

RESTANDOL[®] TESTOCAPS[™]
40MG CAPSULES, SOFT
Testosterone undecanoate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effect gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

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

Restandol Testocaps are soft oval glossy capsules which contain 40 mg 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. It is produced in the body by both men and women.

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.

2. 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
- If you have prostate cancer
- If you have breast cancer
- If you have ever had liver cancer

Take special care with Restandol Testocaps:

Extra supervision by your doctor may sometimes be necessary; particularly if you are elderly. In men over the age of 45, the prostate gland will be investigated by digital rectal examination (DRE) of the prostate and by determination of the serum prostate-specific antigen (PSA) via blood tests.

→ Tell your doctor if you have ever had:

- heart disease
- kidney disease
- liver disease
- high blood pressure
- epilepsy
- migraine
- prostatic complaints, such as problems passing urine
- cancer of the lungs, kidney, breast or bones

→ Also tell your doctor

- if you are diabetic or
- if you are taking anticoagulants (drugs to treat blood clots)

Your medication may need to be monitored more closely.

Children and adolescents

Safety and efficacy have not been adequately determined in children and adolescents.

Extra supervision by a doctor is also necessary in the treatment of young boys since male hormones may cause early sexual development and delay growth.

Extra supervision by a doctor is also necessary in elderly men since male hormones may increase the size of the prostate gland. Furthermore, at regular intervals, blood tests will be done to check the oxygen-carrying substance in your red blood cells (hemoglobin).

In very rare cases the number of red blood cells will increase too much leading to complications.

Taking other medicines

Other medicines may affect how Restandol Testocaps works or Restandol Testocaps may affect how they work.

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.

Restandol Testocaps may also affect how drugs used to treat diabetes and blood clots work.

Please **tell your doctor or pharmacist** if you are using (or intend to use anti-diabetic, anti-clotting medicines, the hormone ACTH or corticosteroids (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma): Restandol Testocaps may increase the risk of water retention, especially if your heart and liver are not working properly.

Restandol testocaps may also affect the results of some laboratory tests (e.g. thyroid gland). Tell your doctor or laboratory staff that you are using Restandol Testocaps.

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

Taking Restandol Testocaps with food and drink

Food allows testosterone undecanoate to be absorbed by your body.

→ Therefore, **Restandol Testocaps must be taken with a normal meal.**

Pregnancy and breast-feeding

Restandol Testocaps must not be taken during pregnancy or when you are breast feeding.

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

Driving and using machines

As far as is known Restandol Testocaps have no adverse effect on alertness or concentration.

Important information about some of the ingredients of Restandol Testocaps

The capsules also contain:

Glycerin which is harmful in high doses and may cause headache, stomach upset or diarrhoea.

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

3. How to take Restandol Testocaps

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

Adults

Usually, the dosage 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 Restandol Testocaps 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.

Prescribed daily dose	No. of capsules to take	
	Morning	Evening
1	1	0
2	1	1
3	2	1
4	2	2

Elderly

Smaller doses, taken less often, may be given if you are elderly.

Your doctor will have chosen the correct dose for you.

Children

Restandol Testocaps should not be given to children who have not reached puberty.

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 it's 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 have any further questions on the use of the product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Restandol Testocaps can have side effects, although not everybody gets them.

Mild side effects include:

- headache
- dizziness
- diarrhoea

Other side effects that may occur during testosterone therapy are:

- rash
- nausea (feeling sick)
- yellowing of the skin or eyes
- increased or decreased sex drive
- depression
- nervousness
- mood disturbances
- muscle pain
- high blood pressure
- changes in the way your body processes fats
- increase in the number of red blood cells
- problems with your liver including liver tumours, though this is rare.
- allergy to sunset yellow, a colour used in the capsules.

In **men**, enlargement of the breasts, growth of the prostate gland, worsening of the early stage of prostate cancer, difficulty passing urine, prolonged painful erection, decreased amounts of ejaculation fluid and sperm.

In **women**, increase in facial or body hair, acne, no or lighter periods and voice changes which may not return to normal.

In **children**, early sexual development and delayed bone growth.

In a few patients stomach pain or discomfort have been reported during the use of Restandol Testocaps.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please **tell your doctor or pharmacist.**

5. How to store Restandol Testocaps

Keep out of the reach and sight of children.

Do not use Restandol Testocaps after the expiry date stated on the package, sachet and blister.

Do not store above 30 °C. Do not refrigerate or freeze.

Keep the blister in the outer carton. 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

What Restandol Testocaps contains

- The active substance is testosterone undecanoate, 40 mg per capsule.
- The other ingredients are:
 - castor oil,
 - propylene glycol laurate (E477),
 - gelatin,
 - medium-chain triglycerides,
 - lecithin and
 - printing ink 'Opacode WB white'.
 - glycerin,
 - Sunset Yellow (E110)

What Restandol Testocaps looks 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. They are filled with a yellow oil.

A box of Restandol Testocaps contains either 3 or 6 sachets. Each sachet contains a blister strip with 10 capsules.

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

Reference number 00025/0595

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last updated in September 2013