

## Package leaflet: Information for the user

**Restandol® Testocaps™**  
40mg CAPSULES, SOFT  
Testosterone undecanoate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

- 1. What Restandol Testocaps are and what they are used for**
- 2. What you need to know before you take Restandol Testocaps**
- 3. How to take Restandol Testocaps**
- 4. Possible side-effects**
- 5. How to store Restandol Testocaps**
- 6. Contents of the pack and other information**

### **1. What Restandol Testocaps are and what they are used for**

Restandol Testocaps are soft oval glossy capsules which contain 40mg of testosterone undecanoate. The active substance testosterone undecanoate is turned into testosterone by your body. Testosterone is a natural male hormone known as an androgen.

In men testosterone is produced by the testicles. It is necessary for the normal growth, development and function of the male sex organs and for secondary male sex characteristics. It is necessary for the growth of body hair, the development of bones and muscles, the distribution of fat, and it stimulates the production of red blood cells. It also makes men's voices deepen.

Restandol Testocaps is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This should be confirmed by two separate blood testosterone measurements and also include clinical symptoms such as impotence, infertility, low sex drive, tiredness, depressive moods, bone loss caused by low hormone levels.

It may also be used to treat a type of bone disease (osteoporosis) in males caused by having too little testosterone.

## 2. What you need to know before you take Restandol Testocaps

### Do not take Restandol Testocaps

- If you are allergic (hypersensitive) to testosterone undecanoate or any of the ingredients of Restandol Testocaps (listed in section 6 "What Restandol Testocaps contain").
- If you have or have had a tumour of your prostate or breast, or are suspected to have one of these tumours
- If you have kidney disease
- If you suffer from heart disease or heart failure
- If you have hypercalcaemia or hypercalciuria (too much calcium in the blood or urine)
- Restandol Testocaps may contain trace amounts of soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product

### Take special care with Restandol Testocaps

Treatment with male hormones like testosterone may increase the size of the prostate gland, especially in elderly men. Therefore your doctor will examine your prostate gland at regular intervals by digital rectal examination (DRE) and blood tests for prostate-specific antigen (PSA).

Additionally, at regular intervals, blood tests will be done to check the oxygen-carrying substance in your red blood cells (haemoglobin). In very rare cases the number of red blood cells will increase too much leading to complications.

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

Medical checks may also be necessary in some other conditions. Therefore, before you start using this medicine you must tell your doctor or pharmacist if you have ever had, still have, or are suspected to have:

- Breast cancer which has spread to the bones;
- Kidney or lung cancer;
- Heart disease;
- Kidney disease;
- Liver disease;
- High blood pressure;
- Diabetes mellitus;
- Epilepsy;
- Migraine, headaches;
- Prostatic complaints, such as problems with passing urine
- Blood clotting problems - thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis – blood clots in blood vessels)
  - Factors that increase your risk for blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; immobility; if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50); or as you get older.

How to recognise a blood clot: painful swelling of one leg or sudden change in colour of the skin e.g. turning pale, red or blue, sudden breathlessness, sudden unexplained cough which may bring up blood; or sudden chest pain, severe light headedness or dizziness, severe pain

in your stomach, sudden loss of vision. Seek urgent medical attention if you experience one of these symptoms.

If you are suffering from severe heart, liver or kidney disease, treatment with Restandol Testocaps may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.

Tell your doctor if you have high blood pressure or if you are treated for high blood pressure as testosterone may cause a rise in blood pressure.

If you have sleep apnoea (temporarily stopping breathing during your sleep), this may get worse if you are using testosterone-containing products. Let your doctor know if you are worried about this. Extra supervision by your doctor may be necessary in case you are overweight or suffer from chronic lung disease.

#### Children and adolescents

The safety and efficacy of this medicine has not been adequately determined in children and adolescents.

Extra supervision by your doctor is necessary in the treatment of children and adolescents since testosterone administration in general may cause early sexual development and limits growth (see section 4 "Children and adolescents").

#### **Other medicines and Restandol Testocaps**

Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines – even those not prescribed.

Other medicines may affect how Restandol Testocaps works or Restandol Testocaps may affect how they work. Therefore you must tell your doctor or pharmacist if you are using or about to use:

- Insulin and/or other medicines to control your blood sugar levels;
- Medicines to reduce the clotting of your blood (anti-coagulants);

The use of androgens like Restandol Testocaps may lead to a reduction of the doses of these medicines.

Also tell your doctor or pharmacist if you are using or about to use the hormone ACTH or corticosteroids (used to treat various rheumatism, arthritis, allergic conditions and asthma). The use of androgens like Restandol Testocaps may increase the risk of water retention especially if your heart and liver are not working properly.

Androgens may also affect the results of some laboratory tests (e.g. thyroid gland). Therefore you must tell your doctor or the laboratory staff performing the tests that you are using this medicine.

The following medicines may decrease the effect of Restandol Testocaps:

- Anti-epileptic drugs such as barbiturates (e.g. primadone),
- Phenylbutazone

#### **Using Restandol Testocaps with food and drink.**

Food allows testosterone undecanoate, the active substance of this medicine, to be taken up by your body.

→ Therefore, **Restandol Testocaps must be taken with a meal** (see section 3).

### **Pregnancy, breast-feeding and fertility**

Restandol Testocaps are not for use in women, therefore this medicine must not be taken by women who are pregnant or think that they are pregnant, or by women who are breast-feeding.

In men, treatment with Restandol Testocaps can lead to fertility disorders by repressing sperm formation.

If you are planning to have a baby, Restandol Testocaps must not be taken during pregnancy or when you are breast feeding.

Ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

As far as is known this medicine has no influence on driving and using machines.

### **Important information about some of the ingredients of Restandol Testocaps**

#### **This medicine contains Sunset Yellow.**

Sunset Yellow (E110, FD & C Yellow no.6) may cause allergic reactions.

Restandol Testocaps may contain trace amounts of soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

### **Improper use**

If you are a patient who participates in competitions governed by the World Anti-Doping Agency (WADA), then you should consult the WADA-code before using this medicine as Restandol Testocaps can interfere with anti-doping testing.

The misuse of this medicine to enhance the ability in sports carries serious health risks and is to be discouraged.

### **Drug abuse and dependence**

Always take this medicine exactly as your doctor or pharmacist has told you.

Abuse of testosterone, especially if you take too much of this medicine alone or with other anabolic androgenic steroids, can cause serious health problems to your heart and blood vessels (that can lead to death), mental health and/or the liver. Individuals who have abused testosterone may become dependent and may experience withdrawal symptoms when the dosage changes significantly or is stopped immediately. You should not abuse this medicine alone or with other anabolic androgenic steroids because it carries serious health risks.

## **3. How to take Restandol Testocaps**

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

The recommended dose is 3-4 capsules daily for the first 2-3 weeks, followed by a gradual decrease to 1-3 capsules daily.

**You must take this medicine with a meal. Swallow the capsules whole without chewing, using some water or other fluid.**

Take half of the daily dose in the morning and the other half in the evening. If the daily dose is an uneven number of capsules, take the bigger number in the morning.

If you have the impression that the effect of this medicine is too strong or too weak, talk your doctor or nurse immediately.

### **Use in children and adolescents**

The safety and efficacy of this medicine have not been adequately determined in children and adolescents. Pre-pubertal children using this medicine will be monitored by your doctor (see section 2 "Take special care with Restandol Testocaps").

### **If you take more Restandol Testocaps than you should**

If you have taken several capsules at once, there is no need for great concern; however you should consult your doctor. The oily substance in the capsule may cause diarrhoea.

### **If you forget to take Restandol Testocaps**

If you have forgotten to take your dose of Restandol Testocaps, do not take a double dose to make up for missed individual doses. Just skip the missed dose and take your next dose at the normal time.

### **If you stop taking Restandol Testocaps**

When treatment with this medicine is stopped, complaints such as those experienced before treatment may re-occur within a few weeks.

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

## **4. Possible side effects**

Like all medicines, Restandol Testocaps can have side effects, although not everybody gets them. In general side effects which are reported with testosterone therapy include:

Common (may affect up to 1 in 10 people)

- Increase in red blood cell count (the cells which carry the oxygen in your blood); haematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen), identified by periodic blood tests;
- Weight gain

Not known (cannot be estimated from available data)

- Itching (pruritus)
- Changes in sexual desire
- Nausea (feeling sick)
- Depression
- Nervousness
- Mood alterations
- Muscle pain (myalgia)
- Changes in liver function tests

- Changes in cholesterol levels (changes in lipid metabolism)
- Fluid retention in the tissues, usually marked by swelling of ankles or feet
- High blood pressure (hypertension)
- Prolonged abnormal, painful erection of the penis
- Decrease amount of ejaculation fluid
- Disturbed formation of sperm
- Breast enlargement (gynecomastia)
- Prostatic growth to a size representative for the concerned age group
- Increased levels of a blood marker which is associated with prostate cancer (PSA increased)
- Increased growth of a small prostate cancer which had not been detected yet (progression of a sub-clinical prostatic cancer)
- Acne

In a few patients diarrhoea and stomach pain or discomfort have been reported during the use of this medicine.

### **Children and adolescents;**

The following side effects have been reported in pre-pubertal children using androgens:

- Early sexual development
- Penis enlargement
- An increased frequency of erections
- Growth limitation (limited body height)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Restandol Testocaps**

Keep this medicine out of sight and reach of children.

Store below 30°C. Do not refrigerate or freeze.

Store in the original package and keep container in the outer carton in order to protect from light.

Do not use this medicine after the expiry date stated on the carton or label after the term "exp" (expiry date). The expiry date refers to the last day of that month.

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

## **6. Contents of the pack and other information**

### **What Restandol Testocaps contain**

- The active substance is testosterone undecanoate, 40 mg per capsule, which is equivalent to 25.3 mg testosterone
- The other ingredients are:

*Capsule contents:*

Each capsule contains 175.8 mg castor oil. In addition, this medicine contains 117.2 mg propylene glycol monolaurate (E477) in each capsule. This quantity corresponds to 34.5 mg propylene glycol which is equivalent to 0.5 mg/kg.

*Capsule shell ingredients:*

- Glycerol,
- Sunset Yellow (E110, FD & C Yellow no.6),
- Gelatin

Printing ink

Opacode-WB white containing:

- Propylene glycol,
- Titanium dioxide,
- Polyvinyl acetate phthalate,
- Macrogol 400,
- Ammonium hydroxide.

Auxiliary substances

- Medium-chain triglycerides and lecithin

**What Restandol Testocaps look like and contents of the pack**

The capsules are transparent and orange in colour. They are oval in shape with a glossy, transparent, orange appearance. Each capsule is imprinted with “OrgDV3” in white. They are filled with a yellow oil.

Restandol Testocaps are available in cartons containing 3, 6 or 12 sachets. Each sachet contains a blister strip with 10 capsules. Not all pack sizes may be marketed.

If you have any further questions or require the full prescribing information for this medicine, please consult your doctor or pharmacist.

**Marketing Authorisation Holder:**

Merck Sharp & Dohme Ireland (Human Health) Limited,  
Red Oak North,  
South County Business Park,  
Leopardstown,  
Dublin 18,  
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**Manufacturer:**

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