Introduction:

Overall aim of training

Enable you to appropriately manage the supply of Flomax Relief (tamsulosin).

Learning objectives

• To gain an overview of benign prostatic hyperplasia (BPH) and its impact on quality of life

• To recognise pharmacy’s contribution to helping BPH sufferers recognise and manage their condition

• To understand the appropriate supply of Flomax Relief through Pharmacy using the pharmacist supervision model and the relevant tools and paperwork provided

Estimated time to complete: 2hrs
Introduction: Competencies

This training guide will help you meet the following Continuing Professional Development (CPD) competencies. The College of Pharmacy Practice (CPP) has accredited this training in line with these competencies.

G1a: Using expert knowledge and skills to benefit patients
G1c: Giving informed and accurate pharmaceutical advice
G1d: Taking a patient-centred approach
G1v: Signposting to other services
G1w: Taking on new roles or responsibilities
G2o: Responding to requests for advice or information
C1a: Assessing the medication needs of patients
C1f: Providing advice and counselling
C2a: Providing information to promote public health and prevent disease
C3: Addressing the health and medication needs of specific client groups

This training can help you meet the RPSGB’s requirements for continuing professional development (CPD). To get the best from this training, refer to the CPD cycle (reflection on practice, planning, action, evaluation) and use this to make an entry on your personal CPD records (www.uptodate.org.uk).

This training is accredited by the College of Pharmacy Practice (CPP) and has been awarded the National Pharmacy Association (NPA) training seal.

These materials have been accredited by the College of Pharmacy Practice against the Royal Pharmaceutical Society’s CPD competency framework.

The NPA training seal is an approval of the training content. The NPA in no way endorses any product(s) or range of products listed. Also the NPA cannot guarantee the content of any website listed.
Introduction to managing BPH in the pharmacy

Benign prostatic hyperplasia (BPH) is a common condition in men that can cause lower urinary tract symptoms (LUTS).

Pharmacists are well placed and well equipped to build this new category of management of LUTS due to BPH, which is now supported by the availability of an effective over-the-counter (OTC) treatment and a pharmacist supervision model.

Why treat BPH in the pharmacy?

- Around 1 in 4 men above the age of 40 years experience some of the symptoms of BPH, yet - in a study - 89% of men with BPH didn’t consult their doctor in the year before the study began

- Men tend to put up with the anxiety, inconvenience, embarrassment and bothersome symptoms that are often associated with BPH, for a variety of reasons:
  - Acceptance of symptoms as a normal part of ageing
  - Belief that symptoms are temporary
  - Possible fears of prostate cancer
  - There is a general tendency among men to cope with illness, not admit to weakness and a reluctance to go to the doctor for fear of wasting their time

The switch of tamsulosin (Flomax Relief) from prescription to Pharmacy classification offers men with BPH convenient access to advice and appropriate treatment, and an exciting new professional and business opportunity in men’s health for pharmacists.
Pharmacists are ideally placed to manage BPH and supply Flomax Relief (tamsulosin) as a newly switched POM to P medicine. It gives the pharmacist, for the first time, a clinically effective and established treatment for BPH and the opportunity to make a significant contribution to managing BPH and increasing awareness of the condition. At the same time, this switch reinforces Pharmacy’s position as a provider of accessible men’s health services.

The supply of Flomax Relief (tamsulosin) involves both the pharmacist and GP. The pharmacist follows a simple pharmacist supervision model and a structured customer Symptoms-check Questionnaire (SQ) to ensure the man is suitable for initial supplies of Flomax Relief while the GP confirms that they are happy for the man to continue to receive Flomax Relief. This approach will help increase men’s access to appropriate treatment while ensuring that safeguards are in place for diagnosis and GP intervention.
Section 1:
About benign prostatic hyperplasia (BPH)

BPH is a progressive enlargement of the prostate gland that leads to lower urinary tract symptoms (LUTS) such as hesitancy, weak stream and urgency.³

The enlargement is caused by long-term exposure of the prostate to testosterone, as a result of ageing. Prostate enlargement puts pressure on the urethra where it passes through the gland, obstructing the flow of urine and causing LUTS. In addition, the bladder wall muscle may thicken and this loss of elasticity may reduce the volume of urine it may hold (see diagram).

The prostate gland

The prostate gland lies beneath the bladder and surrounds the urethra. It is usually about the size of a walnut. Its main function is to excrete prostatic fluid, a constituent of semen, during ejaculation. This fluid contains prostate specific antigen (PSA), which liquidises the ejaculate to improve the chances of fertilisation.
Section 1: Symptoms

Lower urinary tract symptoms due to BPH are classified as:

- **Obstructive** - symptoms related to emptying of the bladder, typically incomplete emptying, intermittency, straining. Patients may use terms such as stopping and starting or dribbling.

- **Irritative** - symptoms related to filling of the bladder, typically increased frequency, urgency, nocturia. Patients may describe frequent trips to the toilet, getting up in the night or worrying that they might not reach the toilet in time.

These urinary tract symptoms are used in the customer Symptoms-check Questionnaire (SQ) to help you ascertain whether the customer’s symptoms are bothersome enough to benefit from treatment with Flomax Relief.

Symptoms and prostate size

There is no direct relationship between the severity of urinary tract symptoms and size of the prostate⁴ – some men have severe symptoms but minimal enlargement of the prostate, while others have minimal symptoms but a very large prostate.

Symptoms and prostate cancer

Although prostate cancer may be a concern for men experiencing lower urinary tract symptoms, those suffering from BPH are no more likely than men without BPH to develop this cancer.⁴ Pharmacists can reassure men that the pharmacist supervision model for Flomax Relief involves a robust assessment and a requirement to see the GP, and will ensure prompt referral and diagnosis where there are any concerns about serious underlying disease.

Impact on quality of life

Lower urinary tract symptoms due to BPH start off as an inconvenience but can become more debilitating as the condition progresses. Some sufferers are unable to leave their homes without knowing where the next toilet will be, and because of this they feel limited from doing everyday activities such as playing sports and visiting the cinema.¹ BPH may also impact on the partner’s quality of life through disturbed sleep or restrictions on social activities due to the frequent and unpredictable need to urinate.
Symptoms

The extent of the problem
In a research sample of men with LUTS due to BPH:
• 70% have the sensation of not completely emptying the bladder after finishing urinating
• 89% get up frequently during the night to urinate
• 70% said their condition is always at the back of their mind and makes them anxious

Based on a sample of 102 men aged 51-60 years with LUTS due to BPH

The ‘bothersomeness’ of LUTS symptoms is a good indicator of the severity of the condition and the extent of impact on quality of life (QoL). These indicators are captured in the SQ (see later) to help you advise if the sufferer could benefit from treatment with Flomax Relief.

International Prostate Symptom Score (IPSS)
IPSS is used to grade LUTS objectively and reproducibly as mild, moderate, or severe. It is not a diagnostic tool but it is valuable for assessing the impact of urinary symptoms on the man, and monitoring progress and response to treatment. The IPSS has been incorporated into the Flomax Relief SQ.

Reflection
Think about how you can demonstrate empathy to men with LUTS. Consider the impact that BPH has on the man and his partner.
In 2004 the British Association of Urological Surgeons (BAUS) produced a set of guidelines for the primary care management of LUTS in men. In May 2010 the National Institute for Health and Clinical Excellence (NICE) also published guidelines on the management of LUTS in men. Below are the key recommendations:

- **Lifestyle advice/conservative management** - not all men with LUTS will require treatment. Management should include a combination of reassurance, lifestyle advice and assessment of the need for medication.

- **Treatment** - alpha₁-blockers, also called alpha₁-adrenoceptor antagonists (e.g. tamsulosin, see Section 3), are a first choice treatment for men with smaller prostates and moderate/severe LUTS. They work by relaxing smooth muscle in the prostate and bladder neck. The 5-alpha reductase inhibitors (e.g. finasteride, dutasteride) are recommended for men with larger prostates with urinary symptoms. They shrink the prostate by a mechanism that involves blocking conversion of testosterone into the more potent dihydrotestosterone.

- **'Alternative' therapies** - herbal medicines, homeopathy and acupuncture are not recommended in the NICE or BAUS guidelines. These have not been clinically proven to be effective for LUTS in men.
Section 2: Pharmacist supervision model for Flomax Relief

Flomax Relief - a new OTC treatment for BPH

Flomax Relief (tamsulosin hydrochloride 0.4 mg modified release capsules) is a new over-the-counter treatment for the urinary symptoms of BPH. Tamsulosin, an alpha1-adrenoceptor antagonist (alpha1-blocker) is a well established and generally well tolerated treatment previously available only on prescription but now classified as a Pharmacy medicine. There are few drug interactions14 reported in association with the drug and side effects are few and generally mild8-10 (refer to the Summary of Product Characteristics [SPC]).

What is the pharmacist supervision model?

The key features of the pharmacist supervision model for the supply of Flomax Relief are:

- Pharmacist assesses suitability of patient for initial supplies of Flomax Relief using structured customer Symptoms-check Questionnaire (SQ) and offers lifestyle advice
- Pharmacist can make an initial supply of 2 weeks of Flomax Relief, and advise the patient to see their GP in the next 6 weeks to confirm that the GP is happy for the patient to continue taking Flomax Relief
- The pharmacist can supply up to a further 4 weeks of Flomax Relief during which time the patient must visit their GP to confirm suitability for long-term OTC treatment, if they have not already done so
- Once the patient has visited the GP, and the GP has confirmed that the patient is suitable for long-term treatment, the pharmacist can continue to supply Flomax Relief long-term. The patient should be advised to revisit the GP every 12 months
- The pharmacist should review symptoms with patients at regular intervals when making subsequent supplies of Flomax Relief in order to monitor their progress and response to treatment
- The pharmacist should strongly encourage the patient to return to the same pharmacy to obtain subsequent supplies of Flomax Relief

Tamsulosin features:

- Alpha1-blockers are a first-line treatment for BPH8
- Acceptable BPH therapy for most men and the UK’s most widely prescribed drug treatment for BPH
- Rapid onset of action with improvement of urinary symptoms within 2 weeks of treatment12
- Is taken as a ONCE-daily dose, as one capsule per day with no dose titration required14
- Few drug interactions14 associated with tamsulosin and side effects are few and generally mild8-10

Flomax Relief - a new OTC treatment for BPH

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Section 2:
Pharmacist supervision model for Flomax Relief

Week 0

Patient presents with lower urinary tract symptoms or requests Flomax Relief

Pharmacist helps customer complete Symptoms-check Questionnaire to determine if suitable for supply of Flomax Relief

Pharmacist offers lifestyle advice (see page 10)

- Man aged 45-75
- Established (minimum of 3 months) ‘bothersome’ urinary symptoms of BPH (see scoring of customer Symptoms-check Questionnaire)
- No red flag symptoms reported by patient that could indicate a serious underlying condition
- No contraindications to taking tamsulosin

- Patient deemed unsuitable for OTC supply of Flomax Relief following completion of questionnaire

- Pharmacist supplies 2-week pack of Flomax Relief and advises patient to see GP in next 6 weeks to confirm GP is happy for patient to continue taking Flomax Relief. Patient can return for a further 4-week supply (see week 2 on next page)

- Pharmacist does not supply Flomax Relief and refers patient to GP
Week 2

Patient returns for further supply of Flomax Relief

- Patient symptoms have improved and patient has not experienced significant side effects
- Patient has not yet had diagnosis/treatment confirmed by GP

- Pharmacist supplies up to 4 weeks further supply and reminds patient to see GP in order to confirm GP is happy for him to continue taking Flomax Relief

- Patient returns with diagnosis/treatment confirmed by GP

- Pharmacist can supply 4-week pack of Flomax Relief. Patient advised to see GP every 12 months for annual consultation

- Patient symptoms have not improved or;
  - Patient symptoms have got worse or;
  - Patient has experienced significant side effects

- Pharmacist does not make a further supply and refers patient to GP for further assessment

Section 2:
Pharmacist supervision model for Flomax Relief
Week 2
Section 2: 
Pharmacist supervision model for Flomax Relief
Week 6 & Week 52

**Week 6**

Patient returns for further supply of Flomax Relief

- Patient has not yet had diagnosis/treatment confirmed by GP
- Pharmacist advises the patient that they cannot be supplied with further Flomax Relief until GP confirms BPH diagnosis

**Week 52**

- Patient has had diagnosis/treatment confirmed by GP
- Pharmacist can supply 2 or 4-week pack of Flomax Relief. Patient advised to see GP every 12 months for annual consultation

- Patient returns for further supply of Flomax Relief
- Pharmacist recommends patient who has been taking Flomax Relief for 12 months to visit GP for annual consultation

**Reflection**

How can you enhance the relationship you have with local GPs? Are there any particular areas of the pharmacist supervision model that you feel you need further discussion with the GP?
Section 2:
Customer Symptoms-check Questionnaire (SQ)

Refer to a copy of the SQ with guidance notes for pharmacists (see Appendix).

The SQ is a validated tool that helps you decide whether Flomax Relief is appropriate for a particular customer.

It asks the man to score how ‘bothersome’ his symptoms are and helps you identify contraindications, and other medicines being taken (including OTC and herbal medicines) which may affect symptoms.

Inclusion criteria for treatment with Flomax Relief:

• Man aged between 45 and 75 years
• Suffering ‘bothersome’ urinary symptoms with an impact on quality of life (see scoring on SQ)
• Symptoms present for at least 3 months
• No symptoms reported that could indicate a serious underlying condition (red flags) and no contraindications to taking tamsulosin
Section 2: When to refer to the GP

There are some conditions that have similar symptoms to BPH, and the SQ helps you to identify men who may have a more serious underlying condition, or a contraindication to the supply of tamsulosin, and should therefore be referred to their GP.

- Pain on urination, bloody or cloudy urine, and fever that may be indicative of a urinary tract infection
- Blood in urine can also be a sign associated with bladder cancer
- Urinary incontinence (uncontrolled leaking of urine) may indicate chronic outflow obstruction of bladder
- Uncontrolled or undiagnosed diabetes can cause damage to the autonomic nervous system which, amongst other things, controls bladder function. This damage can lead to urinary frequency (which is also a symptom of BPH), but other symptoms that may be present with uncontrolled or undiagnosed diabetes include excessive thirst and tiredness
- Heart, liver and kidney problems are contraindications to OTC supply of tamsulosin
- Dizziness, fainting or weakness on standing up can be indicative of postural hypotension. Flomax Relief should not be given to men who experience postural hypotension because, as with other alpha₁-blockers, a reduction in blood pressure can occur in some people during treatment with tamsulosin
- Flomax Relief should not be used in people planning to have an eye operation for cataract, or who have experienced blurred or cloudy vision that has not been examined by a GP or optician. This is because of the potential for a condition called Intraoperative Floppy Iris Syndrome (IFIS) during cataract surgery in some patients who are on or have been previously treated with tamsulosin

When referring someone to the GP, complete the standardised GP referral slip (found in the SQ) for the customer to take with them and show to their GP.
### Section 2: When to refer to the GP

#### Red flags (urgent medical referral)
- Pain on urination
- Fever (unexplained fever could indicate UTI)
- Bloody or cloudy urine in last 3 months (could indicate possible UTI)
- Urinary incontinence (could indicate chronic outflow obstruction of the bladder)

#### Contraindications to OTC supply of tamsulosin
- Prostate surgery undertaken
- Unstable or undiagnosed diabetes (e.g. characterised by excessive thirst and tiredness)
- Problems with liver, kidney or heart
- Fainting, dizziness or weakness when standing up (postural hypotension)
- Eye operation for cataract planned
- Patient has recently experienced blurred or cloudy vision that has not been examined by a GP or optician
- Allergy or bad reaction to tamsulosin

#### Concomitant therapies
- Prescribed treatment for BPH (including prescribed tamsulosin)
- Doxazosin
- Indoramin
- Prazosin
- Terazosin
- Verapamil
Section 2: Support tools

Flomax Relief Symptoms-check Questionnaire

The urinary symptoms and quality of life scores derived from the SQ, date of initial purchase and ongoing purchases of Flomax Relief could also be recorded on the pharmacy’s Patient Medication Records (PMR) but is not required. The SQ itself should be given back to the customer.

Registration Card

There is a registration card on the back of the Men’s Health Booklet which can be found in the Flomax Relief pack. The treatment start date should be recorded on the registration card and will serve as a reminder to you and the customer as to when he should see his GP for a consultation. There is also a space for customers to record any other medication they are taking.

Men’s Health Booklet

Each pack of Flomax Relief will carry a Men’s Health Booklet with prostate health education information including:

- **Careline** – A free phone number 0800 731 9070 is available for pharmacists and consumers

- **Consumer and healthcare professional website** - www.flomaxrelief.co.uk contains comprehensive information and downloadable BPH management tools for both consumers and pharmacists
### Indication

Flomax Relief (tamsulosin hydrochloride 0.4 mg as modified release capsules) is indicated as a once daily dose for the treatment of functional symptoms of BPH (incomplete emptying, frequency, intermittency, urgency, weak stream, straining, nocturia) in men aged between 45 and 75 years. The dose is one capsule daily taken ideally after the same meal each day.\(^{13}\)

### Mode of action

Tamsulosin binds selectively and competitively to post-synaptic α\(_{1}\)-receptors, in particular to the sub-type α\(_{1A}\), and brings about relaxation of the smooth muscle of the prostate. This leads to a reduction in smooth muscle tension in the prostate and urethra, thereby allowing an increased maximum urinary flow rate and providing symptom relief. Flomax Relief has a rapid onset of action producing an effect after the first dose, and symptom relief usually within 7-14 days of starting treatment.\(^{12}\) Symptom relief continues to increase for up to 12 weeks.\(^{15}\)

Tamsulosin is absorbed from the intestine and its absorption is reduced by a recent meal. To maintain constant plasma levels patients should be advised to take their once daily dose of Flomax Relief after the same meal each day.\(^{13}\)
Efficacy

Studies show that tamsulosin is significantly better than placebo in improving urinary flow and reducing symptoms, and efficacy is sustained in the long-term with no evidence of tolerance with prolonged use.

The efficacy of alpha-1-adrenoceptor blockade does not correspond with disease severity, and does not depend on prostate size or relate to prostate specific antigen (PSA) levels.

The efficacy of tamsulosin does not depend on age. It is as effective in men 65 years or older as in younger men, both in the short-term and long-term. In addition, efficacy is comparable in men with and without diabetes.

Safety

Tamsulosin holds the position of being the UK’s most widely prescribed drug treatment for BPH for over 10 years and as an alpha-1-blocker it is a first-line treatment for BPH throughout the world.

There are few drug interactions associated with the drug and side effects are few and generally mild. Flomax Relief can be recommended by the pharmacist to patients taking antihypertensives (other than alpha-1-blockers due to potential additive effect).
Section 4: Pharmacy’s role in improving men’s health

Men do not generally take an active interest in their health and are often reluctant to seek help from traditional NHS services. By considering men’s particular issues such as BPH, community Pharmacy can make itself the first port-of-call for men’s health services. Managing BPH in the community is also consistent with Pharmacy’s increasing role in managing long-term conditions and the RPSGB’s push to make pharmacy more focused on men’s health.

Not all sufferers will require treatment, and management should include a combination of reassurance, lifestyle advice and a review of current medication. However, the availability of OTC tamsulosin will give pharmacists a new opportunity for getting involved in prostate health.

There are a number of ways of encouraging men to seek advice on their health and BPH specifically:

• Linking with local and national men’s health initiatives e.g. Men’s Health Week run by the Men’s Health Forum
• Incorporating some of the pharmacy’s other services into a men’s health package e.g. obesity, diabetes, blood pressure, sexual health
• Increasing awareness of the pharmacy consultation room so that customers know they can access confidential help, information and advice
• Offering Flomax Relief and BPH awareness services as part of the pharmacy’s wider offering on men’s health
• Displaying leaflets about BPH to reassure men that urinary symptoms are relatively common and effective drug treatment is available
• Bag stuffers in dispensing and counter bags can give useful advice and encourage men to ask you about BPH
• Men can also be reached via their partners. For example, a female patient may mention being continually woken by her partner’s visits to the toilet during the night. BPH may be the cause and drug treatment can increase quality of life for both partners
• Featuring men’s products and services more prominently to make the pharmacy more male friendly. Window displays containing footballs, for example, can catch men’s attention
Reflection
Think about your customer base, the extent of your pharmacy’s involvement in men’s health and the potential for extending this? How can you make the most of the opportunities that could arise from the tamsulosin switch in your pharmacy?

Sign-posting
• Flomax Relief  
  www.flomaxrelief.co.uk
• Men’s Health Forum  
  www.menshealthforum.org.uk
• NHS Direct  
  www.nhsdirect.nhs.uk
• Pharmaceutical Services Negotiating Committee  
  www.psnc.org.uk
• Prostate Help Association  
  www.prostatehelp.me.uk
• Prostate Research Campaign UK  
  www.prostateuk.org
• Royal Pharmaceutical Society of Great Britain  
  www.rpsgb.org.uk
• NHS Clinical Knowledge Summaries  
  www.cks.nhs.uk
Section 5:  
CPD elements  
self-assessment questions

Please answer TRUE or FALSE to the following statements:

1) Around 1 in 4 men over 40 years old experience symptoms of BPH  
   
2) Terminal dribbling and straining to void urine are obstructive symptoms found in BPH  
   
3) Patients should be advised to visit their GP to obtain a medical diagnosis after taking Flomax Relief for 6 weeks  

4) Tamsulosin is a 5-alpha reductase inhibitor which blocks the conversion of testosterone into the more potent dihydrotestosterone  
   
5) NHS Clinical Knowledge Summaries recommends the routine measurement of PSA levels in BPH  
   
6) Men suffering from BPH are no more likely than men without BPH to develop prostate cancer  
   
7) Finasteride is a usual first choice drug treatment for men with moderate/severe LUTS  
   
8) A man with pain on urination requires immediate referral  
   
9) Drinking alcohol can stimulate the bladder and help relieve symptoms  
   
10) If urinary symptoms have not improved within 14 days of starting treatment with Flomax Relief, or are getting worse, the patient should be referred to the GP  

Answers: T T T F F T F T F T
For each of the following case studies, consider the points you need to bear in mind, the course of action you would take (including counselling) and whether Flomax Relief is suitable.
Example 1

A 45-year old man asks you for advice on his urinary symptoms. He is having to take frequent trips to the toilet and is concerned because he has to make a long car journey to visit relatives. He is not taking any ongoing medication for any other purpose and is relatively fit and healthy.

Considerations

• Could this man’s symptoms be related to BPH?

• What further information would you need to gather about his symptoms?

• Could Flomax Relief provide symptom relief for the journey?

This man is 45 years old and appears to be suffering from urinary frequency and urgency which are typical symptoms of BPH. However, more information is needed to assess the suitability of supplying OTC tamsulosin.

The customer Symptoms-check Questionnaire (SQ) will help elicit if the man is suffering from other symptoms indicative of BPH or urinary symptoms which require urgent referral to a GP (e.g. pain on urination, blood or cloudiness in the urine). It will also elicit how long he has been suffering symptoms; if the symptoms are not established (less than 3 months) and ‘bothersome’, he is not suitable for OTC treatment with Flomax Relief.

International Prostate Symptom Score (IPSS) and QoL scores on the SQ will help you assess the severity of the symptoms and how bothersome they are. If the man has only mild symptoms as determined by a low IPSS score (IPSS score 1-7) as well as a relatively good quality of life (QoL score 0-3) this does not justify a treatment recommendation for Flomax Relief.

If the man does not meet the criteria for supply of Flomax Relief, provide lifestyle advice e.g. reduce or avoid alcohol intake, which could help improve his symptoms. Ask him to visit his GP to make sure that there are no other problems causing these symptoms.

Provided this man does not report as having any other exclusion criteria in the SQ, and has LUTS of sufficient severity and bothersomeness, he appears to be a suitable patient for treatment with Flomax Relief.

Give him a 14-capsule pack, which includes a Men’s Health Booklet and registration card and ask him to return to the pharmacy to discuss his symptoms and treatment in 2 weeks time. Flomax Relief can improve urinary symptoms from within 1 week of treatment. Give the man lifestyle recommendations that may also be helpful and reassure him that BPH and associated urinary symptoms are common in men of his age. Inform the man that he must see his GP for a consultation, and that he should do so within the next 6 weeks.
Example 2

A 39-year old man presents to the pharmacy complaining of nocturia over the past month and would like something to relieve his symptoms. He is currently taking metformin 500mg three times a day.

Considerations

• Consider the age of this man. Could his symptoms be due to BPH?

• Is the length of time he has been experiencing symptoms relevant?

• The man is taking a prescription medication. How does this affect your diagnosis and treatment recommendations?

Although this man suffers from diabetes and is taking medication this does not necessarily exclude him from receiving OTC tamsulosin. Flomax Relief can be given to patients whose diabetes is stable provided all other criteria are met. There is no interaction with metformin.

However, since he is under the age of 45 years, and he has only been experiencing symptoms for a month, he is NOT a suitable patient for OTC tamsulosin treatment. Discuss his symptoms and refer him to the GP for further assessment.

Example 3

A man has already been taking OTC tamsulosin for the last 2 weeks but his symptoms have not improved. He asks you if he should be taking the capsules more frequently.

Considerations

• Why haven’t his symptoms improved?

• What further information would you need to gather?

The man’s symptoms have not improved so a further supply should not be provided. Explain that it is not appropriate to exceed the dose recommendations so he should not take the capsules more frequently. The man should be referred to the GP for further investigation and perhaps a different treatment.

Discuss the man’s symptoms to find out if he has been following the lifestyle recommendations suggested, and find out whether there is an adherence issue which is preventing the man from gaining benefit from treatment.

Example 4

A man who has already been taking OTC tamsulosin for the past 8 months and his symptoms are still improved, asks you if he needs to see his GP.

Considerations

• Is there any change in the man’s symptoms or quality of life?

• Does this man have any concerns about his medication or symptoms?

Provided the man continues to meet all the criteria for supply of Flomax Relief and his symptoms are relieved, there is no reason why this man needs to see his GP regarding his urinary symptoms, unless his GP has requested him to do so.

Check whether the man has any other symptoms that require referral or concerns that need to be addressed and reassure him that he does not need to see his GP for another 4 months. Explain that Flomax Relief can be taken for a maximum of 12 months before it is advised that he visits his GP for another consultation.
How can I be confident in identifying BPH in Pharmacy?

There are no diagnostic tests for BPH that can be routinely carried out in Primary Care, and your role as a pharmacist is to identify LUTS presumed to be due to BPH (based on the Symptoms-check Questionnaire), exclude ‘red flag’ symptoms and refer patients who require more clinical investigation to their GP. The SQ helps you to do that and to also assess the severity of a patient’s symptoms and whether OTC tamsulosin is an appropriate treatment choice. The pharmacist supervision model requires the GP to confirm diagnosis of BPH.

How will the GP be involved?

The Flomax Relief pharmacist supervision model (featuring pharmacy treatment with tamsulosin) is a step that precedes and leads into confirmation of the diagnosis of BPH by a patient’s GP.

The GP would carry out investigations to confirm diagnosis of BPH, regardless of whether referral was for confirmation of BPH or for red flags/contraindications. Investigations may include a digital rectal examination and urinalysis.

How can I be sure that Flomax Relief is being used appropriately?

Any contraindications to tamsulosin use can be identified using the SQ. Under the pharmacist supervision model for Flomax Relief, any potential risk of inappropriate use or a short delay before diagnosis of a more serious condition is balanced by:

• Increased presentation of men who otherwise may not visit their GP
• Pharmacist symptoms-check via the validated Flomax Relief SQ gives a high degree of confidence for the pharmacy assessment of lower urinary tract symptoms
• Initial short treatment period (e.g. 6 weeks) before confirmed diagnosis by GP
• Provision of a small starter pack and a Men’s Health Booklet
• Limiting treatment to men aged 45 years and above, when lower urinary tract symptoms due to BPH starts to arise more frequently, up to 75 years when it is very common
• Tamsulosin is generally well tolerated and has a profile of non-life threatening side effects

Role of Prostate Specific Antigen (PSA) testing and urinalysis

The PSA level can be raised in many conditions that affect the prostate, including urinary tract infection or inflammation, BPH and prostate cancer, as well as sexual intercourse and strenuous exercise. Clinical Knowledge Summaries do not recommend routine measurement of PSA in BPH and so it does not form part of the OTC tamsulosin supply protocol. Delaying PSA testing for the first few weeks of OTC therapy is unlikely to adversely affect any of these considerations. Urinalysis may be carried out by GPs to exclude complications or other causes of LUTS (e.g. urinary tract infection).
How can I best overcome men’s embarrassment about discussing their symptoms?

Men may be particularly reluctant to discuss potentially embarrassing health issues so the topic of LUTS and BPH needs to be approached sensitively and discreetly. One option is to provide Private Consultation Cards whereby a patient can request a private word with the pharmacist by picking up a card and handing it to the counter assistant.

Once men are aware that a private area is available for confidential discussions they may be able to take the first steps towards treating a problem that is reducing their quality of life.

What is the role of my pharmacy support staff?

Pharmacy support staff, particularly Medicines Counter Assistants (MCAs), are usually the first point of contact and can therefore play a useful role in raising awareness of BPH and prostate health services in the following ways:

- Providing information leaflets
- Making the pharmacy ‘men friendly’
- Referring customers to the pharmacist when appropriate
- Providing BPH customer Symptoms-check Questionnaires before pharmacist review

With appropriate training your assistants can play a role in the pharmacist supervision model and gain the necessary communication skills to deal with this subject sensitively. Their involvement can free up pharmacist time to make your interaction with the customer more effective. A Flomax Relief training guide for pharmacy support staff is available.

How safe is it for pharmacists to supply Flomax Relief for BPH?

Pharmacy’s role in managing BPH safely falls well within the pharmacist’s competence and experience. Intervention involves a validated customer Symptoms-check Questionnaire (SQ) and specific training is available for all staff, along with protocols for supply and RPSGB practice guidance. All Flomax Relief customers will be given comprehensive information at the start of treatment. Furthermore, differential diagnosis by the GP reduces the risk of missed or delayed diagnosis of serious co-morbid conditions. Tamsulosin is generally well tolerated and has a profile of non-life threatening side effects.

Safety of pharmacy supply is further reinforced by the initial pharmacy counselling and pharmacist supervision model which excludes men with contraindications to treatment with tamsulosin. All customers should be reminded of the potential for adverse effects during treatment and encouraged to alert you or their GP so they can be reported on the Yellow Card Scheme (http://yellowcard.mhra.gov.uk). See the SPC for Flomax Relief and patient information leaflet for more detailed information.
Man presents with urinary symptoms

Prostate health counselling by pharmacist with Symptoms-check Questionnaire

Suitable

Flomax Relief 2 week supply

Week 2 symptoms and side effect review

Suitable

Flomax Relief 4 week supply

Week 6 symptoms and side effect review
Check BPH diagnosis has been confirmed by GP

Suitable

Flomax Relief up to 52 week supply

Week 0

Pharmacist to remind patient to visit GP by week 6 for confirmation of BPH diagnosis if not already done so

Week 2

Pharmacist consultation is to rule out red flag conditions and assess severity & duration of LUTS*

Week 6

Pharmacist to remind patient to visit GP by week 6 for confirmation of BPH diagnosis if not already done so

Week 52

*Lower urinary tract symptoms
Appendix:

Symptoms-check Questionnaire (SQ)

### Symptoms-check Questionnaire

If you have been receiving the symptoms-check questionnaire by mail, please complete and return.

**Q1 About you...**

- **Q1a Are you under the age of 45 years?**
  - Yes
  - No

- **Q1b Are you over the age of 75 years?**
  - Yes
  - No

- **Q1c Have you had prostate surgery?**
  - Yes
  - No

- **Q1d Has your doctor ever diagnosed you as having diabetes?**
  - Yes
  - No

**Q2 About your urinary symptoms...**

- **Q2a Has your doctor already diagnosed you as having an enlarged prostate gland (benign prostatic hyperplasia)?**
  - Yes
  - No

- **Q2b If you have answered Yes to Q2a are you currently taking any prescribed medicines for your BPH from your GP?**
  - Yes
  - No

- **Q2c Have you had these urinary (peeing) symptoms for at least 3 months?**
  - Yes
  - No

**Q3 Do you experience any of the following symptoms?**

- **Q3a Frequent (more often than normal) urination (peeing)?**
  - Slight
  - Less than 1 time in 5
  - Less than half the time
  - Over half the time
  - Never

- **Q3b Struggling or straining to begin urination (peeing)?**
  - Never
  - 1 time
  - 2 times
  - 3 times
  - 4 times
  - 5 times or more

- **Q3c Feeling as if you need to go even when your bladder is only partly full?**
  - No
  - 1
  - 2
  - 3
  - 4
  - 5

- **Q3d Having a sensation of not emptying your bladder completely?**
  - No
  - 1
  - 2
  - 3
  - 4
  - 5

- **Q3e Take a long time for your bladder to completely empty?**
  - No
  - 1
  - 2
  - 3
  - 4
  - 5

- **Q3f Take your Flomax Relief...**
  - Yes
  - No

**Q4 Quality of Life Score (QoL)**

- **Q4a Delighted**
  - Pleased
  - Mostly satisfied
  - Mixed - about equally satisfied & dissatisfied
  - Unhappy

Please answer the questions below by ticking the boxes that apply to you.

**Q5 Are you experiencing any of the following conditions?**

- **Q5a Have you suffered from urinary incontinence?**
  - Yes
  - No

- **Q5b If Yes to any of the above, consult your pharmacist before proceeding further with the questionnaire**

**Q6 Have you experienced any of the following conditions?**

- **Q6a Have you ever had a stroke?**
  - Yes
  - No

- **Q6b Have you ever had a heart attack?**
  - Yes
  - No

- **Q6c Have you ever had or had any of the following conditions?**
  - Stroke
  - Heart attack
  - Cancer
  - Diabetes
  - High blood pressure
  - Asthma
  - Lupus
  - MS
  - Arthritis
  - Parkinson’s disease
  - Cerebral palsy
  - Epilepsy
  - Huntington disease
  - Inflammatory bowel disease
  - Multiple sclerosis
  - Alzheimer’s disease
  - Down’s syndrome
  - Heart disease
  - Lupus
  - MS
  - Arthritis
  - Parkinson’s disease
  - Cerebral palsy
  - Epilepsy
  - Huntington disease
  - Inflammatory bowel disease
  - Multiple sclerosis
  - Alzheimer’s disease
  - Down’s syndrome
  - Heart disease

Please note your score for each symptom in the last column and then add up the total symptoms score.

**Q7 Where do you live?**

- **Q7a City/urban area**
  - Yes
  - No

- **Q7b Rural area**
  - Yes
  - No

- **Q7c Have you ever had a heart attack?**
  - Yes
  - No

- **Q7d Have you ever had surgery?**
  - Yes
  - No

- **Q7e Are you taking any prescribed medicines for your BPH from your GP?**
  - Yes
  - No

- **Q7f Refer to GP**
  - Yes
  - No

### Personal Information

Your information will be held on a database outside any other purpose than to deliver the service referred to in this leaflet. Your information and any other data you may volunteer in the future will be used by the companies (including by personal information controllers) and any other data you may volunteer in the future who are working together to deliver the service referred to in this leaflet. This will form part of a programme to which you have agreed to participate.

**Access your FreeFlo benefits: Register now**

- **I prefer to receive information by:**
  - Email
  - Mobile Phone Number
  - Postcode
  - Address
  - First Name
  - Surname
  - Title

I give my permission to be contacted by the below. It will help us to better understand how men like you feel.

**Take your Flomax Relief regularly**

- FreeFlo coupons for future Flomax Relief purchases
- FREE on-the-go water bottle*
- FREE nurse led advice on your urinary condition
- FREE Flomax Relief programme for future Flomax Relief purchases
- FREE in-the-gro summery brochure
- FREE order form for your pharmacy

**Date of preparation:** December 2009/FMX0055

*Offer valid until 23/12/2009

**Privacy Policy**

Read the privacy policy before proceeding further with the questionnaire.

**Terms and Conditions**

By proceeding further with the questionnaire you agree to the privacy statement and terms and conditions outlined below. It will help us to better understand how men like you feel.

Always read the label and take your Flomax Relief as directed. If you have any further questions, refer to GP.
Appendix:

Patient Information leaflet (PIL)

Package Leaflet: Information for the User.

11/2013

FLOMAX

Read all of this leaflet carefully because it contains important information for you. This medicine is subject to a condition called ‘safer use’ and is not recommended for use by women of childbearing potential. If you are pregnant or planning to become pregnant, you must not use FLOMAX relief for 6 weeks before starting treatment. We do not recommend that you start taking FLOMAX relief before you have consulted your pharmacist. You must not use FLOMAX relief in the following situations:

• You have recently had a bladder or kidney surgery
• You have had any of the medicines listed in the section ‘Contra-indications’

Taking before you start

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

Taking during pregnancy

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During feeding

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During breast feeding

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During lactation

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During menstruation

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During pregnancy

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During breast feeding

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During lactation

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

During menstruation

• If you are pregnant or breastfeeding
• If you are taking other medicines that may interact with FLOMAX relief

Appendix 1. Healthcare professionals

Appendix 2. Medicines supplied

Appendix 3. Pharmaceutical resources

Appendix 4. Other side effects

Appendix 5. How to stop FLOMAX relief

Appendix 6. Further information

What FLOMAX RELIEF contains

• The active substance is tamsulosin hydrochloride. Each capsule contains 0.4 mg.
• The other ingredients are microcrystalline cellulose, methacrylic acid-ethyl acrylate copolymer, polyethylene, sodium benzoate, sucrose, titanium dioxide, xanthan gum, and magnesium stearate.
• The capsules are supplied in a blister pack and an aluminum foil strip.

What FLOMAX RELIEF looks like and contents of the pack

• FLOMAX RELIEF capsules are green-cream and are supplied as a blister pack, containing 14 and 28 capsules, suitable for 14 and 28 days treatment, respectively.

The marketing authorisation for FLOMAX RELIEF is held by Boehringer Ingelheim Limited, Consumer Healthcare, Earl Street, Reading, Berkshire, RG1 2PS.

The capsules are manufactured for: Astellas Pharma Europe B.V., Eilandenpark 14, 2521 EN Leidenberg, The Netherlands, at their site at Hengeloseweg 2, PH4 6 Megafog, The Netherlands.

This leaflet was last revised in September 2009.

Averting your symptoms

Your urinary symptoms can be assessed using a ‘questionnaire’ which you will be asked to complete before starting treatment with FLOMAX relief.

To learn more about BPH visit www.bphinfo.com and call the helpful free of charge on 0800 767 1079.

To receive this leaflet free-of-charge in formats such as audio, Braille or large print, please call the Royal National Institute of the Blind (RNIB) freephone on 0800 198 5000. When prompted, please provide the following information:

Product code number 00015/0280 and be ready to confirm the name of this medicine (FLOMAX RELIEF). © Boehringer Ingelheim Limited 2009

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Appendix:

Registration card

Registration card can be found on the reverse of the Men’s Health Booklet
Appendix:

Glossary of terms

BAUS: British Association of Urological Surgeons
BPH: Benign Prostatic Hyperplasia
CKS: Clinical Knowledge Summaries
CPD: Continuing Professional Development
IFIS: Intraoperative Floppy Iris Syndrome
IPSS: International Prostate Symptom Score
LUTS: Lower Urinary Tract Symptoms
MCA: Medicines Counter Assistant
NICE: National Institute for Health and Clinical Excellence
OTC: Over-The-Counter
PMR: Patient Medication Record
PSA: Prostate Specific Antigen
QoL: Quality of Life
SPC: Summary of Product Characteristics
SQ: Customer Symptoms-check Questionnaire
UTI: Urinary Tract Infection
Appendix:

References

Flomax Relief® MR – Product Information.  

Presentation: Flomax Relief MR containing 0.4mg of tamsulosin hydrochloride in a modified release capsule. Indication: Treatment of functional symptoms of benign prostatic hyperplasia (BPH). Dosage: For men aged 45-75 years. For oral use. One capsule daily. Contraindications: Hypersensitivity to any ingredients of the product; a history of orthostatic hypotension; severe hepatic insufficiency. Warnings and Precautions: Men taking an antihypertensive α₁-adrenoceptor blocker should consult a doctor before taking Flomax Relief. In individual cases a fall in blood pressure can occur. Do not give to a man who experiences postural hypotension. Consult a doctor before taking Flomax Relief if a man has heart, renal, or liver disease, uncontrolled diabetes, urinary incontinence, or has had prostate surgery. Do not supply Flomax Relief to a man whose symptoms are of less than 3 months’ duration. Do not supply to a man who reports dysuria, haematuria, or cloudy urine, in the previous 3 months, or who has a fever that might be related to urinary tract infection. Do not initiate treatment in a man planning cataract surgery, or who has recently experienced blurred or cloudy vision not examined by a doctor or optician. If urinary symptoms have not improved within 14 days of starting treatment the patient should be referred to a doctor. Medical review is required for diagnosis of BPH: Patients must see their doctor within 6 weeks of starting treatment for assessment of their symptoms and confirmation to continue taking Flomax Relief long-term from their pharmacist. Every 12 months, patients should be advised to consult a doctor. Adverse Effects: Common: dizziness. Uncommon: headache, palpitations, postural hypotension, rhinitis, constipation, diarrhoea, nausea, vomiting, rash, pruritus, urticaria, abnormal ejaculation, asthenia. Rare: syncope, angioedema. Very rare: priapism. Drowsiness, blurred vision, dry mouth or oedema can occur. IFIS has occurred in some patients during cataract surgery. RRP (ex VAT): 14 capsules £7.65, 28 capsules £14.46. Legal Category: P. Product Licence Number: PL 00015/0280. Date of revision: December 2009. Further information available from: Boehringer Ingelheim Limited, Consumer Healthcare, Ellesfield Avenue, Bracknell, Berkshire RG12 8YS.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).