

Arrow - Testosterone

Testosterone undecanoate 40 mg capsules

What is in this leaflet

This leaflet answers some common questions about ARROW - TESTOSTERONE.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - TESTOSTERONE against the benefits he/she expects it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What ARROW - TESTOSTERONE is used for

ARROW - TESTOSTERONE belongs to a group of medicines called androgens, a type of sex hormone necessary for the normal sexual development of males.

It is used to replace the body's natural sex hormone testosterone when not enough is made by the body.

Because of problems with the pituitary or testis, the production of testosterone by the body decreases.

Men may suffer from complaints such as depression, loss of motivation or concentration, and loss of sexual desire. ARROW – TESTOSTERONE can relieve these complaints. It can also relieve these symptoms in men who have had their testis removed. Relief of symptoms usually starts within a few days, but optimal results are obtained after weeks to months of treatment.

Your doctor may have prescribed ARROW – TESTOSTERONE for another reason. Ask your doctor if you have any questions about why ARROW - TESTOSTERONE has been prescribed for you.

ARROW - TESTOSTERONE is available only with a doctor's prescription.

Before you take ARROW - TESTOSTERONE

Do not take ARROW - TESTOSTERONE if:

- You have a tumour (eg. a breast tumour or enlarged prostate)
- You have or have had severe kidney disease
- You are allergic to testosterone undecanoate or any of the ingredients listed at the end of this leaflet.

Before you start to take it

Tell your doctor if:

- You have or have had heart disease or blood vessel problems
- You have diabetes

- You have or have had kidney disease
- You have epilepsy
- You have migraines
- You have or have had a psychiatric or emotional illness

Tell your doctor if you have had any unusual or allergic reactions to androgens or anabolic steroids.

Tell your doctor if you are on a special diet, eg. low salt, low sugar.

Tell your doctor if you are taking any other medicines.

Before you take ARROW – TESTOSTERONE, it is also important to tell your doctor if you have or have had, too much cholesterol or other fatty substances in the blood.

Tell your doctor if you have been treated with other sex hormones recently.

During long term treatment with ARROW – TESTOSTERONE, regular medical checks, including prostate examination, are recommended.

Extra supervision by a doctor is necessary in the treatment of young boys.

Taking other medicines

Tell your doctor if you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food shop.

Other medicines may influence the effects of ARROW – TESTOSTERONE, or ARROW – TESTOSTERONE may affect other medicines.

You must tell your doctor or pharmacist if you are taking (or intend to take) other medicines such as:

- Barbiturates (medicines for epilepsy or sleeplessness)
- Antidiabetic drugs
- Cyclosporin

ARROW – TESTOSTERONE may interfere with laboratory tests for glucose tolerance, thyroid function and clotting factors.

Your doctor can tell you what to do if you are taking these medicines. If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - TESTOSTERONE.

If you have not told your doctor about any of the above, tell him/her before you start taking ARROW - TESTOSTERONE.

How to take ARROW - TESTOSTERONE Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take ARROW - TESTOSTERONE

Take ARROW – TESTOSTERONE exactly as your doctor has prescribed. Your doctor will tell you how many capsules you need to take each day.

The usual starting dose is 120-160mg (3 to 4 capsules) daily for 2-3 weeks is adequate, followed by a regular dosage of 40-120mg (1 to 3 capsules) daily.

How to take it

ARROW – TESTOSTERONE capsules should be taken with some water or other drink. Swallow the capsules whole, do not chew them.

When to take it

Take capsules daily, as directed by your doctor. ARROW – TESTOSTERONE capsules are to be swallowed after the morning and evening meal. If you are taking an uneven number of capsules, the larger dose should be taken in the morning.

If you forget to take ARROW - TESTOSTERONE

If you forget to take a capsule, take it as soon as you remember. If you do not remember. If you do not remember to take the dose until the next dose is due, then just take one dose, do not double up.

If you take too much ARROW – TESTOSTERONE (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW – TESTOSTERONE capsules.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Symptoms that may occur from overdosage include nausea and vomiting and oily bowel motions.

Keep the telephone numbers for these places handy.

While you are taking ARROW - TESTOSTERONE

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - TESTOSTERONE.

Things you must not do

Do not change the dose without checking with your doctor.

Do not use ARROW - TESTOSTERONE to treat any other conditions unless your doctor tells you to.

Do not give ARROW - TESTOSTERONE to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

As far as is known, ARROW – TESTOSTERONE have no adverse effect on alertness and concentration. If you are unsure of any of the aspects of this product, please discuss with your doctor or pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - TESTOSTERONE.

Like other medicines, ARROW - TESTOSTERONE can cause some side effects but are generally well tolerated.

Tell your doctor if you notice any of the following and they worry you:

- Stomach or bowel complaints: oily bowel motions, abdominal or stomach pain, black, tarry or light coloured stools or dark coloured urine, vomiting, nausea
- Skin irritation: pimply spotty rash, hives
- Sleeplessness, chills, generalised tingling, unusual tiredness
- Headache, anxiety, mental depression, excitation, confusion, dizziness
- Painful, irreversible erection, inflamed testis, bladder irritability
- Sexual dysfunction, disturbed sperm formation
- Blood disorders
- Increase in cholesterol levels
- Shortness of breath
- Swelling of the feet or lower legs (oedema)
- Breast enlargement

These symptoms usually go away when treatment is stopped for a short while. Your doctor will then probably advise you to start at a lower dosage.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking ARROW - TESTOSTERONE

Storage

Keep ARROW - TESTOSTERONE where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep ARROW - TESTOSTERONE in a cool, dry place where the temperature stays below 25°C.

Keep your tablets in the container until it is time to take them.

If you take the tablets out of the container, they may not keep well.

Do not store ARROW - TESTOSTERONE or other medicines in the bathroom or near a sink.

Do not leave the tablets in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW – TESTOSTERONE, ask your pharmacist what to do with any tablets that are left over.

Product Description

What ARROW - TESTOSTERONE looks like

ARROW – TESTOSTERONE capsules are oval, orange clear, soft gelatin capsules, ink-printed in white with "P" logo and "40" on the same line.

Ingredients

The active ingredient in ARROW – TESTOSTERONE capsules is testosterone undecanoate. Each ARROW – TESTOSTERONE capsule contains 40 mg of testosterone undecanoate. It also contains caprylic-capric acid tryglicerides.

The capsule shells contain the following excipients: gelatine, glycerin, sorbitol, methylparaben sodium and propylparaben sodium. The capsules are printed with ink comprising of white Opacode Ink and # 6 Yellow D & C.

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

Supplier

ARROW - TESTOSTERONE is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited
Mount Eden Central Business Park
33a Normanby Road, Mt Eden
Auckland, New Zealand.

Date of preparation

23 March 2010