

# SOUTHERN DERBYSHIRE PRESCRIBING NEWSLETTER



Southern Derbyshire  
Health Authority **NHS**

September 2001

Edition 62

## CONTENTS:

- **PAG update**
- **Transition to CFC-free steroids**
- **Alzheimer's drug update**
- **DVTs and flying**
- **Apomorphine for impotence**
- **Sibutramine**
- **Non- NHS prescribing situations**

## PAG update

**Finasteride** is a 5 alpha reductase inhibitor used in the treatment of benign prostatic hyperplasia (BPH). It has been shown to improve symptoms and reduce complications in men with BPH, especially in men with larger prostates. **It is now included in the Prescribing Guide for use in men with larger prostates and when haematuria is a clinical problem.**

**Tropium** is an anticholinergic drug licensed for the treatment of urinary incontinence. It is now included in the prescribing guide for second line treatment in patients who have experienced adverse anticholinergic side-effects with other agents. **Oxybutynin remains the first choice option.** Finally, just a reminder that **propiverine is not included in the District Prescribing Guide.**

Funding has now been identified for the prescribing of [riluzole](#) by consultant neurologists. Shared care guidelines are attached to this newsletter.

## Drugs approved by the Acute Trust Drug & Therapeutics committee that are not in the Prescribing Guide

In a few cases GPs may come across drugs that have been approved for use in the Acute

Trust but have not been included in the Prescribing guide. These drugs will be used in selected patients only and will be initiated by named consultants. Consultants will write to GPs stating their reasons for prescribing these drugs. As always, if a GP is in doubt about prescribing any drug please contact your prescribing adviser and/or Kirsty MacLean at the Health Authority. [Drug List](#)

## Transition to CFC-free inhaled steroids

The current 'standard' inhaled steroid, both in Trent and nationally, is beclomethasone dipropionate (BDP). More than two-thirds of patients requiring inhaled steroid treatment currently receive BDP. The local view is that BDP continues to offer the best overall combination of safety, cost and effectiveness.

CFC-containing BDP will continue to be available until at least two CFC-free versions are marketed. At present there is only one CFC-free version of BDP ('*Qvar*') (3M) available on the UK market. It is not yet clear when further CFC-free products will become available.

Until further CFC-free steroid inhalers become available, **PAG recommend that there is no need to change patients on BDP to another inhaled steroid, e.g. fluticasone, on CFC-transition grounds.**

Pharmaceutical company activity around CFC-transition is quite high at present. Companies are suggesting switching patients to CFC-free steroid inhalers to avoid the need to change them later on. If patients are switched from generic CFC-containing beclomethasone there may be large cost implications (see cost chart).

GPs in Trent currently spend around £6.5 million per annum on BDP, and a slightly greater amount on alternative, and

significantly more expensive, products (mainly fluticasone and budesonide). **If, on cfc-transition grounds, just half of the patients currently receiving BDP were switched to one of those two products, the average additional cost per HA would be around £600,000 pa (approx. £200,000 per PCT).** In terms of alternative priorities, this expenditure could provide statin treatment to around 1,700 patients per HA (560 per PCT).

## Alzheimer's drug update

Agreement has been reached on the implementation of the NICE Guidance for Alzheimer's Disease Treatment in Southern Derbyshire.

- Consultants in the Community & Mental Health Services Trust have now started assessing new and previously diagnosed patients (including those who have been funding their own treatment) against the NICE criteria. This will be the single point of access for Southern Derbyshire registered patients.
- Consultants will initiate (on FP10 (HP) prescriptions) and continue prescribing these drugs for eligible patients. **Therefore GPs will not be required to prescribe these drugs and no shared care agreement is necessary.**
- This arrangement for prescribing will be reviewed after one year.
- **GPs should identify patients for whom they are currently prescribing these Alzheimer's drugs and alert the patient's consultant to the need for assessment and prescribing (if appropriate) by the Southern Derbyshire Mental Health Service.**

## DVTs and flying

There has recently been widespread publicity about the increased risk of venous thromboembolism associated with long haul flights. There is no clear agreement on the magnitude of the risks associated with such flights. The following recommendations are not yet evidence based but may provide some assistance to practices.

## Definitions

### Long Haul Flights

Flights lasting more than 4 hours

### High Risk Patients

*Patients with a previous well documented deep vein thrombosis or pulmonary embolism. Patients with antithrombin deficiency. Patients with more than one thrombophilia traits.*

### Treatment

This should be a fairly small number of patients for each GP. Due to a number of practical issues these patients should be individually discussed with a haematologist.

### Moderate Risk Patients

Patients would fall in to one of the following categories:-

*Obesity, Older age (More than 55 years of age), Use of the oral contraceptive pill or HRT, Recent Surgery, Pregnancy, Immobilisation in Plaster or Strong family history of thrombosis. Carrier of thrombophilia genes.*

### Treatment

In the absence of a contraindication to aspirin (e.g. asthma or gastrointestinal bleeding) 150mg of aspirin should be taken 24 hours before the flight and on the day of the flight, with the same procedure for the return journey. Support stockings would also be useful (**patients should buy their own**). Continue to use the general measures as outlined below.

**Low Risk Patients:** *Anyone else.*

### Treatment

General measures as outlined below. All patients should be advised about general measures, i.e. to keep as ambulant as possible on a long flight. This would include regular walks around the cabin, standing for periods of the journey, drinking lots of non-alcoholic fluids and general leg exercises to keep a constant leg circulation even when seated.

There have been well-publicised articles concerning the use of compression hosiery and foot pumps. These **may** provide additional protection for moderate and high risk patients

but clear data are lacking. **However if patients wish to use these they can purchase them from their community pharmacist or airline. These items should not generally be prescribed.**

## Apomorphine for impotence

Sublingual apomorphine (*Uprima*) has recently been licensed for the treatment of impotence. This product will shortly be scheduled by the Government in the same way as sildenafil (*Viagra*). The prescribing of drugs for impotence is being reviewed by the Department of Health at the moment and a definite statement on their prescribing is awaited. ***Uprima* has not yet been assessed at PAG and is not included on the Prescribing guide.**

## Sibutramine

Sibutramine has recently been licensed as adjunctive therapy within a weight management programme for:

- Patients with nutritional obesity and a BMI of 30kg/m<sup>2</sup> or higher
- Patients with nutritional excess weight and a BMI of 27 or higher, if other obesity-related risk factors such as type 2 diabetes or dyslipidaemia are present.

The Summary of Product Characteristics (SPC) states that sibutramine should only be given as part of a long-term integrated therapeutic approach for weight reduction under the care of a physician experienced in the treatment of obesity and only to patients who have **not** adequately responded to an appropriate weight-reducing regimen alone.

**Sibutramine is being considered by NICE and will be considered by PAG when the guidance is published. Until this happens it is worth having a look at the published evidence.**

Sibutramine is centrally acting, inhibiting the reuptake of neurotransmitters that control food intake. In theory, it helps patients feel satisfied with smaller portions of food so that they eat less and lose weight. The STORM study has been recently published in the Lancet (Lancet 2000; **356**: 2119-25).

- 605 obese patients (BMI 30-45) aged 17-65 had 6 months of sibutramine 10mg/day and an individualized 600 kcal/day deficit programme. An extra 30 minute walking per day was advised. They were seen by a dietician every 2 weeks and a physician monthly.
- 77% achieved >5% weight loss and were randomised to 10mg/day sibutramine or placebo for a further 18 months. The dose was increased to 15mg if more than 1kg weight gain occurred after month six. If further weight increases occurred, a maximum of 20mg could be used.
- Patient exclusions included: diabetes; epilepsy; schizophrenia; depression; history of heart failure, IHD, stroke, TIA or unstable hypertension; oral beta-blockers; agonists for asthma. Hypertensives stabilized on therapy were included.
- The primary endpoint was the number of patients at year 2 maintaining at least 80% of the weight loss between base line and month 6. The European Medicines Evaluation Agency (EMA), in 1996, gave advice that in trials of drugs used in weight control, the primary efficacy end-point should be at least 10% reduction of baseline weight, which is also statistically greater than that associated with placebo.

Of the 605 patients originally enrolled in the trial, only 204 completed on sibutramine and of these only 89 successfully achieved the primary outcome endpoint. This was significantly more than those with placebo and it works out as a NNT of 6. This NNT seems low but it is not to prevent an MI or save a life but to lose >5% of initial body weight over 6 months and then maintain at least 80% of this weight loss for a further 18 months. How clinically significant is this?

Sibutramine was not without its problems:

- 76% needed an increase in dose to 15mg and then 52% to 20mg.
- 20 (3%) patients were withdrawn because of increases in BP. In the sibutramine group systolic BP rose by 0.1mmHg (SD 12.9), diastolic by 2.3 (9.4), and a pulse rate by 4.1 beats/minute (11.9). BP in the placebo group fell in proportion to weight loss.

	<b><u>Sibutramine</u></b>	<b><u>Placebo</u></b>
Insomnia	8%	3%
Nausea	7%	1%
Increasing BP	8%	3%
Dry mouth	9%	3%
Withdrawals due to adverse events	14%	5%

So, for every 11 patients treated with sibutramine, one withdrew due to adverse events that did not on placebo. Half of patients required a 20mg dose of sibutramine. As the maximum licensed dose is 15mg, it is unlikely that these results will be achieved in practice. This was also a 2 year trial and sibutramine is only licensed for up to a year.

The increases in BP and pulse rate seen in the trial mean that these have to be checked every 2 weeks for 3 months, then monthly for 3 months, then every 3 months. The SPC lays down criteria for weight loss to be achieved if sibutramine is to be continued. The SPC also has a long list of contra-indications and potential drug interactions. As it is a black-triangle drug **ALL** adverse events should be reported to the CSM via a yellow card.

In conclusion, sibutramine is not a magic bullet for obesity. Some patients can lose a worthwhile amount of weight and maintain this for up to 2 years but the trial would suggest this is not a high proportion. Sibutramine would appear not to be for routine use but carefully selected and supported patients may benefit if the correct process is followed.

### Prescribing situations not covered by the NHS

#### After Private Referral

The responsibility for prescribing rests with the doctor who has clinical responsibility for a particular aspect of the patient's care. Where, for instance, an NHS doctor refers a patient (privately or otherwise) to a consultant for advice but, when appropriate, retains clinical responsibility, he/she should issue the necessary prescriptions and at NHS expense.

People who opt to be referred privately (i.e. outside of the NHS) are expected to pay the full cost of any treatment they receive in relation to the care provided privately.

Any drugs prescribed or treatment provided by a clinician in the course of a private consultation should be at the patient's expense. NB. Treatment in respect of subfertility is a case in point and therefore GPs should not be asked to prescribe.

Following a private consultation, there is no obligation for the GP to prescribe the recommended treatment if it is contrary to his/her normal clinical practice.

#### Prescribing of Borderline Foods and Dietary Products

Prescribing should comply with the recommendations of the Advisory Committee on Borderline Substances (ACBS): "Prescriptions for such products on FP10s are regarded as drugs for the treatment of specified conditions. Doctors should satisfy themselves that the products can safely be prescribed, that patients are adequately monitored and that, where necessary, expert hospital supervision is available." A complete list of conditions can be found in the BNF or Drug Tariff. Most conditions can be included in the following categories:-

- Metabolic disorders
- Malabsorption states
- Liver disease
- Specific skin disorders
- Dysphagia
- Gastrectomy
- Malnutrition (disease-related)
- Inflammatory Bowel Disease
- Renal failure

There are several areas where prescriptions for dietary products do not comply with the above recommendations and responsibility lies with individual GPs who may use their judgement and make exceptions. This may occur following recommendations from a dietician or for a medical condition requiring nutritional support for a defined period of time. For example, a patient having had maxillo-facial surgery, being discharged from hospital with a wired jaw and requiring nutritional support for 6-8 weeks post-operation. Such a patient would be unlikely to receive adequate nutrition from a manageable volume of liquidised foodstuffs.

Comments and questions as ever are welcomed.

Please contact Kirsty MacLean

01332 626322

kirsty.macleaen@mail.sderby-ha.trent.nhs.uk