Combodart
(dutasteride/tamsulosin)

For the treatment of Benign Prostatic Hyperplasia (BPH)

This leaflet is only for use by patients who have been prescribed Combodart. Please see Patient Information Leaflet for full information on Combodart.

Please contact your doctor, nurse of pharmacist if you have any questions or concerns.
What is BPH?
BPH refers to benign enlargement of the prostate.
It is a common condition in men as they get older, especially over the age of 50, and can cause problems with urination.

50% of men between the ages of 51 and 60, and up to 90% of men over the age of 80 will experience BPH symptoms.

BPH is a benign condition and is not prostate cancer.
In BPH, the prostate gland enlarges. The enlarging prostate gland can squeeze the urethra, the tube that carries urine out of the body. This can cause men to have trouble urinating leading to the symptoms of BPH (See Figure 1).

What are the key symptoms associated with BPH?
Men with BPH can suffer a reduction in their quality of life, because of their symptoms. These can be one or more of the following:

- The need to pass urine often, or with no warning
- Waking up more often during the night to urinate
- Difficulty in starting to pass urine
- Weak or interrupted urine stream
- Unable to completely stop the flow of urine when you want
- Feeling that the bladder is not empty after you have been to the toilet
- Leaking and dribbling of urine
What happens if BPH gets worse?

As it gets worse, BPH can lead to:

- Continued prostate growth
- An increased risk of complete blockage of urine flow (acute urinary retention) and/or the need for surgery
- Worsening symptoms.

Other complications include bladder stones, bladder infections, blood in the urine or damage to kidneys from back pressure caused by retaining large amounts of extra urine in the bladder.

Men aged 50 years or older, with moderate to severe symptoms associated with BPH, an enlarged prostate size (a doctor assesses this) and an elevated prostate specific antigen (PSA) level may be at risk of BPH getting worse.
Frequently asked Questions

Combodart is used to treat men with an enlarged prostate (benign prostatic hyperplasia) - a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.

Please refer to the package insert/patient leaflet for full information on your medicine.

1) What is Combodart and how does it work?

It is the combination of two different medicines called dutasteride and tamsulosin.

Dutasteride helps to shrink the prostate, reducing the risk of acute urinary retention and the need for prostate surgery.

Tamsulosin relaxes the muscles in your prostate gland and urethra, making it easier to pass urine, and improves symptoms.

2) How to take Combodart?

You should always take Combodart exactly as the doctor has prescribed.

The usual dose is one capsule once a day, 30 minutes after the same meal each day, with a glass of water.

This is a long-term treatment. You should continue treatment for a long as your doctor prescribes it.
3) What are the possible side effects?
Like all medicines, Combodart can cause side effects, although not everybody gets them.

For a complete list of potential side effects, please read the patient information leaflet.

The likelihood of side effects is higher during the first year of treatment, and decreases over the following years.

**Common side effects (these may affect up to 10% of men taking Combodart) are:**

- impotence (not able to achieve or maintain an erection)*
- decreased sex drive (*libido*)*
- difficulty with ejaculation, such as a decrease in the amount of semen released during sex*
- breast enlargement or tenderness (*gynecomastia*)
- dizziness.

*In a small number of people some of these events may continue after you stop taking Combodart.

*Please contact your doctor, nurse or pharmacist if you have concerns or experience any side effects.*

Always take Combodart exactly as your doctor has directed. If you do not take it regularly the monitoring of your PSA levels may be affected. Please check with your doctor or pharmacists if you are not sure.
BPH refers to **benign** enlargement of the prostate. It is common in **men over the age of 50**; in fact 50% of men between the ages of 51 and 60, and up to 90% of men over the age of 80 will experience BPH symptoms.

Men with BPH can suffer a significant reduction of their quality of life because of their symptoms.

Remember that if BPH is **not treated appropriately** it is likely to **get worse** and can lead to complete blockage of urine flow (acute urinary retention) and/or the need for surgery.

Combodart is prescribed to improve BPH symptoms and to reduce the risk of acute urinary retention and the need for prostate surgery.

**If you experience any side effects, you should contact your doctor, nurse or pharmacist.**

**It is important to continue with your BPH treatment, even if you are feeling better, as it is likely to get worse again without it.**

**Always take Combodart exactly as your doctor has directed. If you do not take it regularly the monitoring of your PSA levels may be affected. Please check with your doctor or pharmacist if you are unsure.**

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