ANDROCAP

40mg Capsule

Testosterone **Undecanoate INN**

Read this leaflet carefully before you start using this medicine.

- 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 personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

- 1. What ANDROCAP® are and what they are used for
- 2. Before you take ANDROCAP®
- 3. How you take ANDROCAP®
- 4. Possible side effects
- 5. Storing ANDROCAP®
- 6. Packaging of ANDROCAP®

Presentation:

ANDROCAP® 40mg Capsule

The active substance is Testosterone Undecanoate.

1. What ANDROCAP® are and what they are used for

The active substance of ANDROCAP® is turned into Testosterone by your body. Testosterone is the natural male hormone, necessary for the normal growth, development and function of the male sex organs and for secondary male sex characteristics. Preparations containing Testosterone are usually prescribed to replace the hormone if the body is unable to produce enough

ANDROCAP® are soft oval glossy capsules, transparent, orange red colour, with a oily fill.

2. Before you take ANDROCAP®

Do not take ANDROCAP®

- if you have a tumour of the prostate or the breast
- if you are hypersensitive (allergic) to Testosterone Undecanoate or any of the other ingredients of ANDROCAP®

Take special care with ANDROCAP®:

Extra supervision by a doctor is necessary in the treatment of young boys. since Testosterone suppletion may cause early sexual development and disturb growth. Extra supervision by a doctor is also necessary in the treatment of elderly men, since male hormones may increase the size of the prostate gland.

Medical checks may also be necessary in some other conditions.

Therefore, tell your doctor if you have or have ever had:

- · heart disease
- · kidney disease
- high blood pressure
- epilepsy
- migraine headaches
- prostatic complaints, such as problems with passing urine

Taking ANDROCAP® with food and drink

Food allows Testosterone Undecanoate to be taken up by your body. Therefore, ANDROCAP $^{\! B}$ must be taken with a meal.

Driving and using machines

As far as is known ANDROCAP® have no adverse effect on alertness and concentration.

Using other medicines

Other medicines may influence the effects of ANDROCAP® or ANDROCAP® may affect other medicines. You must tell your doctor or pharmacist if you are using (or intend to use) rifampicin (an antibiotic) or medicines for epilepsy or sleeplessness.

3. How you take ANDROCAP®

Usually, the dosage is 3-4 capsules daily during the first 2-3 weeks, followed by a gradual decrease to 1-3 capsules daily. You must take ANDROCAP® 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 larger number in the morning.

If you have the impression that the effect of ANDROCAP® is too strong or too weak, inform your doctor immediately.

If you take more ANDROCAP® 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 ANDROCAP®:

Do not take a double dose to make up for forgotten individual dose.

Effects when treatment with ANDROCAP® is stopped:

When treatment with ANDROCAP® is stopped, complaints as those before treatment may re-occur within a few weeks.

4. Possible side effects

Like all medicines, ANDROCAP® can have side effects.

In general:

- increased sexual desire
- fluid retention in the tissues, usually marked by swelling of ankles or feet

- prolonged abnormal, painful erection of the penis
- · disturbed formation of sperm
- · decreased amount of sperm with seminal discharge

In elderly men:

· problems with passing urine

In young boys:

- · early sexual development
- erections occurring more often than normal
- enlarged penis
- disturbed growth

Tell your doctor as soon as possible if any side-effect becomes troublesome or continues.

5. Storing ANDROCAP®

Keep ANDROCAP® out of reach and sight of children.

Store at 8°C-30°C.

Store in the original package in order to protect from light.

Do not use ANDROCAP® after the expiry date stated on the package, sachet and blister.

6. Packaging ANDROCAP $^{\tiny{(B)}}$ 40mg Capsule: Each box contains (3X10) Capsules in blister pack within Alu-Alu pillow pack.

