

Consumer Medicine Information

FINTRAL[®]

Finasteride

5mg Tablet

What is in the leaflet:

This leaflet answers some common questions about FINTRAL.

It does not contain all possible information, nor does it take the place of talking to your doctor or pharmacist.

Since all medicines have risks and benefits your doctor has weighed the risks of you taking FINTRAL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

What FINTRAL is used for

FINTRAL is for men only.

FINTRAL is used to treat a medical condition in men known as benign prostatic hyperplasia or BPH. BPH is a condition where the prostate gland (which is near your bladder) gets bigger making it more difficult to pass urine. This can lead to symptoms such as:

- delay before you start to pass urine
- weak or interrupted stream of urine
- needing to pass urine often, especially at night
- feeling that you must pass urine right away.
- feeling that you cannot empty your bladder completely.

BPH occurs only in men over the age of 50 years. If not treated, it could lead to serious problems, including urinary tract infections and sudden difficulty in passing urine.

The prostate gland does grow very slowly; thus, the symptoms of BPH may take a long time to develop. FINTRAL works in slowly reducing the size of your prostate gland. This may lead to a gradual improvement in your urine flow and other symptoms over several months. FINTRAL also helps reduce the risk of developing a sudden inability to pass urine (acute urinary retention) and the need for surgery. This may happen whether or not you notice any improvement or change in symptoms.

If prescribed for another reason, do ask your doctor if you have any questions about why FINTRAL has been prescribed for you.

FINTRAL is not addictive.

Before you use FINTRAL

When you must not take it

Please, do not take FINTRAL if:

- you have an allergy to FINTRAL or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction to FINTRAL may include skin rash or swelling of the lips or face.
- A torn package or shows signs of tampering
- the expiry date on the pack has passed

If you are not sure whether you should start taking FINTRAL, ring your doctor.

Do not give FINTRAL to women or children

Women who are pregnant or may get pregnant should not be allowed to take FINTRAL or even handle broken tablets. If the active ingredient in FINTRAL is absorbed after swallowing the tablet or through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormal sex organs.

FINTRAL tablets are coated and will prevent contact with the active ingredient during normal handling, provided the tablets are not broken or crushed.

In case a pregnant woman swallows FINTRAL or handles broken tablets, she should consult her doctor, immediately.

Prior to taking the drug: Tell your doctor if:

- you have or have had any medical conditions
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- If you are taking any other medicines, even those bought from the pharmacy, supermarket or health food shop.

Using FINTRAL

How much to take

Take FINTRAL only when prescribed by your doctor. The usual dose for men is one tablet per day taken with a glass of water.

The doctor's instructions should be followed carefully as they may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

When to take it

Preferably you should take FINTRAL once a day at about the same time each day. This will help you to remember to take the tablets.

It does not matter if you take FINTRAL before or after food.

How long to take it

FINTRAL shrinks the prostate gland very slowly. Therefore, you may need to take FINTRAL for at least 6 months or longer to see whether it helps you. If it does help your symptoms, you may need to take FINTRAL every day. Continue taking FINTRAL for as long as your doctor prescribes. If you stop taking the medicine the prostate gland is likely to grow again.

If you forget to take it

If it is almost time for your next dose, please skip the missed dose and take your next dose. Otherwise, take it as soon as you remember, and then go back to taking your tablet as you would normally.

If you are still unsure you should talk to your doctor or pharmacist.

Never take a double dose to make up for a missed dose.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (New Zealand telephone 0800 POISON or 0800 764 766) for advice, if you think that you or anyone else may have taken too much FINTRAL. Do this even if there are no signs of discomfort or poisoning.

While you are using FINTRAL

Things you must do

- Go for regular checkups
- Check for prostate cancer once a year if you are over 50. While BPH is not cancer and does not lead to cancer, the two conditions can exist at the same time.
- If you are having a PSA (prostate-specific antigen) level, tell your doctor you are taking FINTRAL as it can affect the results of this test.
- Even if you are started on any new medicine do tell your doctor and pharmacist that you are taking FINTRAL.
- Promptly report to your doctor if there are any changes in the breast tissue such as lumps, pain, increase in size (gynaecomastia) or nipple discharge.

Things you must never do

- Never ever give FINTRAL to anyone else, even if they have the same condition as you.

Side Effects

Inform your doctor or pharmacist as soon as possible if you do not feel well while you are taking FINTRAL.

FINTRAL helps most men with BPH, but it may have unwanted adverse effects in a few people. Medical treatment may be needed if you get some of the adverse effects.

Tell your doctor if you notice any of the following and they worry you:

- impotence (inability to have an erection)
- less desire for sex
- changes or problems with ejaculation, such as decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function).

These are the more common adverse effects of FINTRAL. For the most part these have been mild. In some cases, these adverse effects disappear while the patient still continues to take FINTRAL. If symptoms persisted, they usually resolved on stopping the tablets.

Inform your doctor immediately if you notice any of the following:

- testicle pain
- breast swelling and/or tenderness
- breast lumps and/or pain
- breast nipple discharge

- skin rash, itchiness
- hives

These are uncommon adverse effects that have been reported.

Inform your doctor immediately or go to the accident and emergency at your nearest hospital if the following happens:

- swelling of the face or lips. These maybe symptoms of a serious allergic reaction to FINTRAL which may cause difficulty in swallowing or breathing. You may also need urgent medical attention.

There are some adverse effects not listed above which may also occur in some patients. Do inform your doctor if you notice any other effects.

Do not be worried by this list of possible adverse effects. You may not experience any of them.

After using FINTRAL

Storage

Keep your tablets in the blister pack until it is time to take them. Never put the tablets in another box or container, as they might get mixed up.

Keep FINTRAL in a cool dry place away from light where the temperature stays below 25°C.

Do not leave it in the car or on window sills. Keep it far a way from children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

How does the tablet look like

FINTRAL 5mg tablets is a round, biconvex, white tablet with “F” on one side and “5” on the other side.

A pack contains 30s, 60s or 90s tablets.

Ingredients

Active ingredient:

- Finasteride 5 mg per tablet.

Inactive ingredients:

- Sodium Laurilsulfate
- Starch
- Lactose monohydrate
- Cellulose, microcrystalline
- Sodium starch glycolate type A
- Magnesium stearate
- Hypromellose
- Macrogol 8 stearate type 1

FINTRAL does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

FINTRAL is supplied in New Zealand by:
Douglas Pharmaceuticals Ltd.,
Central park Drive, Lincoln,
Auckland, N.Z.

Date of Preparation

January 2010