



TADENAN® 50mg

Pygeum africanum extract

1. PRODUCT IDENTIFICATION

• TRADE NAME:

TADENAN® 50 mg, soft capsule.

• QUALITATIVE AND QUANTITATIVE COMPOSITION:

Pygeum africanum extract (Prunus africana).....50mg
Excipients: arachis oil (peanut oil), gelatin, glycerol, titanium dioxide (E171), cupric hydrosoluble chlorophyllin (E141).

• PHARMACEUTICAL FORM:

Soft capsule, box of 30 or 60 capsules.

• PHARMACO-THERAPEUTIC CLASSIFICATION:

Other drugs used in the benign prostatic hyperplasia. (G04CX01: Genito urinary system and sex hormones)

• Laboratoires FOURNIER S.A.

153, Rue de Buzenval - 92380 GARCHES - FRANCE

Phone number: 33 (0)1 47 10 88 00

Holder/Manufacturer:

Laboratoires FOURNIER S.A.

42, rue de Longvic - 21300 CHENOVE - FRANCE

2. INDICATIONS AND USAGE

This drug is recommended in the treatment of certain forms of micturitional disorders (emission of urine) associated with benign prostatic hyperplasia (increase in prostate volume).

3. WARNING!

• SITUATIONS IN WHICH THIS MEDICINE SHOULD NOT BE USED:

IN CASE OF ANY DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

• PRECAUTIONS FOR USE:

Use of the drug does not exempt patient from usual medical follow-up of the prostate. This drug cannot be used as a substitute for surgical intervention when necessary.

Keep out of the reach and sight of children.

IN CASE OF DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

• DRUG INTERACTIONS AND OTHER INTERACTIONS:

TO AVOID DRUG INTERACTIONS IT IS NECESSARY TO INFORM YOUR DOCTOR OR PHARMACIST OF ALL OTHER CURRENT MEDICATIONS.

• PREGNANCY - BREAST FEEDING:

The therapeutic indication does not apply to women.

• LIST OF EXCIPIENTS HAVING A RECOGNIZED EFFECT:

Arachis oil.

4. HOW TO USE THIS MEDICINE?

• DOSAGE, METHOD AND ROUTE OF ADMINISTRATION:

Oral route.

The dose is adapted to each individual case.

Usually, 1 capsule in the morning and in the evening preferably before meals.

Usually, a 6 weeks treatment which can be extended to 8 weeks.

This treatment can be renewed if necessary.

IN ANY CASE RESPECT YOUR DOCTOR'S PRESCRIPTION.

5. UNWANTED AND DISTURBING EFFECTS

LIKE ALL ACTIVE DRUGS, THIS ONE MAY, IN SOME CASES, GENERATE ADVERSE EVENTS WHICH MAY PROVE TROUBLESOME:

Eventuality of digestive troubles (nausea, constipation, diarrhoea).

This drug contains peanut oil, risk of allergic reactions (urticaria, severe allergic reaction).

YOU SHOULD INFORM YOUR DOCTOR OR PHARMACIST OF ANY UNWANTED AND DISTURBING EFFECTS OTHER THAN THOSE MENTIONED IN THIS LEAFLET.

6. STORAGE

• DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE BOX

• SPECIAL STORAGE CAUTIONS:

Do not store above 25°C.

7. DATE OF REVISION OF THIS LEAFLET:

September 2003

THIS DRUG WAS PRESCRIBED TO YOU IN A SPECIFIC SITUATION:

- IT CANNOT BE USED IN ANY OTHER CASE

- DO NOT REUSE IT WITHOUT CONSULTING YOUR DOCTOR

- DO NOT RECOMMEND IT TO ANYBODY ELSE.

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