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PAN MERSEY AREA PRESCRIBING COMMITTEE  
 PRESCRIBING POLICY STATEMENT



Pan Mersey

Area Prescribing Committee

REF: PS36 FINAL

FIRST APC BOARD DATE: 08 JAN 2014

LAST APC BOARD DATE: 28 MAR 2018

## FINASTERIDE 5mg tablets

GREEN

The Pan Mersey Area Prescribing Committee recommends **FINASTERIDE** 5mg tablets as the 5-alpha reductase inhibitor of choice for men with lower urinary tract symptoms (LUTS) as detailed below.<sup>1</sup>

The Pan Mersey Area Prescribing Committee (APC) recommends **FINASTERIDE** as the 5-alpha reductase inhibitor of choice for men with LUTS who have prostates estimated to be larger than 30g or a PSA level > 1.4nanogram/mL, and who are considered to be at high risk of progression (for example, older men).<sup>1</sup>

Consider adding in an alpha blocker for men with bothersome moderate to severe LUTS<sup>1</sup> which should be prescribed as the separate components, as the Pan Mersey APC does not recommend oral combination products e.g. [Combodart<sup>®</sup>](#) (dutasteride + tamsulosin).

- The EPICS study found, when dutasteride or finasteride were administered for 12 months, they were similarly effective at 3 months and 12 months in reducing prostate volume, improving Q<sub>max</sub> (maximum urinary flow rate) and urinary symptoms associated with benign prostatic hyperplasia (BPH) in men with an enlarged prostate.<sup>2</sup>
- Finasteride is significantly less expensive than the alternative 5-α reductase inhibitor dutasteride.<sup>3</sup>

Current expenditure on dutasteride (Avodart<sup>®</sup>) and Combodart<sup>®</sup> (combination of dutasteride and tamsulosin) across the Pan Mersey locality is > £157,000 per annum.

If all the dutasteride (Avodart<sup>®</sup>) was prescribed as finasteride and all the Combodart<sup>®</sup> was prescribed as finasteride and tamsulosin separately, there could be a saving of > £106,000 across the Pan Mersey locality.

**Note:** Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. If appropriate, an exceptional funding request will be required following the usual locally defined process.

## FINASTERIDE 5mg tablets

### EFFECTIVENESS

Finasteride & dutasteride block the conversion of testosterone to dihydrotestosterone (DHT) by the enzyme 5 $\alpha$ -reductase. DHT is associated with the development of benign prostatic hyperplasia (BPH). Finasteride is selective for type 2 isoenzyme of 5 $\alpha$ -reductase, which is found in male genitalia and the prostate. Dutasteride is non-selective and inhibits both isoenzyme type 2 and type 1 (which is located predominantly in the skin, hair follicles and sebaceous glands).<sup>4</sup> EPICS, a multicentre, randomised, double-blind, double-dummy, 12 month parallel-group study where men with a clinical diagnosis of BPH received finasteride 5mg daily (n=817) or dutasteride 500 micrograms daily (n=813) for 48 weeks. The study found at month 3 a mean percentage reduction in prostate volume of 18.5% and 18.3% for the finasteride and dutasteride groups respectively (p = 0.76) and at month 12, the reduction was 26.7% for finasteride and 26.3% for dutasteride groups (p = 0.65). At month 3 the Q<sub>max</sub> improved by 1.6 mL/s for the dutasteride and 1.5 mL/s for the finasteride group. By month 12 this had improved to 1.7 mL/s and 2.0 mL/s in the finasteride and dutasteride groups respectively (p=0.14).<sup>2</sup>

### SAFETY

In the EPICS study there were no differences in the overall numbers of adverse events between the finasteride and dutasteride groups.<sup>2</sup> Common adverse events were; decreased volume of ejaculation, impotence and decreased libido which resolve, for most, with continued treatment. Contraindications; hypersensitivity to any component, children, use in women when they are or may potentially be pregnant.<sup>5</sup> Breast cancer has been reported in men taking finasteride, patients should be instructed to promptly report any changes in their breast tissue.<sup>5</sup> See relevant SPC for most up to date information.

### COSTS (per patient per year)

Dutasteride (Avodart<sup>®</sup>) £159.43/year<sup>7</sup>  
 Dutasteride & Tamsulosin (Combodart<sup>®</sup>) £240.24/year<sup>3</sup>  
 Finasteride £13.00/year<sup>3</sup>  
 Doxazosin immediate release tablets £8.71-18.98/year<sup>7</sup>  
 Tamsulosin **capsules** £46.96 (tablets £127.04)/year<sup>3</sup>  
 Current expenditure within primary care across the Pan Mersey locality on Combodart<sup>®</sup> and Avodart<sup>®</sup> is > **£157,000** (ePACT)

### PATIENT FACTORS

For finasteride no dosage adjustment is required in the elderly or in patients with varying degrees of renal insufficiency (CrCl as low as 9 mL/min).<sup>5</sup> No data available for hepatic insufficiency.<sup>5</sup>

### PRESCRIBING INFORMATION

The dose of finasteride for benign prostatic hypertrophy is 5mg daily, taken orally with or without food.<sup>5</sup>

### IMPLEMENTATION NOTES

Patients can be managed in primary care - see [NICE Clinical Knowledge Summary](#) for full guidance. Exclude or manage causes of obstructive symptoms, for example drugs, neurological conditions, urethral stricture, and cancer (prostate, bladder, rectum). If the man has an enlarged prostate (if it weighs more than 30 g) and is considered to be at high risk of progression, offer finasteride. Prostatic enlargement can be estimated clinically by digital rectal examination, or indirectly with the prostate specific antigen (PSA) test - PSA higher than 1.4 nanogram/mL is a sign of an enlarged prostate. Review the man's symptoms, quality of life, and adverse effects at 3–6 months, and then every 6–12 months. If treatment fails to adequately relieve symptoms then consider offering a referral to a urologist for assessment and further management.<sup>6</sup> Digital rectal examination as well as other evaluations for prostate cancer are recommended prior to initiating finasteride and periodically thereafter. Generally a baseline PSA > 4 ng/mL prompts further evaluation, however PSA < 4ng/mL does not exclude prostate cancer. N.B. when PSA levels are evaluated consideration should be given to the fact finasteride decreases levels in treated patients (by approximately 50%).<sup>5</sup>

### REFERENCES

1. [NICE Clinical Guideline 97](#). Lower urinary tract symptoms. May 2010 (reviewed June 2015)
2. Curtis Nickel J, et al. Comparison of dutasteride and finasteride for treating benign prostatic hyperplasia: the Enlarged Prostate International Comparator Study (EPICS). *BJU international* 2011; 108(3):388-394.
3. National Health Service England and Wales. Drug Tariff. January 2018.
4. Clark R V, et al. Marked Suppression of Dihydrotestosterone in Men with Benign Prostatic Hyperplasia by Dutasteride, a Dual 5 $\alpha$ -Reductase Inhibitor. *J Clin Endocrinol Metab* 2004; 89(5):2179-2184.
5. [Summary of Product Characteristics](#): Finasteride 5 mg tablets (Actavis). Accessed 28/12/17
6. Clinical Knowledge Summaries. [LUTS in men](#). Accessed 28/12/17
7. NHS BSA DM+D accessed 28/12/17