

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

The medicine is dispensed with a doctor's prescription only

Armonia

Soft capsules

Each soft capsule contains: Dutasteride 0.5 mg
The list of additional ingredients is detailed in Section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar. **For use in men only.** This medicine is not intended for women, children or adolescents.

1. WHAT IS THE MEDICINE INTENDED FOR?

Armonia is intended for:

- Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
- To reduce the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH.

Therapeutic group

5-alpha-reductase enzyme inhibitors.

Armonia is used to treat men with an enlarged prostate gland (BPH) – a noncancerous tumor of the prostate gland, caused by overproduction of a hormone called dihydrotestosterone. Enlargement of the prostate gland can lead to urinary system problems, such as difficulty passing urine and frequent need to go to the bathroom. In addition, it may slow or weaken urine flow. If left untreated, there is risk that your urine flow will become fully blocked (acute urinary retention). This condition requires immediate medical treatment. In certain cases, there is a need to surgically remove or reduce the size of the prostate. **Armonia** reduces the production of dihydrotestosterone, thereby helping reduce the size of the prostate and relieving symptoms. This will reduce the risk of acute urinary retention and the need for surgery. **Armonia** can also be used with another medicine called tamsulosin (used to treat BPH symptoms).

2. BEFORE USING THE MEDICINE

❑ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, to other 5-alpha-reductase inhibitors, soya, peanuts or to any of the other ingredients contained in the medicine, as detailed in section 6.
- You have a severe liver disease.

Tell your doctor if you think any of these apply to you.

The medicine is intended for men only! Do not use this preparation in women, children or adolescents.

Special warnings regarding use of the medicine

- In some clinical trials, more patients who took dutasteride and another medicine called an alpha blocker, such as tamsulosin, experienced heart failure, than patients who took dutasteride only or alpha blocker only. Heart failure means that your heart does not pump blood adequately.
- Be sure that your doctor knows if you have liver problems. If you had any ailment that affected the liver, you may need to undergo additional tests when taking **Armonia**.
- Women, children and adolescents must avoid contact with leaking capsules of **Armonia**, since the active ingredient can be absorbed through the skin; therefore, if any contact is made with the skin, wash the contact area immediately with soap and water.
- Use a condom during sexual contact. Dutasteride has been found in sperm of men taking **Armonia**. If your partner is pregnant or may be pregnant, you must avoid exposing her to your sperm, since dutasteride may affect the normal development of a male fetus. Dutasteride has been found to reduce sperm counts, semen volume and sperm motility. This may reduce fertility.
- **Armonia** affects the PSA (prostate specific antigen) blood test, which is sometimes used to detect prostate cancer. Your doctor should be aware of this effect and can still use this test to detect prostate cancer. If you undergo a PSA blood test, tell your doctor that you are taking **Armonia**. Men taking the medicine should check their PSA regularly.
- In a clinical study in men with increased risk of prostate cancer, men who took **Armonia** developed a severe degree of prostate cancer more frequently than men who did not take **Armonia**. The effect of **Armonia** on the severity of prostate cancer is unknown.
- **Armonia** may cause breast enlargement or tenderness. If this becomes bothersome, or if you notice lumps in the breast, or discharge from the nipple, talk to your doctor about these changes, as they may be signs of a severe medical problem, such as breast cancer.

Refer to your doctor or pharmacist if you have any questions regarding use of **Armonia**.

❑ If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist.

Certain medicines may react with **Armonia**, which may increase the likelihood that you will have side effects. These medicines include:

- Verapamil or diltiazem (for high blood pressure)
- Ritonavir or indinavir (for AIDS)
- Itraconazole or ketoconazole (for fungal infection)
- Nefazodone (for depression)
- Alpha blockers (to treat an enlarged prostate gland or high blood pressure)

Tell your doctor if you are taking any of these medicines. The **Armonia** dosage may have to be reduced.

❑ Use of the medicine and food

Armonia can be taken with or without food.

❑ Pregnancy and breastfeeding

Women who are pregnant (or who may be pregnant) must avoid contact with leaking capsules. Dutasteride is absorbed through the skin and may affect the normal development of a male fetus. This risk is increased during the first 16 weeks of pregnancy.

Use a condom during sexual contact. Dutasteride has been found in semen of men taking **Armonia**. If your partner is pregnant or may be pregnant, you must avoid exposing her to your sperm.

Armonia has been found to reduce sperm counts, semen volume and sperm motility. Therefore, male fertility may be reduced.

Tell your doctor if a pregnant woman has come into contact with dutasteride.

❑ Driving and using machines

It is unlikely that **Armonia** will affect your ability to drive or operate machines.

❑ Important information about some of the components of the medicine

This medicine contains soya lecithin which may contain soya oil. If you are allergic to peanuts or to soya, do not use this medical product.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. If you do not take the medicine regularly, monitoring of your PSA levels may be affected. Check with the doctor or pharmacist if you are uncertain.

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

The recommended dosage is one capsule (0.5 mg), taken once a day.

Treatment with **Armonia** is long-term. Some men will notice an early improvement in their symptoms. However, others will have to take **Armonia** for 6 months or more before it begins to have an effect. Continue taking **Armonia** for as long as your doctor tells you to.

Do not exceed the recommended dose

Swallow the capsule whole with water. **Do not chew or open the capsule.** Contact with the content of the capsule may cause pain in your mouth or throat.

If you accidentally took a higher dosage, consult your doctor or pharmacist. If a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult a doctor.

Do not stop treatment without consulting a doctor.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Armonia** may cause side effects in some users. Do not be alarmed when reading the list of side effects; you may not suffer from any of them.

Allergic reaction

The signs of an allergic reaction can include:

- Skin rash (which can be itchy)
- Urticaria (like a nettle rash)
- Swelling of the eyelids, face, lips, arms or legs

Tell your doctor immediately if you notice any of these symptoms and stop using **Armonia**.

Additional side effects

Common side effects

These may occur in up to 1 in 10 men taking **Armonia**:

- Inability to achieve or maintain erection (impotence); the effect can persist after discontinuing treatment with **Armonia**.
- Reduced sexual drive (libido); the effect can persist after discontinuing treatment with **Armonia**.
- Ejaculation disturbances; the effect can persist after discontinuing treatment with **Armonia**.
- Breast enlargement (gynecomastia) or tenderness.
- Dizziness when taken with tamsulosin.

Uncommon side effects

These may occur in up to 1 in 100 men taking **Armonia**:

- Heart failure (the heart becomes less effective in pumping blood through the body. You may have symptoms such as shortness of breath, extreme tiredness and swelling of your ankles and legs).
- Hair loss (usually from the body) or hair growth.

Side effects of unknown frequency

The frequency can not be estimated from the existing data:

- Depression
- Testicular pain and swelling

If a side effect occurs, if any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "[Report Side Effects of Drug Treatment](#)" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects.

Alternatively, they can be reported to "[Unipharm Ltd.](#)".

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!

Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following ingredients:

Glycerol monaciparilate Type I, Butylhydroxytoluene (BHT) - (E-321), Gelatin, Glycerol, Purified Water, Titanium Dioxide (E-171), Yellow Iron Oxide (E-172), Triglycerides medium chain, Lecithin (soya) (E-322)

What the medicine looks like and the contents of the package:

Armonia are soft, yellow capsules.

They are available in packs of 10, 30, 50, 60, 90 capsules. Not all package sizes may be marketed.

Armonia is packaged in trays (blister), which are inserted into a carton package.

License holder and address: Unipharm Trading Ltd., P.O.B. 21429, Tel Aviv, 6121301.

Manufacturer and address:

Cipla Limited, D-7 MIDC Industrial Area, Kurkumbh, District Pune, Maharashtra, IN-413 802 India

This leaflet was checked and approved by the Ministry of Health in 12/2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

157-51-34697-00