälje, Sweden  
Telephone: +46 8 553 280 00

This product is authorised in the Member States of the EEA under the following name(s):

CRESTOR 5 mg, 10 mg, 20 mg and 40 mg (NL, AT, BE, DK, GR, FI, IC, IE, IT, LU, PT, SE, UK), and 5 mg, 10 mg and 20 mg (FR).

This leaflet was last approved in 10/2006.



### Take special care with CRESTOR:

- **If you have problems with your kidneys.**
- **If you have problems with your liver.**
- **If you have had repeated or unexplained muscle aches or pains**, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- **If you regularly drink large amounts of alcohol.**
- **If your thyroid gland** is not working properly.
- **If you take other medicines called fibrates** to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- **If the patient is a child:** CRESTOR should not be given to children
- **If you are over 70** (as your doctor needs to choose the right start dose of CRESTOR to suit you)
- **If you are of Asian origin** – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of CRESTOR to suit you.

If any of the above applies to you (or if you are not sure):

- **Do not take CRESTOR 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of CRESTOR.**

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# Example 3: children and medicines

**DIDEM** 2/2/04

- ~~JURIFEN (si d'adulte)~~
- ~~LYMPHOMYOSOT~~  
3x5 gtt<sub>s</sub> ⇒ 2 mois
- ~~NASONEX~~  
1x ⇒ 1 mois
- ~~LYSOX~~  
2x3 ml ⇒ 3 j.
- ~~FLUIMUCIL~~  
1 gtt<sub>e</sub> x 3/j ⇒ 3 j.

**IREM** 2/2/04

- ~~NASONEX~~  
1x ⇒ 1 mois
- ~~ZYRTEC~~  
2x4 ml ⇒ 1 sem.
- ~~VENTOLIN~~  
3x5 ml ⇒ 3 j.
- ~~LYSOX~~  
1x3 ml ⇒ 3 j.
- ~~CUPE homioopathique~~  
1x j. à jeun 1 art<sub>l</sub> d'après
- ~~eczéma~~ PROTOLIC (2x) ?

## Dilut° Adrenaline

$\leq 10 \text{ kg}$

0,1 ml Adr. + 9,9 ml s $\psi$

→ 1 ml dil = 0,1 mg Adr

$\geq 10 \text{ kg}$

1 ml Adr + 9 ml s $\psi$

→ 10 ml dil = 1 mg Adr

→ 1 ml dil = 0,1 mg Adr

Dosage : 0,01 mg / kg  
= 9,1 ml / kg  
(dil)

Clinique du Parc Léopold

mg de 20.00 à 20.10 avant et avec rendez-vous

les internes : Coller ici une vignette d'identification  
ambulants : Coller ici une vignette muette

USE

SÉROLOGIE BACTÉRIENNE  
premier 0

ADU  
200  
2004

Antibiogramme  
Méthode de L. pour 1000  
1000

ALLERGIE

(voir 2 pages)

Phar

Dans le

## Example 5: pictogram



## Example 5: pictogram



### What does single-use mean?

**Do not reuse.** A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

## Five issues:

1. Visual elements are poorly designed
2. Information is not structured 'for use'
3. Information is not convincing
4. Information does not identify the origin
5. The information is not seen as a dialogue

# Is this a problem?

Compliance: 50% or less?

Errors: 1 casualty per million per day

Costs: + 7% per year

Increased use: more elderly & elder elderly

+ increased anxiety, confidence reduction

1 Examples: what is the problem?

**2 What are the causes?**

3 What's stopping us?

4 Why is that difficult?

5 What's next?

2






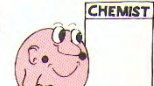
# United Kingdom: 1988-1990

## What you should know about Anti-Inflammatory Analgesics.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is \_\_\_\_\_  
This is one in a group of medicines called Anti-Inflammatory Analgesics. These can relieve pain such as headache, toothache, arthritis and period pain. They can also reduce fever.

### Things to remember about Anti-Inflammatory Analgesics.

- 1 Make sure it is safe for you** to take Anti-Inflammatory Analgesics *(see the back of this leaflet)*. ♦
- 2 Look at the label** on your tablets. It will tell you when to take them. 
- 3 Anti-Inflammatory Analgesics sometimes cause problems** You can find these listed on the back of this leaflet. \* 
- 4 Keep your tablets out of reach of children.** 
- 5 Remember to return any unused tablets** to the pharmacist or flush them down the toilet. 

You will find more about Anti-Inflammatory Analgesics on the back of this leaflet.



# European legislation: EC 2004/27/EC

L 136/34

EN

Official Journal of the European Union

30.4.2004

## DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE  
EUROPEAN UNION,

Having regard to the Treaty establishing the European  
Community, and in particular Article 95 thereof,

- (4) The main purpose of any regulation on the manufacture and distribution of medicinal products for human use should be to safeguard public health. However, this objective should be achieved by means which do not hinder the development of the pharmaceutical industry or trade in medicinal products in the Community.

## **EU-legislation:** EC 2004/27/EC article 65

‘2. The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official language or languages of the Member State in which the medicinal product is placed on the market.

# Readability guideline (2009)

## GENERAL CONSIDERATIONS

The package leaflet is intended for the patient/user. If the package leaflet is well designed and clearly worded, this maximises the number of people who can use the information, including older children and adolescents, those with poor literacy skills and those with some degree of sight loss. Companies are encouraged to seek advice from specialists in information design when devising their house style for the package leaflet to ensure that the design facilitates navigation and access to information.

## 2. DESIGN AND LAYOUT OF THE INFORMATION

The use of “justified” text (that is text aligned to both left hand and right hand margins) should in principle not be used.

Line spaces should be kept clear. The space between lines is an important factor influencing the clarity of the text. As a general rule the space between one line and the next should be at least 1.5 times the space between words on a line, where practical.

Contrast between the text and the background is important. Factors like paper weight, colour of the paper, size and weight of the type, colour of the type and the paper itself should be considered. Too little contrast between the text and the background adversely affects the accessibility of the information. Therefore, background images should in principle not be placed behind the text since they may interfere with the clarity of the information making it harder to read.

A column format for the text can help the reader navigate the information. The margin between the columns should be large enough to adequately separate the text. If space is limited a vertical line to separate the text may be used. Related information should be kept together so the text flows easily from one column to the next. Consideration should be given to using a landscape layout which can be helpful to patients. Where a multi-lingual leaflet is proposed there should be a clear demarcation between the different languages used; all the information provided in each language should be assembled.

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## Current situation:

- Aimed at pharmaceutical industry
- Focused on package insert only
- Poor legal guidance and poor support
- Poor knowledge about design process
- ‘People/users’ are rarely involved



1 Examples: what is the problem?

2 What are the causes?

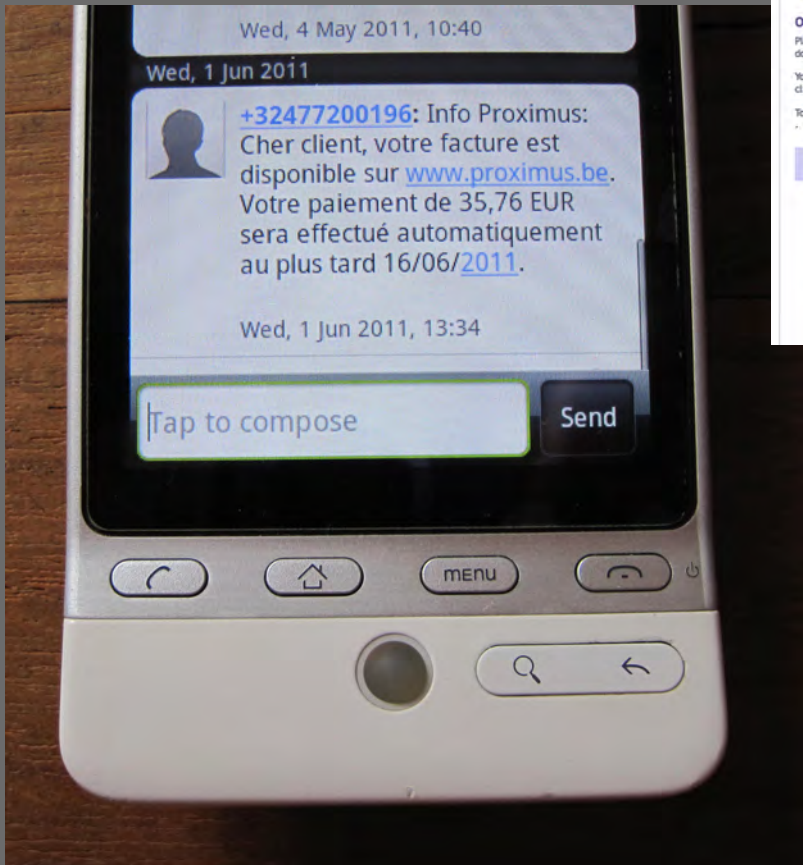
**3 What's stopping us?**

4 Why is that difficult?

5 What's next?

3

# Example 1: phone bill



Proximus Private

Private Self-employed and SMEs Large enterprises

Telephony Internet Mobiles and PCs Promotions Customer zone Help

Home > Customer zone > My e-Services > Access to e-Services

In short: Enter MyProximus/ MyPay&Go

### My bill online

Welcome to your bills on MyProximus.

#### Online Copies of your Invoices

Please find below the online copies of your invoices. They cannot be used for tax purposes. The original paper invoices remain the legal documents.

You can download and save the online copies on your computer in the PDF format. You can also consult your invoice details in HTML format by clicking on the links in the column "Period".

To be able to read PDF files, you must have Acrobat Reader on your computer. You can download this program for free from the [Adobe website](#).

Period	Document number	Total amount to pay (VAT incl.)	Download
28-04-2011 - 27-05-2011	112700933412	€ 35,76	
28-03-2011 - 27-04-2011	112700633905	€ 25,82	
28-02-2011 - 27-03-2011	112700498909	€ 23,24	
28-01-2011 - 27-02-2011	112700310280	€ 21,36	
28-12-2010 - 27-01-2011	112700049303	€ 46,50	
28-11-2010 - 27-12-2010			

Access to e-Services

You are currently connected to MyProximus/MyPay&Go. [Logout](#)

Contact

- > Customer service
- > Points of sale

Download your Flash

Your Belgacom bills via internet

www.belgacom.be

belgacom

Meer informatie?  
www.belgacom.be/factuur  
Of zie keerzijde

Klanten nr. 187081286  
Overeenkomst 1

Factuur 6110670714  
Pagina 1

Dhr Van der Waerde Karel  
Solariumlaan, 15  
1982 Eleewijt

Uw factuur van 11 januari 2011

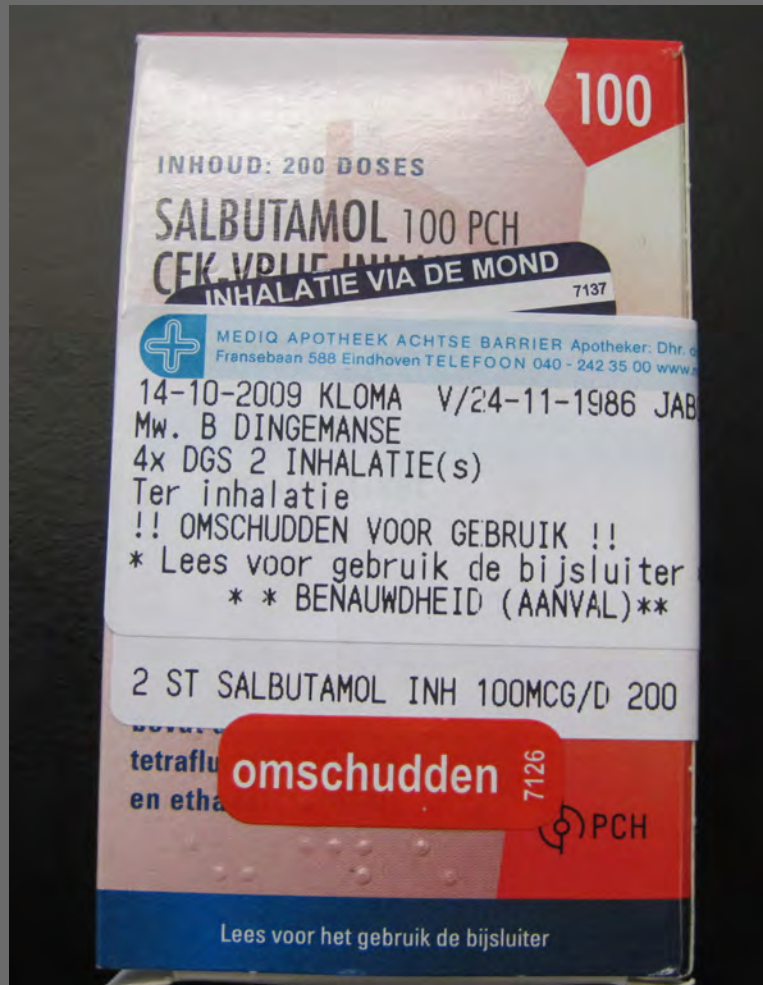
	*bedrag incl. btw
Abonnementen	81,73
Totaal bedrag van de factuur	81,74
<b>Totaal te betalen</b>	<b>81,74 €</b>

Uw financiële instelling wordt verzocht om deze som op 27 januari 2011 te storten op onze bankrekening BE50 0001 7100 3118 met BIC BPOTBEB1. Met mededeling ++611/0670/71429+++ Bedankt.

Indexatie op 01/01/2011

In overeenstemming met de bepalingen in de algemene voorwaarden zullen onze tarieven voor vaste telefonie en internet worden aangepast aan de evolutie van de index der consumptieprijs. Meer details i.v.m. de tarieven op [www.belgacom.be/tarieven](#). Algemene voorwaarden vaste telefonie: artikel 5b. Algemene voorwaarden internet: artikel 5 a. 12.

# Example 2: Packaging Asthma inhaler



## EU-legislation: EC 2004/27/EC article 65

'2. The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official language or languages of the Member State in which the medicinal product is placed on the market.

# What's stopping us?

1. Patients expect improvements
2. Designers are capable of making improvements
3. Legislation allows improvements
4. Industry wants to make improvements
5. Technology is available (track&trace, xml, ...)

1 Examples: what is the problem?

2 What are the causes?

3 What's stopping us?

**4 Why is that difficult?**

5 What's next?

**4**

# Three different approaches

## 1. Legal framework

European Union,

Guidelines and templates,

European Medicines Agency

# Three different approaches

## 1. Legal framework

European Union,

Guidelines and templates,

European Medicines Agency

## 2. Economic framework

Pharmaceutical industry

Insurance, healthcare



# Three different approaches

## 1. Legal framework

European Union,

Guidelines and templates,

European Medicines Agency

## 2. Economic framework

Pharmaceutical industry

Insurance, healthcare

## 3. Health

Patients, doctors, pharmacists

# Three different approaches

1. Legal criteria

2. Financial criteria

3. Health criteria

## Legislation (2010/84/EU)

‘4. By 1 January 2013, the Commission shall present to the European Parliament and the Council an assessment report on current shortcomings in the summary of product characteristics and the package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals. The Commission shall, if appropriate, and on the basis of the report, and consultation with appropriate stakeholders, present proposals in order to improve the readability, layout and content of these documents.’

1 Examples: what is the problem?

2 What are the causes?

3 What can we do?

4 What's stopping us?

**5 What's next?**

5

## EU-legislation: EC 2004/27/EC article 65

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**enabling<sup>4</sup>**

**users<sup>1</sup>**

**to act<sup>2</sup>**

**appropriately<sup>3</sup>**

# <sup>1</sup> **'users' = every person involved**

- pharmacist
- hospital pharmacist
- nurse
- doctor
- specialist doctor
- manufacturer
- wholesaler
- patient
- carer
- packaging-experts
- regulator
- national authority
- EU-authority
- lawyer

## <sup>2</sup> **'to act' = every action**

- check
- compare
- warn
- instruct
- swallow
- dilute
- read
- inject
- dispense
- store
- select
- consider
- question
- advise



### **3 'appropriately' = decide on criteria**

- check (70% of patients should check precautions?)
- compare (80% of nurses must compare names?)
- warn (100% of chemists must warn for otc-products?)
- instruct (50% of pharmacists must instruct patches?)
- swallow (90% of patients must swallow tablets?)
- dilute (100% of pharmacists must be able to dilute?)
- read (75% of patients must be able to read a pack?)

## 4 **'enabling' = empower, facilitate**

- by design (tactile, shape, colour, ...)
- through systems (support, help, ...)
- by training (exercise and feedback, ...)
- through a process (check at every step, ...)
- providing information (suitable arguments, ...)
- ...

# **‘enabling users to act appropriately’**

1. Make a list of ‘users’
2. Make a list of ‘actions’ for each user
3. Set performance based standards  
(Benchmark now and set future aims.)
4. Design things that ‘enable’ users

## Concluding part 5

In order to ‘*enable users to act appropriately*’:

- we must start from the *actions of users*,
- find out how we can *enable* these actions,
- and determine for each action what *appropriate* is.

## Concluding part 4

Consider different approaches simultaneously:

- *health*: do no harm
- *legal*: information must be regulated
- *financial*: information must consider costs

# Concluding part 3

There are no excuses:

- Patients expect better information
- Industry wants to develop information
- Legislation allows better information
- Technology is available

## Concluding part 2

- Involve all producers of information
- Look at all information in a specific situation
- Provide usable guidance
- Base guidance on design processes
- Involve people/users

# Concluding part 1

Communication approaches:

**Logic** : provide a clear structure

**Rhetoric** : provide convincing motivations

**Dialectic** : include people in dialogues



**Thank you**

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waarde@glo.be