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RA 1530 UK PI (Ref 1.0)

INFORMATION FOR THE PATIENT

**Testosterone Implant 100mg or 200mg
(Testosterone)**

What you should know about your medicine
This leaflet has been written to help you understand your medicine.
If you have any questions or worries, ask your doctor or pharmacist.
At the end of the leaflet you will find a list of things to remember
about your medicine. Please keep this leaflet until you have finished
your medicine. You may want to read it again.

What Is A Testosterone Implant?

Testosterone implants are pellets containing 100mg or 200mg of testosterone and are sold in a glass ampoule. Each implant is packed in a cardboard carton. There are no other ingredients in the pellet. These implants are used in hormone replacement therapy in men and women. Testosterone is a natural male hormone, known as an androgen, which controls normal sexual development in men.

The Product Licence Is Held By:

Organon Laboratories Limited, Science Park, Milton Road,
Cambridge, CB4 0FL

Testosterone Implants Are Made By:

Organon (Ireland) Ltd
P O Box 2857
Drynam Road
Swords
Co Dublin
Eire

What Are Testosterone Implants Used For?

- Testosterone implants are used in testosterone replacement therapy for male sexual problems for example:
 - impotence caused by hormonal disorders
 - after castration or a similar problem called eunuchoidism
 - decreased sex drive and decreased mental and physical activity
 - bone loss caused by low hormone levels.
- Implants can also be used in women together with other forms of hormone replacement therapy to relieve symptoms such as decreased sexual drive and loss of energy.

Before Your Implant is Inserted:

Men

- Do you have or think you may have cancer of the prostate or breast?

Women

- Do you think you may be pregnant?
- Are you breast-feeding?

If the answer to any of these questions is YES,

- Did you tell your doctor at the last visit, or an earlier visit?

If NOT, then you should do so as soon as possible.

Even so your doctor may still want you to have the implant.

What Do You Need To Know Before Having An Implant?

Extra supervision by your doctor may be necessary in some cases particularly the elderly.

Tell your doctor if you have ever had:

- heart disease
- kidney disease
- liver disease
- high blood pressure
- epilepsy
- migraine

Testosterone should be used carefully in women as it can cause hoarseness of the voice. In young boys testosterone can cause early sexual development and delay growth.

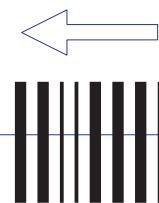
What Other Medicines Are You Taking?

Other medicines may affect how the testosterone implant works or testosterone may affect how they work. Certain types of drugs can cause more enzymes to be made in the liver. These are called "enzyme inducing drugs" for example medicines used to treat epilepsy; phenobarbital. Tell your doctor if you are taking any medicines for diabetes. Also, tell your doctor if you are taking medicines that thin the blood, such as warfarin. Tell your doctor if you are taking or intend to take any other medicines.

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How A Testosterone Implant Is Given?

How much?
The dose is chosen by your doctor. In men usually a dose of 100mg-600mg implant is given, but this depends on each individual.
In women a dose of 50mg-100mg is usual, together with another form of hormone replacement therapy.

How the implant is inserted?

Testosterone implants are inserted under the skin into the lower abdominal wall or buttock by your doctor. You are usually given a local anaesthetic in this area before the implant is inserted and the small cut made is dressed with a bandage afterward. The implant usually lasts for 4-5 months.

What To Do If Someone Is Accidentally Given Too Much?

If the dose is too much it can cause a woman's voice to deepen and cause frequent erections in men. If this occurs tell your doctor immediately. He/She may want to remove the implant.

What About Side Effects?

Testosterone may cause side effects in some people. If you have any of the following side-effects tell your doctor. He may decide to stop treatment for a while.

- slight bleeding or infection at the implantation site
- the implant may start to come out of the implantation site
- water retention

In men it may cause:

- prolonged painful erection
- increased sexual desire
- decreased amounts of ejaculation fluid
- low sperm count

In young boys, early sexual development, erections occurring more often than normal, enlarged penis, delayed growth

In women it may cause hoarseness of the voice and excess hair growth.

Tell your doctor if you have any side effects which are serious or troublesome and if side effects continue.

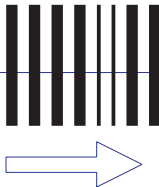
How Should Testosterone Implants Be Stored?

Testosterone implants should not be used after the 'use by' date on the pack. Do not store the implants above 25°C (room temperature). Store in the original container out of reach and sight of children.

This information was written in July 2005.

Other Things To Remember About Medicines.

1. This medicine has been prescribed for your current medical problems. Do not use it for other medical problems.
2. Do not allow other people to use your medicines and do not use medicines meant for other people.
3. Tell any doctor treating you what medicines you are taking. Always carry a medical information card showing which medicines you are using. This can also be very important if you are involved in an accident.
4. Return any medicine that you do not use to the pharmacy, they will dispose of it safely.
5. Make sure that other people you may live with or who look after you read this information.



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