What is Restandol Testocaps used for?

Restandol Testocaps are 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.

Restandol Testocaps are used if your body does not make enough testosterone of its own, for example:

- impotence caused by hormonal disorders
- after castration or a similar problem called eunuchoidism
- decreased sex drive and decreased mental and physical activity
- certain types of infertility because you don’t make enough sperm

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

What you need to know before taking Restandol Testocaps

- Do not take Restandol Testocaps: If you are allergic (hypersensitive) to testosterone undecanoate or any of the ingredients of this medicine (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 ever had liver cancer
**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. In men over the age of 45, the prostate gland will be investigated 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 check may also be necessary in some other conditions.

Tell your doctor 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 passing urine
- Blood clotting problems - thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis – blood clots in blood vessels)

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 raise in blood pressure.

If you have sleep apnea (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.

Also tell your doctor:
- If you are taking anticoagulants (drugs to treat blood clots)

Your medication may need to be monitored more closely.

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

Extra supervision by the 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 are 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 following medicines may decrease the effect of Restandol Testocaps:

- antibiotics such as rifampicin
- anti-epileptic drugs such as barbiturates, carbamazepine, dichloralphenazone, phenylbutazone, phenytoin and primidone.

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 conditions such as 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.

Laboratory tests:
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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using Restandol Testocaps with food and drink
Food allows testosterone undecanoate, the active substance of this medicine to be absorbed by your body.
Therefore, Restandol Testocaps must be taken with a normal 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, 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 or using machines.

Important information about some of the ingredients of Restandol Testocaps
This medicine contains:

- Sunset yellow (E110) which can cause allergic type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

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 ability in sports carries serious health risks and is to be discouraged.

3. How to take Restandol Testocaps

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

Adults
The recommended dose is 3–4 capsules daily during the first 2–3 weeks, followed by a gradual decrease to 1–3 capsules daily. Look at the label on the pack to see how many capsules your doctor would like you to take each day.

You must take this medicine with a normal meal.
Swallow the capsules whole without chewing, using some water or other fluid.
Depending on the dose prescribed for you, take the capsules as shown in the table below.

<table>
<thead>
<tr>
<th>Prescribed daily dose</th>
<th>No. of capsules to take</th>
<th>Morning</th>
<th>Evening</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
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<tr>
<td>2</td>
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<tr>
<td>4</td>
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<td>2</td>
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</tr>
</tbody>
</table>

Elderly
Smaller doses, taken less often, may be given if you are elderly. Your doctor will have chosen the correct dose for you.

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 tell your doctor. The castor oil in the capsule may cause diarrhoea.

If you forgot to take Restandol Testocaps:
Don’t worry.
If you miss the morning dose and it is more than 2 hours after breakfast, wait until lunch-time and then take the dose. If you miss the evening dose, and its more than 2 hours after dinner, don’t take the missed dose. Take the next morning dose as normal.
Remember to always take Restandol Testocaps with food.

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.

**Common (may affect up to 1 in 10 people)**
- increase in red blood cell count (the cells which carry the oxygen in your blood); hematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen), identified by periodic blood tests.

**Not known (cannot be estimated from available data)**
- itching (pruritus)
- acne
- nausea (feeling sick)
- problems with your liver including liver tumours, though this is rare
- changes in the way your body processes fats
- depression
- nervousness
- mood alterations
- muscle pain
- fluid retention in the tissues, usually marked by the swelling of ankles or feet
- high blood pressure
- increased or decreased sex drive
- prolonged painful erection
- decreased amounts of ejaculation fluid and sperm
- enlargement of the breasts
- growth of the prostate gland
- increased levels of a blood marker which is associated with prostate cancer (PSA)
- worsening of the early stage of prostate cancer
- yellowing of the skin or eyes
- difficulty passing urine
- allergy to sunset yellow, a colour used in the capsules.
- electrolyte changes (sodium, potassium, calcium, inorganic phosphate and water retention)
- no sperm count

In a few patients diarrhoea, 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).
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 the sight and reach of children.
Do not use this medicine after the expiry date stated on the package, sachet and blister, after the term “exp” (expiry date). The expiry date refers to the last day of that month.
Do not store above 30 °C.
Do not refrigerate or freeze.
Store in the original package and keep the blister in the outer carton.

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 to protect the environment.

6. Contents of the pack and other information

What Restandol Testocaps contain
The active substance is: Testosterone undecanoate, 40 mg which is equivalent to 25.3 mg testosterone.
The other ingredients are:
- Capsule contents:
  Castor oil and propylene glycol laurate (E477)
- Capsule shell ingredients:
  Glycerin, Sunset Yellow (E110) and gelatin
- Printing ink:
  Opacode WB® white
- Auxiliary substances:
  Medium-chain triglycerides and Lecithin

What Restandol Testocaps looks like and contents of the pack
Restandol Testocaps are soft oval glossy capsules, transparent, orange in colour containing a yellow oily fill.
A box of Restandol Testocaps contains either 3 or 6 sachets. Each sachet contains a blister strip with 10 capsules.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Merck Sharp & Dohme Limited,
Hertford Road, Hoddesdon,
Hertfordshire, EN11 9BU, UK

Manufacturer:
N.V. Organon, Kloosterstraat 6
5349 AB Oss, The Netherlands

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only)

Please be ready to give the following information:
Product name  Restandol Testocaps,
               40 mg Capsules, Soft