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OTC statin: mixed messages for patients and the NHS

Simvastatin 10mg, marketed as Zocor Heart-Pro[®], can now be purchased from community pharmacies over the counter (OTC) at an approximate cost of £13 a month. The UK is the first country to allow a statin to be sold in this way. Zocor Heart-Pro[®] is only available at low dose and is only for primary prevention of coronary heart disease (CHD). Patients with cardiovascular disease, diabetes, high blood pressure or familial hypercholesterolaemia should seek advice from their GP rather than buying OTC simvastatin. Lothian guidelines do not currently recommend statins for primary prevention of CHD for people with 10-year CHD risk <30% because of concerns about cost-effectiveness. Some people with CHD risk <30% may choose to buy OTC simvastatin.

Over the counter simvastatin

The benefits of statins in prevention of CHD are well recognised. Simvastatin 10mg will lower cholesterol, however, there is little scientific evidence to suggest that it is effective at reducing cardiovascular mortality and morbidity.

OTC simvastatin is licensed for individuals at moderate risk of CHD. The assessment of risk is based on age, smoking status, BMI > 25kg/m², family history of premature CHD, and ethnicity.

Tests of cholesterol, liver function tests and blood pressure are not required. Patients are given advice about side effects, advised not to drink grapefruit juice, and should be monitored annually.

Some people may see OTC simvastatin as an alternative to more cost-effective forms of primary prevention including physical exercise and smoking cessation. High risk patients may not be detected.

Prescribed statins

The Lothian Prescribing Guidelines for Treating Hypercholesterolaemia¹, based on national guidelines, requires estimation of 10-year CHD risk, based on age, gender, smoking status, blood pressure and cholesterol levels.

Primary prevention of CHD using a statin is recommended for patients with cholesterol ≥ 5mmol/L and 10-year CHD risk ≥ 30%, though these thresholds may change with the revised Joint British Societies Guidelines (due October 2004)².

There is evidence that statins, at doses higher than 10mg, can reduce the risk of cardiovascular events in people with 10-year CHD risk as low as 6%.

LFTs should be checked before and after starting treatment. The usual starting dose is 20 to 40mg simvastatin, titrating dose to subsequent cholesterol levels.

Key messages:

- Simvastatin 10mg is now licensed OTC for primary prevention of heart disease.
- Patients purchasing simvastatin may not necessarily receive all checks offered routinely to patients receiving prescribed statins, including BP, cholesterol and LFTs.
- True CHD risk may not be known and some individuals purchasing simvastatin may receive an inappropriate low dose of statin.
- Patients should be given advice and support about other lifestyle changes, and encouraged to make these changes before considering statin treatment.
- Good communication between community pharmacists and GPs is essential to ensure the best use of statins for the benefit of patients.

References:

1. Prescribing Guidelines for Treating Hypercholesterolaemia. NHS Lothian. July 2004 (DRAFT).
2. Joint British Society Guidelines. Wood DA *et al.* Joint British recommendations on prevention of coronary heart disease in clinical practice. Heart 1998;80(suppl):S1-29.

Z drugs

Hypnotics are used to induce sleep but they should only be prescribed after consideration of non-pharmacological measures. Practical measures that promote sleep include creating a suitable environment for sleep and avoiding daytime naps, strenuous exercise, heavy meals, alcohol and caffeinated drinks at night. Cognitive and behavioural therapies may also be of help.

When hypnotics are considered appropriate for the management of severe insomnia interfering with normal daily life, they should be prescribed short term only. Hypnotic agents licensed for insomnia include benzodiazepines and Z drugs (zaleplon, zolpidem, zopiclone). Advice from the National Institute of Clinical Excellence, endorsed by NHS Quality Improvement Scotland, is that there is no compelling evidence of a clinically useful difference between Z drugs and shorter acting benzodiazepine hypnotics.

There is also no evidence that if a patient does not respond to one hypnotic drug they are likely to respond to another.

The guidance advises that switching between hypnotics should only occur if a patient experiences adverse effects considered to be directly related to a specific agent. Patients who have not responded to one of these hypnotic drugs should not be prescribed any of the others.



Z drugs are not included in the Lothian Joint Formulary (LJF) but they currently account for 14% of prescribed hypnotics/anxiolytics in primary care.

Key messages:

- The hypnotic of choice in the LJF is temazepam; Z drugs are *not recommended* in Lothian for insomnia.
- Temazepam may be prescribed for insomnia after consideration of non-pharmacological measures.
- Temazepam should be prescribed short term only, for the management of severe insomnia interfering with normal daily life.
- Hypnotics should not be put on a repeat prescription system and existing patients receiving a hypnotic should be reviewed and offered the chance to stop or reduce (see BNF withdrawal protocol).
- The Lothian Prescribing Indicator for hypnotics including temazepam gives a target cost per patient ≤ £0.15 per quarter.

References:

1. Anon. Benzodiazepines and "Z" drugs for insomnia. WeMeReC 2003; 10(3):1-4
2. National Institute for Clinical Excellence. Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia. Technology Appraisal 77. April 2004. <http://www.nice.org.uk/pdf/TA077fullguidance.pdf>

Influenza and Pneumococcal Immunisation Programme 2004-05

Influenza vaccine

The influenza immunisation policy for 2004-05 remains unchanged but there is greater emphasis on the "at risk" patient groups from 6 months and under 65 years including the younger "at risk" groups and "at risk" children.

- § The uptake target for those aged over 65 years and over remains at 70%
- § A new uptake target for the "at risk" groups under 65 years is set at 60%

Pneumococcal vaccine

The arrangements for immunisation programme in 2004-05 build on last year's programme.

The "at risk" groups have been amended in 2004-05 to now include "at risk" children under 5 years of age rather than under 2 years of age as previously recommended.

The clinical risk groups recommended for pneumococcal immunisation have been revised to include individuals with CSF shunts and children under 5 years of age who have previously had invasive disease such as pneumococcal meningitis or bacteraemia.

For further detailed information:

1. Immunisation Against Infectious Disease "The Green Book". www.dh.gov.uk/policyandguidance/healthandsocialcaretopics/greenbook/fs/en
2. SEHD/CMO(2004)15 Influenza and Pneumococcal Immunisation programme. [http://www.show.scot.nhs.uk/sehd/cmo/CMO\(2004\)15.pdf](http://www.show.scot.nhs.uk/sehd/cmo/CMO(2004)15.pdf)

Prescribing Injections - Managing the Risk

The CRAG Good Practice Statement for the Preparation of Injections in Near-Patient Areas, including Clinical and Home Environments, was published by the Scottish Executive in 2002 and divisions are required to implement the recommendations made in the document.

The main issues are:

Be aware of the risk

- § The use of injections is associated with an increased risk to patients
- § Medication incidents resulting from errors in the prescribing, preparation and administration of injections are common. Such incidents can harm patients and cause distress to the professionals involved

Avoid the risk if possible

- § Do not prescribe a medicine by the injection route unless:
 - the medicine cannot be administered by another route
 - there is no therapeutically equivalent medicine that could be given by a safer route
 - the oral, rectal or other possible route, e.g. via enteral feeding tube, is not suitable due to the clinical condition of the patient
 - the medicine must be injected to achieve immediate effect, or the required therapeutic level

Minimise the risk

- § If you must prescribe a medicine by injection:
 - write a specific finishing date on the prescription, or
 - review the prescription at least once every 24 hours, and
 - change to a less hazardous route of administration at the earliest opportunity

- § Prescribe bolus injections wherever possible and only add to infusions in the following circumstances:
 - constant plasma concentrations are needed
 - a minimum administration time is required
 - a more concentrated solution would be harmful
 - the volume required for a bolus, due to the dose required, is excessive

- § Review prescribing and minimise the number of injections by:
 - using an alternative route
 - using an alternative medicine
 - considering medicines with lowest dosing frequencies

- § Consider prescribing injections that are available in a ready-to-use form or injections which are simple to prepare with easy to calculate doses

- § All injections must be transferred to the administration device in near patient areas and used immediately

- § Injections must be clearly identifiable at all stages during preparation and administration. This can be done by labelling the injection

- § Good aseptic technique is essential at all stages of preparation and administration to reduce the risk of contamination

Key messages:



The use of injections is more hazardous than other methods of medicine administration.



Only use an injection when no other route is suitable.



If an injection is unavoidable, use a ready-to-use form wherever possible.



If you must prescribe an injection, review the prescription at least once every 24 hours, and change to a less hazardous route at the earliest opportunity.

References

1. Good Practice Statement for the Preparation of Injections in Near-Patient Areas including Clinical and Home Environments. Clinical Resource and Audit Group, Scottish Executive, 2002.
2. Good Practice Statement for the Preparation of Injections in Near-Patient Areas including Clinical and Home Environments. Scottish Executive Health Department NHS HDL (2002) 91.

Our thanks to Jane Renton, Principal Pharmacist, Medicines Information, LPCD, Pharmacy Department, Royal Edinburgh Hospital for contributing this article.

Use of NHS Prescriptions

The British Medical Association and the Royal Pharmaceutical Society provide joint guidance on the security and validity of prescriptions¹.

Prescriptions should be written in such a manner that the pharmacist can dispense the medication without further reference to the prescriber. If there is any doubt as to the prescriber's intention it is good practice for the pharmacist to contact the prescriber. This is commonly in relation to a clinical concern where the pharmacist has a shared professional duty to ensure that there are no unsafe interactions between the medicines, and more generally to ensure patient understanding of why a particular medicine is being recommended. Pharmacists are advised to contact the prescriber where there is any doubt about the authenticity of a prescription¹.

When an NHS prescription is handed to the community pharmacist the patient is required to make a declaration as to whether they are required to pay, or whether they are exempt from, NHS charges. The community pharmacist has a specific professional obligation 'to take reasonable steps' to ensure that this declaration is accurate. It is

appropriate, on occasion, for the prescriber to act as the patient's agent and to make the appropriate declaration on behalf of their patient, and thus facilitate the receipt of the prescribed medication by their patient.

The GP10 and GP10N should normally be issued only to patients registered with the prescriber's practice. It is accepted that a GP10 and GP10N can be used in other circumstances, e.g. temporary residents, to prescribe medication to a patient - where this would normally be available under the NHS. It is good practice for the patient's own registered practice to be informed of any such prescription.

A recent investigation by the NHS Scotland Counter Fraud Service identified the fraudulent use of a GP10 prescription form. The GP involved had been obtaining medication for personal use using a false name and also making fraudulent declaration of exemption from NHS charges. This matter has now been reported to the Procurator Fiscal (as required by the Counter Fraud Service rules) and to the General Medical Council.

Key messages:

- 🔑 **The responsibility to ensure the appropriate use of NHS prescriptions is important and regarded as one of the most significant professional duties placed on an individual prescriber.**
- 🔑 **You as prescriber, or a community pharmacist, have a duty to protect and ensure the appropriate use of NHS prescription pads.**
- 🔑 **Prescription pads should not be left unattended at reception desks.**
- 🔑 **Prescription pads should not be left in a car where they may be visible.**
- 🔑 **When not in use, prescription pads should be kept in a locked drawer within the surgery or at home.**

References:

1. British National Formulary www.bnf.org
2. Old contract - schedule 1, para 29 - 31 of The National Health Service (General Medical Services) (Scotland) Regulations 1995 as amended.
3. New contract - schedule 5, para 38 - 45 of The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004.

Learn more about using eLJF-GPASS

Four new eLJF-GPASS training sessions have been organised. A letter has been sent to all Practices with details - places are limited so book early. The courses are ideal for new users (e.g. new GPs, retainers, registrars, non Principals, and those GPs who currently do not use eLJF-GPASS but would like a helping hand in order to be able to do so). For further information please contact your Primary Care Pharmacist or Anne Gilchrist, Medicines Management Team.

Correction

We would like to acknowledge an error in the article 'Be alert - BAN to rINN' on page 3 of Issue No. 9 - June/July 2004.

Hydroxycarbamide is the rINN (new name) and hydroxyurea is the BAN (old name).

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