

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS
(PREPARATIONS) 1986

This medicine can be sold under doctor's prescription only

PRO-CURE[®] 5 mg

Tablets

Each tablet contains:
Finasteride 5 mg

For a list of inactive ingredients see section 6.1 "What **PRO-CURE 5 mg** contains". See also section 2.6 "Important information about some of the ingredients of **PRO-CURE 5 mg**".

Read all of this leaflet carefully before you start taking this medicine.

- This leaflet contains concise information about **PRO-CURE 5 mg**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.
- The condition which **PRO-CURE 5 mg** is prescribed occurs only in men. This medicine is not intended for women or children.

1. WHAT PRO-CURE 5 MG IS AND WHAT IT IS USED FOR?

Therapeutic group: 5 α -reductase inhibitor

For the treatment and control of benign prostatic hyperplasia (BPH) to cause regression of the enlarged prostate, and by this improve urinary flow and improve symptoms associated with BPH. **PRO-CURE 5 mg** reduces the risk of acute urinary retention and the need for prostate surgery.

2. BEFORE YOU TAKE PRO-CURE 5 MG

2.1 Do not take PRO-CURE 5 mg if you:

- are a woman and you are or may potentially be pregnant. Women should also not handle crushed or broken tablets of **PRO-CURE 5 mg** (see also section 2.5 "pregnancy").
- This medicine is not intended for women or children.
- are hypersensitive (allergic) to finasteride or any of the other ingredients of **PRO-CURE 5 mg** (for a list of inactive ingredients, see section 6.1).

2.2 Special warnings concerning use of PRO-CURE 5 MG

Before starting treatment with PRO-CURE 5 mg, tell your doctor if:

- you are suffering, or have suffered in the past, from impaired function of the liver.
- **PRO-CURE 5 mg** can affect a blood test called PSA. If you have a PSA test done, tell your doctor that you are taking **PRO-CURE 5 mg**.
- you are sensitive to any type of food or medicine.

2.3 Taking other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.

2.4 Taking PRO-CURE 5 mg with food

You may take **PRO-CURE 5 mg** with or without food.

2.5 Pregnancy

PRO-CURE 5 mg is for use by MEN only.

Women who are or may potentially be pregnant must not use **PRO-CURE 5 mg**. They should also not handle crushed or broken tablets of **PRO-CURE 5 mg**.

If a woman who is pregnant with a male baby absorbs the active ingredient in PRO-CURE 5 mg after oral use or through the skin, it may cause the male baby to be born with abnormalities of the sex organs. PRO-CURE 5 mg tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed. If a woman who is pregnant comes into contact with the active ingredient in PRO-CURE 5 mg, a doctor should be consulted.

2.6 Important information about some of the ingredients of PRO-CURE 5 mg

PRO-CURE 5 mg contains lactose.

2.7 Additional warnings

BPH develops over a long period of time. Some patients show early improvement in symptoms, but you may need to take **PRO-CURE 5 mg** for at least six months to see if it improves your symptoms. Whether or not you notice any improvement or change in symptoms, therapy with **PRO-CURE 5 mg** may reduce your risk for a sudden inability to pass urine and the need for surgery. You must visit your doctor regularly for periodic check-ups and evaluation of your progress.

Your doctor has prescribed **PRO-CURE 5 mg** for symptomatic BPH and not for cancer — but a man can have BPH and prostate cancer at the same time. Doctors usually recommend that men be checked for prostate cancer once a year when they turn 50 (or 40 if a family member has had prostate cancer). These checks should continue while you take **PRO-CURE 5 mg**.

PRO-CURE 5 mg is not a treatment for prostate cancer.

3. HOW TO TAKE PRO-CURE 5 MG ?

Always take **PRO-CURE 5 mg** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure.

The dosage and method of treatment will be determined by the doctor only.

The usually recommended dose unless otherwise prescribed by your doctor is: one tablet once a day. Swallow the medicine with a small amount of water, with or without food.

Do not exceed the recommended dose.

To avoid forgetting to take **PRO-CURE 5 mg**, it may be helpful to take it at the same time every day. Remember that it took many years for your prostate to grow large enough to cause your symptoms. **PRO-CURE 5 mg** can treat your symptoms and control the disease only if you continue to take it over the long term.

If you take more PRO-CURE 5 mg than you should

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take PRO-CURE 5 mg

If you forgot to take this medicine at the specific time, do not take a double dose. Take the next dose at the usual time.

Complete the full course of treatment as instructed by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

How can you contribute to the success of the treatment?

Even though the prostate shrinks, you may NOT notice an improvement in urine flow or symptoms. You may need to take **PRO-CURE 5 mg** for six (6) months or more to see whether it improves your symptoms.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, **PRO-CURE 5 mg** can cause side effects, in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

Refer to the doctor as soon as possible, if you develop any of the following signs:

- any changes in your breasts such as lumps, pain or nipple discharge.

Additional side effects

As with any medicine, in addition to the desired effect of the medicine, adverse reactions may occur during the course of treatment with this medicine, for example: impotence (an inability to have an erection), or less desire for sex.

Some men taking **PRO-CURE 5 mg** may have changes or problems with ejaculation, such as a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to interfere with normal sexual function. In some cases these side effects went away while the patient continued to take **PRO-CURE 5 mg**.

In addition, some men may have breast swelling and/or tenderness. You should promptly report to your doctor any changes in your breasts such as lumps, pain or nipple discharge.

Some men have reported allergic reactions such as rash, itching, hives, and swelling of the lips, tongue, throat and face; testicular pain; an inability to have an erection that continued after stopping the medication; problems with ejaculation that continued after stopping the medication; male infertility and/or poor quality of semen. Improvement in the quality of semen has been reported after stopping the medication; depression; decrease in sex drive that continued after stopping the medication.

In rare cases, male breast cancer has been reported.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

What you need to know while taking **PRO-CURE 5 mg**:

About Prostate-Specific Antigen (PSA). Your doctor may have done a blood test called PSA for the screening of prostate cancer. Because **PRO-CURE 5 mg** decreases PSA levels, you should tell your doctor(s) that you are taking **PRO-CURE 5 mg**. Changes in PSA levels will need to be evaluated by your doctor(s). Any increase in follow-up PSA levels from their lowest point may signal the presence of prostate cancer and should be evaluated, even if the test results are still within the normal range. You should also tell your doctor if you have not been taking **PRO-CURE 5 mg** as prescribed because this may affect the PSA test results. For more information, talk to your doctor.

PRO-CURE 5 mg may increase the chance of a more serious form of prostate cancer.

If any of the side effects gets serious or if you suffer from side effects not mentioned in this leaflet, consult your doctor.

5. HOW TO STORE PRO-CURE 5 mg?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use **PRO-CURE 5 mg** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Store in the original package below 30°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

6.1 What PRO-CURE 5 mg contains

- The active substance is: finasteride.
- Each tablet contains 5 mg of finasteride.
- In addition to the active ingredient the medicine also contains inactive ingredients:
Lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, hydroxypropyl cellulose, hydroxypropyl methylcellulose, titanium dioxide, magnesium stearate, talc, docusate sodium, FD&C Blue 2 aluminum lake and yellow ferric oxide.
Each tablet contains 106.4 mg lactose monohydrate.

6.2 What PRO-CURE 5 mg looks like and contents of the pack

PRO-CURE 5 mg is available as blue, apple-shaped film-coated tablets, one side engraved 72, the other side plain.

Pack size: 28 tablets in blisters.

Marketing authorization holder:

Merck, Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

Manufacturer: Merck Sharp & Dohme UK Ltd., Cramlington, UK

This Leaflet was checked and approved by the Ministry of Health on May 2015

Drug registration no. listed in the official registry of the Ministry of Health:
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