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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

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Introduction:

This training guide will help you meet the following Continuing Professional Development (CPD) 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 record. (www.uptodate.org.uk)
Introduction:

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 ideally placed to manage BPH and supply Flomax Relief (tamsulosin). The pharmacist is able to provide 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. This also reinforces the pharmacy’s position as a provider of accessible men’s health services.

The availability of Flomax Relief (tamsulosin) from a pharmacy offers men with BPH convenient access to advice and appropriate treatment, and an exciting professional and business opportunity in men’s health for pharmacists.

Pharmacist Training Guide

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 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 began¹

• Men tend to put up with the anxiety, inconvenience, embarrassment and bothersome symptoms that are often associated with BPH, for a variety of reasons:¹
  • 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 time²

¹ The availability of Flomax Relief (tamsulosin) from a pharmacy offers men with BPH convenient access to advice and appropriate treatment, and an exciting professional and business opportunity in men’s health for pharmacists.

² Pharmacists are ideally placed to manage BPH and supply Flomax Relief (tamsulosin). The pharmacist is able to provide 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. This also reinforces the 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.
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.

The enlargement is caused by long-term exposure of the prostate to androgen, 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 prostatic specific antigen (PSA), which liquefies the ejaculate to improve the chances of fertilisation.

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 prostate – 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. 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. 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.
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.

The extent of the problem
Men with LUTS due to BPH commonly:
• have the sensation of not completely emptying the bladder after finishing urinating
• get up frequently during the night to urinate
• worry about their condition.

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 – alpha-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 for men with larger prostates. 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.

Lifestyle advice
Some men with an enlarged prostate have found that the following lifestyle changes can alleviate symptoms:
• Avoid drinking large amounts of liquid at any time – however, it is important to keep well hydrated
• Avoid drinks altogether before going to bed – exact quantities and timescales are determined by the individual
• Reduce the amount of alcohol consumed (alcohol can stimulate the bladder)
• Cut back on coffee, tea, cola or any other drinks that contain caffeine because it can stimulate the bladder
• Check any medicines being taken. Tricyclic antidepressants, antimuscarinics (drugs with anticholinergic action), and sedating antihistamines can cause retention of urine and make problems with urinating worse.
Supply starts

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

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 page 2 on next page)

Pharmacist does not supply Flomax Relief and refers patient to GP

Section 2: Pharmacist supervision model for Flomax Relief

Week 0

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

Section 2: Pharmacist supervision model for Flomax Relief

Flomax Relief - an OTC treatment for BPH

Flomax Relief (tamsulosin hydrochloride 0.4 mg modified release capsules) is an over-the-counter treatment for the urinary symptoms of BPH. Tamsulosin, an alpha-adrenoceptor antagonist (alpha-blocker) is a well established and generally well tolerated treatment available on prescription and from the pharmacy. There are few drug interactions11 reported in association with the drug and, as with all medications, side effects may occur, but the pharmacist is able to supply Flomax Relief after consultation and taking through the questionnaire (SQ).10

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 re-visit 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:

- Alpha-blockers are a first-line treatment for BPH
- 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 treatment
- Is taken as a ONCE-daily dose, as one capsule per day with no dose titration required
- Few drug interactions11 associated with tamsulosin and, as with other medications, side effects may occur, but Flomax Relief can be provided to suitable men.10

Pharmacist offers lifestyle advice

Week 1

Patient can return for a further 4-week supply (see page 2 on next page)
Section 2:
Pharmacist supervision model for Flomax Relief

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
  - Pharmacist can supply 4-week pack of Flomax Relief. Patient advised to see GP every 12 months for annual consultation
  - Pharmacist does not make a further supply and refers patient to GP for further assessment

Week 6

- Patient returns for further supply of Flomax Relief
  - Patient has not yet had diagnosis/treatment confirmed by GP
  - Patient has had diagnosis/treatment confirmed by GP
  - Pharmacist advises the patient that they cannot be supplied with further Flomax Relief until GP confirms BPH diagnosis
  - Pharmacist can supply 2 or 4-week pack of Flomax Relief. Patient advised to see GP every 12 months for annual consultation
  - Pharmacist recommends patient who has been taking Flomax Relief for 12 months to visit GP for annual consultation

Week 52

- Patient has not yet had diagnosis/treatment confirmed by GP
  - Patient has had diagnosis/treatment confirmed by GP
  - Pharmacist advises the patient that they cannot be supplied with further Flomax Relief until GP confirms BPH diagnosis
  - Pharmacist can supply 2 or 4-week pack of Flomax Relief. Patient advised to see GP every 12 months 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?

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Section 2: Customer Symptoms-check Questionnaire (SQ)

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.

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 alpha-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 glaucoma, 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 or glaucoma 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 GP¹⁰

### 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 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 planned for cataract or glaucoma
- 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

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**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.

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**Men’s Health Booklet**

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

- Consumer and healthcare professional website - www.flomaxrelief.co.uk contains comprehensive information and downloadable BPH management tools for both consumers and pharmacists
Section 3: Flomax Relief

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 after the same meal each day.

Mode of action
Tamsulosin binds selectively and competitively to post-synaptic alpha1-receptors, in particular to the sub-type alpha1A, 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. Symptom relief continues to increase for up to 12 weeks.

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.

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 alpha1-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 15 years and as an alpha1-blocker it is a first-line treatment for BPH.

There are few drug interactions associated with the drug and, as with all medications, side effects may occur, but Flomax Relief can be supplied to suitable men after consultation and reviewing the questionnaire (SQ). Flomax Relief can be recommended by the pharmacist to patients taking antihypertensives (other than alpha-blockers due to potential additive effect).

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Section 4: 
Pharmacy’s role in improving men’s 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
• 1in4men
  www.1in4men.co.uk
• Men’s Health Forum
  www.menshealthforum.org.uk
• Prostate Cancer Research Centre
  www.prostate-cancer-research.org.uk
• Royal Pharmaceutical Society of Great Britain
  www.rpsgb.org.uk
• NICE Clinical Knowledge Summaries
  www.cks.nice.org.uk

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 point-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.

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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


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 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 at 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 urinary frequency and urgency. 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 at this 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 metformin, there is no interaction suggested, and find out whether there is an adherence issue which is preventing the man from gaining benefit from treatment.

The man should be referred to the GP for further investigation and perhaps a different treatment.

Example 3

A man has already been taking OTC tamsulosin for the past 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.

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. As with all medicines side effects may occur, but Flomax Relief can be supplied to suitable men after consultation and reviewing the questionnaire (SQ).  

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. NICE guidelines recommend offering men with LUTS information, advice and time to decide if they wish to have PSA testing. 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 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 as with all medications, there are side effects, but it can be safely supplied to suitable men after consultation and reviewing the questionnaire (SQ).

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.

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.
Appendix: Symptoms-check Questionnaire (SQ)

**Man presents with urinary symptoms**

- Week 0
  - Suitable
    - Flomax Relief 2 week supply
  - Unsuitable
    - Refer to GP

- Week 2
  - Suitable
    - Flomax Relief 4 week supply
  - Unsuitable
    - Refer to GP

- Week 6
  - Suitable
    - Check BPH diagnosis has been confirmed by GP
  - Unsuitable
    - Refer to GP

Week 52

- Flomax Relief up to 52 week supply

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

**Q1 ABOUT YOU…**
- Are you under the age of 45 years? Yes No
- Are you over the age of 75 years? Yes No
- Have you had prostate surgery? Yes No
- Has your doctor ever diagnosed you as having diabetes? Yes No

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

**Q2 ABOUT YOUR MEDICAL HISTORY…**
- Any problem with your liver? Yes No
- Any problem with your kidneys? Yes No
- Any problem with your eyes? Yes No
- Any problem with your heart? Yes No
- No eye operation planned? Yes No
- Any blurred or cloudy vision that has not been examined by your GP or optician? Yes No
- Fainting, dizziness or weakness when you stand up? Yes No

**Q3 DO YOU EXPERIENCE ANY OF THE FOLLOWING SYMPTOMS?**
- Frequency.
- Urgency.
- Intermitency.
- Straining.
- Push or strain to begin urination (peeing).
- Over the past month, how often have you had to most typically get up to urinate (pee) from the time you most typically get up in the morning?
- Never 1 time 2 times 3 times 4 times 5 times or more
- 0 1 2 3 4 5

Total Symptoms Score:

**Q4 QUALITY OF LIFE SCORE (QOL)**
- Delighted
- Pleased
- Mostly satisfied
- Mixed - about equally satisfied & dissatisfied
- More dissatisfied
- Completely after you finish urinating (peeing)

Over the past month, how do you feel about that?
- Never 1 time 2 times 3 times 4 times 5 times or more
- 0 1 2 3 4 5

What medicines are you currently taking, either prescribed by your doctor, or that you are buying?

**Q5 DO ANY OF THESE STATEMENTS APPLY TO YOU?**
- I am currently experiencing pain on urination (peeing) Yes No
- I have had cloudy urine (pee) in the last 3 months Yes No
- I have got a fever at the moment Yes No
- I have got leaking of urine (incontinence) Yes No

**Q7 Have you ever had an allergy to tamsulosin or a bad reaction to it?** Yes No

**Q5c I have had cloudy urine (pee) in the last 3 months**

**Q5e I have got leaking of urine (incontinence)**

**Q5d I have got a fever at the moment**

**Q5a I am currently experiencing pain on urination (peeing)**

**Q7 Have you ever had an allergy to tamsulosin or a bad reaction to it?** Yes No

**Appendix:**

Flomax Relief is not suitable for this man and I have advised him to see you.

I would be grateful if you could assess him.

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

Pharmacist supervision model

Man presents with urinary symptoms

Prostate health counselling by pharmacist with Symptoms-check Questionnaire

Suitable

Unsuitable

Flomax Relief 2 week supply

Flomax Relief 4 week supply

Flomax Relief up to 52 week supply

Week 2 symptoms and side effect review

Week 2 symptoms and side effect review

Week 6 symptoms and side effect review

Check BPH diagnosis has been confirmed by GP

Suitable

Unsuitable

Refer to GP

Refer to GP

Refer to GP

"Lower urinary tract symptoms"
1. What FLOMAX RELIEF is and what it is used for

FLOMAX RELIEF is used to treat the lower urinary tract symptoms (LUTS) of a common condition called benign prostate hyperplasia (BPH). It is also called benign prostatic enlargement.

FLOMAX RELIEF is a medication that helps to relieve the symptoms of BPH, such as:

- Difficulty starting to urinate
- Frequent urge to urinate
- Urinating more often than usual
- Urinating during the night
- Weak stream or a stream that stops and then starts again
- Feeling that you have not completely emptied your bladder after urination
- Straining to urinate
- Urinary urgency
- Urging to urinate
- Urinating in a hurry
- Loss of your bladder control

FLOMAX RELIEF should be used only by men who have BPH.

2. Before you start FLOMAX RELIEF

Read the information on the patient leaflet that comes with this medicine. If you have any questions, ask your doctor or pharmacist for advice.

3. How to take FLOMAX RELIEF

Take the capsules whole with water after a meal. Take one capsule daily at the same time each day, usually in the evening.

4. Possible side effects

This medicine can cause side effects, although not everybody gets them. Common side effects include:

- Feeling faint
- Feeling sick or being sick
- Drowsiness
- Headache
- Stomach pain or indigestion

Less common side effects include:

- Nervousness
- Dizziness
- Dry mouth
- Numbness or tingling

Rare side effects include:

- Swollen hands or feet
- Feeling dizzy (common - affects less than 1 in 100 people)
- Feeling faint (common - affects less than 1 in 100 people)
- Feeling sick or being sick (common - affects less than 1 in 100 people)
- Drowsiness
- Headache

Serious side effects are rare or very rare. Stop taking FLOMAX RELIEF and see your doctor straight away if you experience any of the following:

- Swollen lymph glands
- Rash
- Queasy feeling
- Difficulty breathing
- Swelling of the face
- Breathing difficulty
- Chest pain
- Combination of chest pain, nausea, and sweating

If you take more of this medicine than you should, talk to a doctor or pharmacist straight away.

Side effects not listed in this leaflet. You can also report side effects you can help provide more information. To report a side effect you can help provide more information. To report these side effects you can help provide more information. To report these side effects you can help provide more information.

5. How to store FLOMAX RELIEF

Do not use the capsules after the expiry date. To find this information, look on the base of the pack or container. The expiry date is stated on the base of the pack. This medicine should be stored in a cool, dry place.

6. Further information

If you think you have diabetics and it is not controlled, consult a doctor.

If you are about to undergo eye surgery for cataract and you are taking tamsulosin. The operation may need to be postponed if you are taking tamsulosin. The operation may need to be postponed if you are taking tamsulosin.

If you are currently taking FLOMAX RELIEF, you should tell your doctor or pharmacist before taking these capsules.

If you have recently had blurred or cloudy vision and at sometime in the last year your vision has become cloudy or bloodied, contact your doctor or pharmacist.

This lets urine pass more freely through the urethra, making it easier to urinate.

FLOMAX RELIEF is used to treat the lower urinary tract symptoms (LUTS) of a common condition called benign prostate hyperplasia (BPH). It is also called benign prostatic enlargement.

FLOMAX RELIEF is a modified release capsule which contains a medicine called tamsulosin. This medicine is Pan Black.

Print colors:

• Black

The name of your medicine is FLOMAX RELIEF MR.
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

References

10. Fioms Relief MIR Summary of Product Characteristics.

Warnings and Precautions: Men taking an antihypertensive alpha1-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. Do not use in combination with strong inhibitors of CYP3A4 (e.g. ketoconazole) in patients with poor metaboliser CYP2D6 phenotype. Use with caution in combination with strong (e.g. ketoconazole) and moderate (e.g. erythromycin) inhibitors of CYP3A4. 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 experiences 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 or glaucoma 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, ejaculation disorders. Uncommon: headache, palpitations, orthostatic hypotension, rhinitis, constipation, diarrhoea, nausea, vomiting, rash, pruritus, urticaria, asthenia. Rare: syncope, angioedema. Very rare: Stevens-Johnson syndrome, priapism. Drowsiness or oedema can occur. Blurred vision, vision impairment, dry mouth, epistaxis, erythema multiforme, dermatitis exfoliative, atrial fibrillation, arrhythmia, tachycardia, and dyspnoea have been reported. IFIS has occurred in some patients during cataract or glaucoma surgery. RRP (ex VAT): 14 capsules £7.65, 28 capsules £14.46. Legal Category: P. Product Licence Number: PL 00015/0280. Date of revision: April 2014. Further Information available from: Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire RG12 8YS.

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

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