DUOFLOW 0.5 MG/0.4 MG HARD CAPSULES

Dutasteride/ tamsulosin hydrochloride (0.5mg/0.4mg)

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What DUOFLOW is used for

DUOFLOW is to treat men with moderate to severe symptoms of benign prostatic hyperplasia (BPH) - a non-cancerous growth of the prostate gland caused by producing too much of a hormone called DHT (dihydrotestosterone). DUOFLOW reduces the risk of acute urinary retention and the need for surgery in people with moderate to severe symptoms of BPH.

How DUOFLOW works

DUOFLOW is a combination of two different medicines called dutasteride and tamsulosin. Dutasteride belongs to the group of medicines called 5-alpha reductase inhibitors and tamsulosin belongs to the group of medicines called alpha blockers.

As the prostate grows, it can lead to urinary problems such as difficulty in passing urine and a need to urinate more frequently. It can also cause your urine stream to be smaller and less strong. If left untreated, there is a risk that the flow of urine will be completely blocked.

Dutasteride helps to shrink the prostate and relieve symptoms, by reducing the amount of DHT your body produces.

Tamsulosin works by relaxing the muscles of the prostate, making it easier to pass urine and quickly improving symptoms.

Before you use DUOFLOW

When you must not use it

Do not take DUOFLOW
- if you are allergic (hypersensitive) to dutasteride, other 5-alpha reductase inhibitors, tamsulosin or to any of the other ingredients of this medicine.
- if you experience fainting due to a drop in blood pressure when changing posture (sitting and standing) (orthostatic hypotension).
- if you have severe liver disease.
- if you are female or age 21 years and below. This medicine is for adult men only.

Before you start to use it

Take special care with DUOFLOW
- In clinical studies with dutasteride, some individuals taking dutasteride and an alpha-blocker had heart failure more often than individuals taking only dutasteride or only an alpha-blocker. (Heart failure means your heart does not pump blood as well as it should.) Caution is advised in individuals with coronary heart disease and swallowing disorder.
- If you have mild to moderate liver disease, check with your doctor that DUOFLOW is suitable for you. You may need extra check-ups while you are taking DUOFLOW.
- If you have severe kidney impairment, incomplete bladder emptying and/or severely impaired urine flow.
- If you are going to have cataract (cloudy lens), glaucoma (increased eye pressure) surgery. Tell your doctor or eye specialist before your operation that you are taking, or have previously taken DUOFLOW. They may ask you to temporarily stop taking DUOFLOW 1-2 weeks before your operation.
- Women, children and adolescents must not handle leaking DUOFLOW capsules, because the active ingredient can be absorbed through the skin. Wash the affected area immediately with soap and water if there is any contact with the skin.
- DUOFLOW may cause breast enlargement and tenderness. If this becomes troublesome, or if you notice breast lumps or nipple discharge you should talk to your doctor about these changes as these may be signs of a serious condition, such as breast cancer.

Taking other medicines

Tell your doctor if you are taking any other medicine, or have recently taken any. This includes medicines purchased without a prescription.

Do not take DUOFLOW with these medications:
- other alpha blockers (for an enlarged prostate or high blood pressure).

Taking DUOFLOW with these medications is not recommended:
- *ketoconazole, itraconazole, fluconazole* (used to treat fungal infections).

Certain medicines can interact with DUOFLOW which can lead to side effects for you. Some of these medications are:
- *PDE5 inhibitors* (used to help achieve or maintain an erection)
- *warfarin* (to prevent blood clotting)
- *erythromycin, clarithromycin* (antibiotics used to treat infections)
- *verapamil, diltiazem, amiodarone* (to treat irregular heartbeat)
- *cimetidine* (to treat heartburn)
- *paroxetine* (an antidepressant)

This is not a complete list of interactions. Tell your doctor if you are taking any of these medications.

How to use DUOFLOW

Always take DUOFLOW exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

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How much to take
The usual dose of DUOFLOW is one capsule taken once a day.
When to use it
Swallow DUOFLOW whole with some water, approximately 30 minutes after the same meal each day. Do not chew or open the capsules. Contact with the contents of the capsules may make your mouth or throat sore.

How long to use it
Take DUOFLOW for as long as your doctor recommends. Don't stop taking it without talking to your doctor first.

On discontinuing DUOFLOW the prostate can go back to the size it was prior to the treatment.

If you forget to use it
Do not take extra capsules to make up for a forgotten dose. Take the next dose at the usual time.

If you use too much (overdose)
Contact your doctor or pharmacist for advice if you take too many DUOFLOW capsules. If possible, show them the DUOFLOW pack. Acute low blood pressure (systolic blood pressure 70 mmHg), vomiting and diarrhea were observed in these people.

While you are using it

Things you must do
Men taking dutasteride had a serious form of prostate cancer more often than men who did not take dutasteride.

A blood test to measure the amount of a substance called PSA (prostate specific antigen) in your blood can help your doctor to tell if you have prostate disease, including prostate cancer. If you have a higher-than-normal amount of PSA in your blood it could mean that you have prostate cancer.

Men taking DUOFLOW should have their PSA measured 6 months after starting treatment and regularly thereafter.

Taking DUOFLOW will reduce the amount of PSA measured in your blood. You could still be at risk for prostate cancer even though your PSA is lower. Your doctor can still use PSA to help detect prostate cancer, by comparing your test results each time you have a PSA test.

It is important to take your medicine as your doctor recommends. If you do not take it regularly it may interfere with your doctor's ability to monitor your PSA.

Things you must not do
This medicine has been prescribed for you personally. Don't pass it on to other people as it may harm them even if their symptoms seem to be the same as yours.

Things to be careful of
Pregnancy and breast-feeding
Women who are pregnant (or may be) must not handle leaking capsules. Dutasteride is absorbed through the skin and can affect the normal development of a male baby. Contact your doctor for advice if a pregnant woman has come into contact with the contents of DUOFLOW.

Male Fertility
DUOFLOW has been shown to reduce sperm count, semen volume and sperm movement. However, it is not clear if male fertility is affected by DUOFLOW.

Driving and using machines
DUOFLOW can make some people feel dizzy and have vision disturbance. Don't drive or operate machinery unless you're feeling well.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dizziness, light-headedness and fainting:
DUOFLOW can cause dizziness, light-headedness and on rare occasions fainting. Take care when moving from a lying down or sitting position to sitting or standing, particularly if you wake up in the night, until you know how this medicine affects you. If you feel dizzy or light-headed at any time during treatment, sit or lie down until the symptoms pass.

Allergic reaction:
Signs can include:
- raised and itch rash (hives)
- swelling, sometimes of the face or mouth (angioedema) causing difficulty in breathing
- collapse

Contact a doctor immediately if you get any of these symptoms. Stop taking DUOFLOW.

Severe skin reactions:
Signs can include:
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome).

Contact your doctor immediately if you have these symptoms and stop using DUOFLOW.

Common side effects:
- not able to achieve or maintain an erection)
- decreased sex drive*
- difficulty in ejaculation*
- breast enlargement and tenderness
- dizziness

*these may continue after you stop taking DUOFLOW.

Uncommon side effects:
- feeling of fast heart beat
- constipation, diarrhea, vomiting, feeling sick (nausea)
- weakness or loss of strength
- itchy, blocked or runny nose

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Very rare side effects:
- persistent and painful erection of the penis

Contact a doctor urgently if this happens to you. You may need to have treatment to avoid serious complications.
- depressed mood
- pain and swelling in your testicles.

Other side effects:
Other side effects have occurred but their exact frequency is unknown:
- irregular or fast heartbeat
- shortness of breath
- breast cancer in men

If you get side effects
Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of DUOFLOW

Storage
Keep this medicine out of the sight and reach of children.

The product must be used within 90 days after opening.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store below 30°C.

Disposal
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

What it looks like
Oblong hard gelatin capsule of brown color and cap of beige color with C001 printed in black ink in the cap. Content of the capsule: oblong soft gelatine capsule (approximately 16.5 x 6.5 mm) of light yellow colour, filled with transparent liquid and pellets of tamsulosin of white to off white color.

Ingredients
Active Ingredient
The active substance of DUOFLOW is 0.5 mg dutasteride and 0.4mg tamsulosin hydrochloride.

Inactive ingredients

Hard capsule shell:
Black iron oxide (E172)
Red iron oxide (E172)
Titanium Dioxide (E171)
Yellow iron Oxide (E172)
Bovine Gelatin

Dutasteride capsule, soft:
Propylene Glycol Monocaprylate
Butylhydroxytoluene (E321)
Bovine Gelatin
Glycerol
Titanium dioxide (E171)
Triglycerides (medium chain)
Lecithin (may contain soya oil)

Tamsulosin pellets:
Methylacrylic acid and ethyl acrylate copolymer (1: 1) dispersion 30 percent (contains polysorbate 80 and sodium lauryl sulfate)
Cellulose Microcrystalline
Dibutyl sebacate
Polysorbate 80
Colloidal hydrated silica
Calcium stearate

Black inks:
Shellac
Black iron oxide (E172)
Propylene glycol
Ammonia solution, concentrated
Potassium hydroxide

MAL number
MAL24066026AZ

Manufacturer
Laboratorios León Farma, S.A
Polígono Industrial Navatejera,
C/ La Vallina s/n,
Villaquilambre- León, 24193 Spain

Product Registration Holder
Intega Sdn Bhd
12B(B), Jalan SJ6,
Taman Selayang Jaya
68100 Batu Caves,
Selangor

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