

Nonprescription Simvastatin in the United Kingdom

Michael L. Koenig, Ph.D.
Interdisciplinary Scientist
Division of Over-the-Counter Drug Products



Center for Drug Evaluation and Research

Overview

1. Classification of medicines in UK
2. Reclassification (“switch”)
3. Issues considered in switch of simvastatin



Classification of Medicines in UK: Prescription

Prescription Only Medicines (POM)

- Safety concerns
 - Requires doctor's supervision
 - Contains substance(s) requiring investigation
 - Requires injection
- All new medicines

Classification of Medicines in UK: Nonprescription

Pharmacy (P)

- Pharmacies (only)
- Under pharmacist/staff supervision
- US: “Behind-the-counter”
- Simvastatin

General Sales List (GSL)

- Pharmacy shelves, supermarkets
- Analgesics, cough-cold medications
- US: “Over-the-counter”

Overview

1. Classification of medicines in UK
2. Reclassification (“switch”)
3. Issues considered in switch of simvastatin

Application to Reclassify Medicines: POM to P

- Safety profile
 - Reports of adverse reactions
 - Post-marketing surveillance studies
 - Published literature
 - Safety reviews
- Patient information (proposed labeling)
- Training and education of pharmacists & staff
- Evaluation by clinical expert (sponsor)

Reclassification Process

1. Submission of application to Medicines & Healthcare Products Regulatory Agency (MHRA)
2. Application Review
 - May include Committee on Safety of Medicines (CSM)
3. Consultation letter
4. Review of responses
5. MHRA action

Zocor Heart-Pro®

Each Zocor Heart-Pro® film-coated tablet contains 10 mg simvastatin.

Simvastatin belongs to a group of medicines known as statins which significantly reduce the amount of cholesterol in your blood. Too much cholesterol in your blood builds up in the walls of the arteries and causes plaques to form. This can lead to a narrowing of the coronary arteries, just like hard water furs up a water pipe. Heart attacks can then happen when a blood clot forms in a narrowed coronary

ketoconazole, HIV protease inhibitors, erythromycin, clarithromycin, telithromycin or nefazodone or if you are already taking a prescription cholesterol lowering medicine.

Please read the enclosed patient information leaflet for important safety information.

Do not store the tablets above 30°C. Keep them out of the reach and sight of children.

Zocor Heart-Pro® is for people who have a moderate risk of coronary heart disease (heart disease due to build up of plaques in the coronary arteries).

Your Pharmacist can advise you further and help you to identify your risk level.

Swallow one tablet every evening. Do not take more than one tablet each day.

Do not take Zocor Heart-Pro® if: you know that you have liver disease, or you know that you have abnormal liver function blood tests; you could become, are pregnant or breast-feeding; you are allergic to any of the ingredients; you have had muscle problems after taking a cholesterol lowering medicine in the past; you are taking itraconazole,




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Merck background package, p. 343


Questionnaire



HEART HEALTH



ZOCOR HEART-PRO® QUESTIONNAIRE



Contains atorvastatin

Please answer all the questions below by ticking the boxes that apply to you.
If you are not sure about any of the questions, leave them blank and the pharmacist will help you. Date:

1 | ABOUT YOU...

Are you:

- Male and aged 45 to 54? Male and aged 55 to 70?
- Female and aged 55 to 70?
- If you are female, have you reached the menopause? Yes No

If none of these applies to you, talk to the pharmacist before going further.

Do any of the following risk factors apply to you?

- Current smoker, or a smoker within the last five years Yes No
- A family history of early heart disease:
 - your father or brother had a heart attack or angina before the age of 55
 - your mother or sister had a heart attack or angina before the age of 65

Angina is heart pain in the chest brought on by exercise or exertion.

- Overweight Yes No

Your pharmacist can help with this if you know your height, weight and waist measurement.

Height ft or inches Weight stonekg Waist inches

- Family origin from South Asia* Yes No

(for example, India, Pakistan, Bangladesh or Sri Lanka)
*Being of South Asian origin means your risk of heart disease is higher.

2 | ABOUT YOUR MEDICAL HISTORY...

Has your doctor told you that you have or have had any of the following?

- Diabetes Yes No
- Heart problems (for example, heart attack or anginal, a stroke or peripheral vascular disease (for example, poor blood flow to the legs with pain on walking)) Yes No

Why not join the Healthy Heart Programme today?

The Healthy Heart Programme is a free service from Johnson & Johnson MSD. Register today at www.heartpro.co.uk and you'll find it's full of informative, encouraging and helpful features:

- Lifestyle advice on exercise and diet
- Your personalised heart health profile
- Special offers and discounts on heart-related products and services
- The ability to receive your confidential Heart-Pro™ Cholesterol Test results online

To register, simply go online to www.heartpro.co.uk

Alternatively, to receive free information and offers by post from the Healthy Heart Programme on improving your heart health, complete and return the top copy of this form to: HEALTHY HEART PROGRAMME, FREEPOST, LOUDWATER, HIGH WYCOMBE, HP10 0BR

I give explicit consent for Johnson & Johnson MSD to contact me in the future about the Healthy Heart Programme and heart-related products. Yes No


Tel: (Mr, Mrs, Ms, Miss) First name: Last name:

Address and postcode:

Email:

Name and town of pharmacy:

I give explicit consent for this pharmacist to keep the bottom copy of this form to contact me in the future with information about Heart-Pro™ products. Yes No



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Merck background package, p. 348

Patient Information Leaflet

Zocor Heart-Pro® 10mg tablets (simvastatin)

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR TABLETS. KEEP IT IN CASE YOU WANT TO READ IT AGAIN.

WHAT IS ZOCOR HEART-PRO®?

Each film-coated tablet contains 10mg simvastatin as the active ingredient.

The tablets also contain ascorbic acid (E300), butylated hydroxyanisole (E320), citric acid monohydrate (E330), lactose, magnesium stearate (E372), microcrystalline cellulose (E460), pregelatinized maize starch, hydroxypropylcellulose (E463), methylhydroxypropylcellulose (E464), tsc (E533b), titanium dioxide (E171), red iron oxide (E172) and yellow iron oxide (E172). Zocor Heart-Pro® tablets come in calendar packs containing 28 film-coated tablets.

The marketing authorisation holder is: Johnson & Johnson MSD Consumer Pharmaceuticals, Enterprise House, Station Road, Loughwater, High Wycombe, Buckinghamshire HP12 3JF.

Product Licence Number: PL 12349.0039

Manufacturer: Merck Manufacturing Division, Merck Sharp and Dohme Limited, Northumbria Road NE23 3JL, UK.

WHAT IS ZOCOR HEART-PRO® FOR?

Zocor Heart-Pro® tablets can reduce the risk of heart attack in people who have a moderate risk of coronary heart disease (heart disease because of build up of plaques in the coronary arteries). Moderate risk means your chances of having a heart attack in the next 10 years are at least 1 in 10.

The active ingredient in Zocor Heart-Pro®, simvastatin, belongs to a group of medicines known as statins. These significantly reduce the amount of cholesterol in your blood. Zocor Heart-Pro® reduces the level of LDL, 'bad' cholesterol and fatty substances called lipoproteins in your blood and raises HDL, 'good' cholesterol. LDL cholesterol is called "bad" cholesterol because it is the cholesterol that clogs your coronary arteries. HDL is called "good" cholesterol because it helps to protect against heart disease. Too much cholesterol in your blood builds up in the walls of the coronary arteries causing plaques to form. This leads to a narrowing of the coronary arteries, just like hair water runs up a water pipe. Heart attacks can then happen when a blood clot forms in a narrowed coronary artery.

Taking these tablets can significantly reduce cholesterol levels and help to reduce build-up of artery-narrowing plaques. In order to benefit from treatment, these tablets should be taken regularly on a long-term basis. The risk of heart attacks increases as you age because of the build up of plaques. Reducing this risk with these tablets and changes to your lifestyle needs to be a lifelong effort.

Zocor Heart-Pro® reduces the levels of 'bad' cholesterol in the blood by around 27%. Studies show that reducing cholesterol by this much can reduce the risk of a heart attack by about one third after 3 years of treatment.

You are likely to be at moderate risk if you are a man aged 55 or over. You are also likely to be at moderate risk if you are a man aged between 45 and 54 or a woman aged 55 or over and you answer yes to one or more of the questions below:

- Do you have a parent, brother or sister who suffered a heart attack younger than 55 for men or 65 for women?
- Do you smoke or have you smoked within the past 5 years?
- Are you overweight? This means you have a body mass index over 25 (your weight in kilos divided by your height in metres squared), or your waist is greater than 40 inches or 102 cm (for men), or 35 inches or 88 cm (for women). Your pharmacist can help you answer this question.
- Are you of South Asian origin (i.e. from the Indian subcontinent that includes India, Bangladesh, Pakistan or Sri Lanka)?

If, in addition, you take no physical exercise other than normal daily activities, your risk of a heart attack is further increased.

WHAT ELSE CAN I DO TO REDUCE MY RISK OF A HEART ATTACK?

At the same time as taking Zocor Heart-Pro® tablets, try to reduce your risk of coronary heart disease by doing the following:

- **Stop smoking** - there is strong evidence to link cigarette smoking with heart disease. The risks increase with the number of cigarettes you smoke each day, but risks still exist even if you smoke as little as five a day. It is better to stop smoking altogether rather than just cut down on how much you smoke. Your pharmacist can advise you on a suitable programme to help you stop smoking.
- **Eat a healthy diet** - a healthy diet will not only help towards preventing coronary heart disease, but has also been shown to reduce the risk of stroke and a number of cancers. Try to increase the amount of fruit and vegetables in your diet and reduce the amount of sugar, salt and fat.
- **Loss weight** - being overweight can cause a rise in your blood pressure, increase your risk of developing diabetes and increase the risk of developing heart disease due to high cholesterol levels. Change your diet as described previously and be more exercise.
- **Exercise** - a brisk walk to the shops can help. Swimming is a good all-round exercise that you could consider doing, as it is something you can gradually build up without overdoing it to start with. You could try doing the following to your daily routine: vigorous housework, walk upstairs more often (and don't take the lift or escalator when you are out), and gardening.

Your pharmacist can provide details of a Healthy Heart Programme to help you.

For more information e-mail zocor@jnjmed.co.uk.

IS ZOCOR HEART-PRO® RIGHT FOR ME?

Do not take these tablets if you:

- know you have liver disease or you have been told you have abnormal liver function blood tests;
- drink more than 2 units of alcohol a day for men and 2 units of alcohol a day for women (one unit is 1/2 pint of beer, a pub measure of wine or one spirit);
- have had an allergic reaction to this or similar medicines or to any of the ingredients in the pack;
- are already taking prescription drugs to lower your cholesterol;
- could become pregnant, are pregnant, are planning to become pregnant, or are breast feeding;
- discover you are pregnant while taking Zocor Heart-Pro®. In this case you should stop taking these tablets immediately and contact your doctor;
- have had muscle problems in the past after taking a cholesterol lowering medicine;
- are taking one of the following medicines:
 - oral anti-fungal medicines called itraconazole or terbinafine;
 - antibiotics called erythromycin, telithromycin or clarithromycin;
 - medicines for HIV infections called protease inhibitors (such as zidovudine, didanosine, zalcitabine or zalcitabine);
 - the antidepressant nefazodone.

If you have an under active thyroid gland (hypothyroidism), kidney problems, a family history of muscle disorders or are aged over 70, you should check with your doctor before taking this product.

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Zocor Heart-Pro® should not be used by children.

If you are in one of the groups below, you are at a higher risk of coronary heart disease. You should discuss your condition with your doctor since you are likely to need more than these tablets to reduce your risk.

- "You already have angina or you have had a heart attack."
- "You have diabetes and/or you have had a stroke."
- "You have had a stroke."
- "You have disease of the arteries of your legs or neck."
- "You have rheumatoid arthritis in the family, very high blood cholesterol levels."

If you would like to receive further advice and information on a healthy lifestyle and reducing your risk of a heart attack, register onto the Healthy Heart Programme website.



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If you think any of these apply to you or you are unsure that you have one of these conditions, go and talk to your pharmacist or doctor first.

If your doctor has told you that you have high blood pressure, check with your doctor before taking Zocor Heart-Pro®.

You have your cholesterol levels checked and you find that you have a fasting LDL-cholesterol measurement greater than 5.5 mmol/L, you should talk to your doctor because you may need more than Zocor Heart-Pro® to reduce your cholesterol levels.

BEFORE YOU TAKE ZOCOR HEART-PRO®

If you are taking any other medicines, speak to your pharmacist before taking Zocor Heart-Pro®.

DRIVING AND ZOCOR HEART-PRO®

This product can cause dizziness. If affected, do not drive or operate machinery.

WHILE YOU ARE TAKING ZOCOR HEART-PRO®

Very rarely, these tablets can affect the muscles. If this problem develops, it can be serious especially if you continue to take the drug. Stop taking your tablets immediately and check with your doctor if you develop generalised muscle pain, tenderness or weakness, unless it is clearly the result of flu, unaccustomed exercise, or recent strain or injury.

The chance of your muscles being affected is greater if you drink a lot of grapefruit juice, (see below) or if you have kidney problems or are taking certain medicines.

In addition to the medicines listed in the section "If Zocor Heart-Pro® is right for me?" this medicine can react with the following drugs to cause muscle problems:

- Clozapine (an immunosuppressant medicine);
- Prescription cholesterol-lowering medicines such as bezafibrate, gemfibrozil and high doses of niacin or nicotinic acid (more than 1000mg/day).

If you go into hospital for major surgery, tell your doctor you are taking Zocor Heart-Pro® as you will need to stop taking it a few days beforehand.

If your skin or whites of your eyes turn yellow or your urine appears very dark in colour, this may mean that you have a liver problem. So, stop taking your tablets and see your doctor.

WHAT ELSE DO I NEED TO KNOW?

Grapefruit juice contains one or more substances that alter the metabolism of some medications, such as Zocor Heart-Pro®. Do not drink very large quantities (more than 1 litre a day). However, just drinking one 250 ml glass a day is unlikely to cause problems.

DEES ZOCOR HEART-PRO® REACT WITH OTHER MEDICINES?

In addition to the medicines listed in the section "While you are taking Zocor Heart-Pro®", other medicines may cause problems when you take them with these tablets.

These are:

- medicines for thinning the blood, such as warfarin;
- high doses of niacin or nicotinic acid (more than 1000 mg a day) for poor blood flow to the hands or feet.

If you are taking any prescription medicine, your pharmacist may advise you to check with your doctor before taking Zocor Heart-Pro®. If your doctor prescribes a new medicine for you while you are taking this product (for example, if you develop an infection and your doctor decides to give you a course of antibiotics), you should mention that you are taking Zocor Heart-Pro®.

WHAT IS THE DOSE OF ZOCOR HEART-PRO®?

Take one tablet every evening. Swallow the tablet with a drink of water. The evening is the best time because it means that your medicine will be working when your body is producing the most cholesterol. Zocor Heart-Pro® should be taken regularly and on a long-term basis in order to gain the full benefits of treatment. Never take more than one tablet each day.

If you forget a dose, just take one dose the next evening you remember. Do not take an extra one to make up.

If you take too many tablets by mistake, contact your doctor or pharmacist.

If you would like to receive other advice and information on a healthy lifestyle and reducing your risk of a heart attack, register onto the Healthy Heart Programme.

Please give your exact address for us to contact you by filling in the form. We will use the details for just 1 year to send you information and the Healthy Heart Programme website. We will give you permission to contact you.



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CHECKING YOUR CHOLESTEROL

If you have a moderate risk of heart disease, reducing the level of cholesterol in your blood will reduce your risk. Your pharmacist can arrange to check your cholesterol level, but it is not necessary to know this before you start Zocor Heart-Pro®. Checking your cholesterol can provide additional information and can be helpful to show your progress while taking Zocor Heart-Pro®. If your fasting LDL-cholesterol measurement is above 5.5 mmol/L, speak to your doctor.

WHAT ABOUT SIDE EFFECTS?

Like all medicines, Zocor Heart-Pro® may occasionally cause side effects in some people. The most common side effects are stomach upsets (such as sickness, stomach pain, constipation, diarrhoea, and flatulence (wind)), rash, dizziness, weakness, headache or indigestion. The following have also occurred: hair loss, dizziness, abdominal pain, tingling and numbness, abnormal blood test results for liver and muscle function.

Rarely, a few patients have experienced the following: liver disease (e.g., yellowing of the skin or the whites of your eyes, dark coloured urine, muscle disease (aches and pains) which can be severe (see "While you are taking Zocor Heart-Pro®" section), or an allergic reaction. The allergic reaction may include swelling of the face or neck, muscle and joint pains, joint and blood vessel inflammation, itchy, runny nose, (hives, rashes, rash), a high temperature, flushing, difficulty in breathing, or tiredness.

If any of these happen to you, or you have any other unusual symptoms or feelings, stop taking the tablets and contact your doctor or pharmacist immediately.

HOW SHOULD I STORE THE TABLETS?

Do not store your tablets above 30°C. Keep them out of the sight and reach of children. Do not put them in another container as they might get mixed up. Do not take them after the expiry date on the blister and carton.

REMEMBER this medicine is for you. Do not share it with anyone else. It may not suit them.

Date the leaflet was prepared: May 2004.

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If you would like to receive other advice and information on a healthy lifestyle and reducing your risk of a heart attack, register onto the Healthy Heart Programme.

Please give your exact address for us to contact you by filling in the form. We will use the details for just 1 year to send you information and the Healthy Heart Programme website. We will give you permission to contact you.



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Joint NDAC/EMDAC Meeting
January 13, 2005

pp. 344,
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Overview

1. Classification of medicines in UK
2. Reclassification (“switch”)
3. Issues considered in switch of simvastatin

Public Consultation Letter: Issues Considered by MHRA

- Potential for myopathy/rhabdomyolysis
- Potential for liver toxicity
- Possible use by pregnant women
- Consumers' ability to self-diagnose
- Consumer knowledge of LDL-C levels
- Adequacy of pharmacy staff training

MHRA: Potential for Myopathy/Rhabdomyolysis

- Sufficiently rare
- Adequate warning

Do not take these tablets if you:

- know you have liver disease or you have been told you have abnormal liver function blood tests;
- drink more than 4 units of alcohol a day for men and 3 units of alcohol a day for women (one unit is 1/2 pint of lager, 100ml measure of wine or one short);
- have had an allergic reaction to this or similar medicine or to any of the ingredients in the past;
- are already taking prescription drugs to lower your cholesterol.

Do not take these tablets if you:

- have had muscle problems in the past after taking a cholesterol lowering medicine;

- are taking one of the following medicines:
 - oral antifungal medicines called itraconazole or ketoconazole;
 - antibiotics called erythromycin, telithromycin or clarithromycin;
 - medicines for HIV infections called protease inhibitors (such as indinavir, nelfinavir, ritonavir or saquinavir);
 - the antidepressant nefazodone.

WHILE YOU ARE TAKING ZOCOR HEART-PRO®

Very rarely, these tablets can affect the muscles. If this problem develops, it can be serious especially if you continue to take the drug. Stop taking your tablets immediately and check with your doctor if you develop generalised muscle pain, tenderness or weakness, unless it is clearly the result of flu, unaccustomed exercise, or recent strain or injury.

problems or are taking certain medicines.

In addition to the medicines listed in the section "Is Zocor Heart-Pro® right for me?" this medicine can react with the following medicines to cause muscle problems:

immunosuppressant medicine).
cholesterol-lowering medicines (such as bezafibrate, gemfibrozil and high doses of niacin or nicotinic acid (more than 1000mg/day)).

WHAT ELSE DO I NEED TO KNOW?

Grapefruit juice contains one or more substances that alter the metabolism of some medications, such as Zocor Heart-Pro®. Do not drink very large quantities (more than 1 litre a day). However, just drinking one 250 ml glass a day is unlikely to cause problems.

MHRA: Potential for Liver Toxicity

- Extremely rare
 - routine testing not required
- Adequate warnings

Do not take these tablets if you:

- know you have liver disease or you have been told you have abnormal liver function blood tests;
- drink more than 4 units of alcohol a day for men and 3 units of alcohol a day for women (one unit is 1/2 pint of lager, a pub measure of wine or one short);

- could become pregnant, are pregnant, are planning to become pregnant, or are breast feeding;
- discover you are pregnant while taking Zocor Heart-Pro®. In this case you should stop taking these tablets immediately and contact your doctor;
- have had muscle problems in the past after taking a cholesterol lowering medicine;
- are taking one of the following medicines:
 - oral antifungal medicines called itraconazole or ketoconazole;
 - antibiotics called erythromycin, telithromycin or clarithromycin;
 - medicines for HIV infections called protease inhibitors (such as indinavir, nelfinavir, ritonavir or saquinavir).
 - the antidepressant nefazodone.

♥ WHILE YOU ARE TAKING ZOCOR HEART-PRO®

Very rarely, these tablets can affect the muscles. If this problem develops, it can be serious especially if you continue to take the drug. Stop taking your tablets immediately and check with your doctor if you develop generalised muscle pain, tenderness or weakness, unless it is clearly the result of flu, unaccustomed exercise or recent strain or injury.

The chance of your muscles being affected is greater if you drink grapefruit juice, (see below) or if you have kidney problems or are taking certain medicines.

In addition to the medicines listed in the section "Is Zocor Heart-Pro® right for me?" this medicine can react with the following drugs to cause muscle problems:

- Cyclosporin (an immunosuppressant medicine).
- Prescription cholesterol-lowering medicines (such as bezafibrate, gemfibrozil and high doses of niacin or nicotinic acid (more than 1000mg/day)).

If you go into hospital for major surgery, tell your doctor you are taking Zocor Heart-Pro® as you will need to stop taking it a few days beforehand.

If your skin or whites of your eyes turn yellow or your urine appears very dark in colour, this may mean that you have a liver problem. So, stop taking your tablets and see your doctor.

MHRA:

Possible Use by Pregnant Women

- Not a concern
- Labeled for use by women 55 and over
- Adequate warnings

♥ IS ZOCOR HEART-PRO® RIGHT FOR ME?

Do not take these tablets if you:

- know you have liver disease or you have been told you have abnormal liver function blood tests;
- drink more than 4 units of alcohol a day for men and 3 units of alcohol a day for women (one unit is 1/2 pint of beer, a pub

Do not take these tablets if you:

- could become pregnant, are pregnant, are planning to become pregnant, or are breast feeding;

contact your doctor;

- have had muscle problems in the past after taking a cholesterol lowering medicine;
- are taking one of the following medicines:
 - oral antifungal medicines called itraconazole or ketoconazole.
 - antibiotics called erythromycin, telithromycin or clarithromycin.
 - medicines for HIV infections called protease inhibitors (such as indinavir, nelfinavir, ritonavir or saquinavir).
 - the antidepressant nefazodone.



MHRA: Consumers' Ability to Self-Diagnose

- Pharmacist-assisted identification of (moderate) risk
 - Age
 - Risk factors
- Questionnaire
- Patient Information Leaflet (PIL)

Questionnaire

AGE

RISK FACTORS

1 | ABOUT YOU...

Are you:

- Male and aged 45 to 54? Male and aged 55 to 70?
- Female and aged 55 to 70?
- If you are female, have you reached the menopause? Yes No

If none of these applies to you, talk to the pharmacist before going further.

Do any of the following risk factors apply to you?

- Current smoker, or a smoker within the last five years Yes No
- A family history of early heart disease:
 - your father or brother had a heart attack or angina before the age of 55
 - your mother or sister had a heart attack or angina before the age of 65 Yes No

Angina is heart pain in the chest brought on by exercise or exertion.

- Overweight Yes No

Your pharmacist can help with this if you know your height, weight and waist measurement.

Height ft/in or m/cm Weight stone/kg Waist in/cm

- Family origin from South Asia* Yes No

(for example, India, Pakistan, Bangladesh or Sri Lanka)

*Being of South Asian origin means your risk of heart disease is higher.



Patient Information Leaflet

ZocorHeart-Pro[®]
10mg tablets

If, in addition, you take no physical exercise other than normal daily activities, your risk of a heart attack is further increased.
WHAT ELSE CAN I DO TO REDUCE MY RISK OF A HEART ATTACK?

If you think any of these apply to you or you are unsure that you have one of these conditions, go and talk to your pharmacist or doctor first.
If your doctor has told you that you have high blood pressure.

CHECKING YOUR CHOLESTEROL.
If you have a moderate risk of heart disease, reducing the level of cholesterol in your blood will reduce your risk. Your pharmacist can arrange to check your cholesterol level, but it is not

You are likely to be at moderate risk if you are a man aged 55 or over.

You are also likely to be at moderate risk if you are a man aged between 45 and 54 or a woman aged 55 or over and you answer yes to one or more of the questions below:

- Do you have a parent, brother or sister who suffered a heart attack younger than 55 for men or 65 for women?
- Do you smoke or have you smoked within the past 5 years?
- Are you overweight? This means you have a body mass index over 25 kg/m² (your weight in kilos divided by your height in metres squared), or your waist is greater than 40 inches or 102 cm (for men), or 35 inches or 88 cm (for women). Your pharmacist can help you answer this question.
- Are you of South Asian origin i.e. from the Indian subcontinent that includes India, Bangladesh, Pakistan or Sri Lanka?

AGE

RISKS

MHRA: Consumer Knowledge of LDL-C Levels

- Reducing LDL-C reduces risk of CHD
- No specific requirement to know initial LDL-C or monitor after starting
 - Identification of consumers at higher risk (Questionnaire – Medical History)
 - Opportunities to determine LDL-C levels
 - Referral to doctor

MHRA:

Pharmacy Staff Training Package

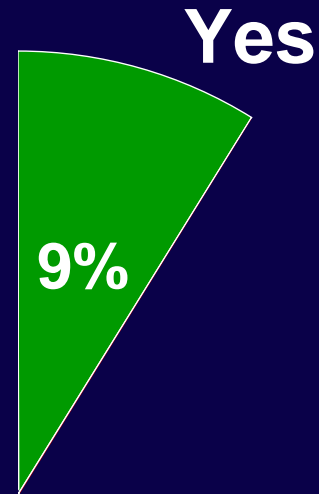
- Prepared in consultation with National Pharmacy bodies
- Distributed to pharmacists and medicine counter assistants
- Education:
 - Pathophysiology of CHD and major risk factors
 - Contraindications, precautions, possible adverse effects
 - Other interventions (e.g., lifestyle changes)



Responses to Consultation Letter

- Circulated within health services (> 250)
- 100 responses:
 - NHS Trusts (21)
 - Pharmacy bodies (14)
 - Healthcare professionals (12)
 - Royal medical colleges (9)
 - Patients (6)
 - Industry (5)
 - Other (33): medical bodies, academia, replies with no comment

Responses to Consultation Letter: POM to P Switch?



Concerns Raised in Response to Consultation Letter

- Dose (10 mg) too low / no clinical trials ($\geq 40\%$)
- Need for cholesterol testing ($\geq 27\%$)
- Need for liver function testing ($\geq 21\%$)
- Potential to ignore lifestyle changes ($\geq 21\%$)
- Cost of OTC statins ($\geq 21\%$)

Concerns Raised in Response to Consultation Letter

- Pharmacist burden/training ($\geq 16\%$)
- Record keeping/patient management ($\geq 16\%$)
- Interactions with other medications ($\geq 10\%$)
- Side effects ($\geq 10\%$)

Summary

No direct or indirect danger to
consumer health without medical supervision

BUT...

*“with the advice of a pharmacist and supported by a
comprehensive pharmacy training package.”*