FINLESTA-5
Finasteride Tablets BP 5 mg

COMPOSITION:
Each film coated tablet contains:

Finasteride BP	5 mg
Excipients	q.s.

Colour: Titanium Dioxide BP

DESCRIPTION:
FINLESTA-5 is Film-coated Tablets contains Finasteride BP 5 mg indicated for the treatment and control of benign prostatic hyperplasia (BPH) in patients with an enlarged prostate to:
- cause regression of the enlarged prostate, improve urinary flow and improve the symptoms associated with BPH
- reduce the incidence of acute urinary retention and the need for surgery including transurethral resection of the prostate (TURP) and prostatectomy

PHARMACODYNAMICS:
Pharmacotherapeutic group: Agent used in benign prostatic hyperplasia, testosterone-5-α-reductase inhibitor
ATC code: G04CB01
Mechanism of action
Finasteride is a competitive inhibitor of human 5 α-reductase, an intracellular enzyme which metabolises testosterone into the more potent androgen dihydrotestosterone (DHT). In benign prostatic hyperplasia (BPH), enlargement of the prostate gland is dependent upon the conversion of testosterone to DHT within the prostate. Finasteride is highly effective in reducing circulating and intraprostatic DHT. Finasteride has no affinity for the androgen receptor.

PHARMACOKINETICS:
After an oral dose of ^{14}C-finasteride in man, 39% of the dose was excreted in the urine in the form of metabolites (virtually no unchanged drug was excreted in the urine), and 57% of total dose was excreted in the faeces. Two metabolites have been identified which possess only a small fraction of the Type II 5 α-reductase activity of finasteride.
The oral bioavailability of finasteride is approximately 80%, relative to an intravenous reference dose, and is unaffected by food. Maximum plasma concentrations are reached approximately two hours after dosing and the absorption is complete within 6-8 hours.
Protein binding is approximately 93%. Plasma clearance and the volume of distribution are approximately 165 ml/min and 76 l, respectively.
Elderly
In the elderly, the elimination rate of finasteride is somewhat decreased. Half-life is prolonged from a mean half-life of approximately six hours in men aged 18-60 years to eight hours in men aged more than 70 years. This is of no clinical significance and does not warrant a reduction in dosage.
Chronic renal impairment
In patients with chronic renal impairment, whose creatinine clearance ranged from 9-55 ml/min, the disposition of a single dose of ^{14}C-finasteride was not different from that in healthy volunteers. Protein binding also did not differ in patients with renal impairment. A portion of the metabolites which normally is excreted renally was excreted in the faeces. It therefore appears that faecal excretion increases commensurate to the decrease in urinary excretion of metabolites. Dosage adjustment in non-dialysed patients with renal impairment is not necessary.
Hepatic insufficiency
There are no data available in patients with hepatic insufficiency.
Finasteride has been found to cross the blood-brain barrier. Small amounts of finasteride have been recovered in the seminal fluid of treated patients.

INDICATION:
FINLESTA-5 indicated for the treatment and control of benign prostatic hyperplasia (BPH) in patients with an enlarged prostate to:
- cause regression of the enlarged prostate, improve urinary flow and improve the symptoms associated with BPH
- reduce the incidence of acute urinary retention and the need for surgery including transurethral resection of the prostate (TURP) and prostatectomy

DOSAGE AND ADMINISTRATION:
Posology
The recommended adult dose is one 5 mg tablet daily, with or without food. The tablets should be swallowed whole and should not be broken or crushed.
FINLESTA-5 Tablets can be administered alone or in combination with the alpha-blocker doxazosin.
Although early improvement in symptoms may be seen, treatment for at least six months may be necessary to assess whether a beneficial response has been achieved. Thereafter, treatment should be continued long term.
No dosage adjustment is required in the elderly or in patients with varying degrees of renal insufficiency (creatinine clearances as low as 9 ml/min).
There are no data available in patients with hepatic insufficiency.
FINLESTA-5 Tablets are contra-indicated in children.

CONTRAINDICATION:
FINLESTA-5 Tablets are not indicated for use in women or children.
FINLESTA-5 Tablets are contraindicated in the following:
Hypersensitivity to any component of this product
Pregnancy - Use in women when they are or may potentially be pregnant

SPECIAL WARNING AND PRECAUTION FOR USE:
General
To avoid obstructive complications it is important that patients with large residual urine and/or heavily decreased urinary flow are carefully controlled. The possibility of surgery should be an option.
Effects on prostate specific antigen (PSA) and prostate cancer detection
No clinical benefit has yet been demonstrated in patients with prostate cancer treated with finasteride. Patients with BPH and elevated serum prostate specific antigen (PSA) were monitored in controlled clinical studies with serial PSAs and prostate biopsies. In these BPH studies, finasteride did not appear to alter the rate of prostate cancer detection and the overall incidence of prostate cancer was not significantly different in patients treated with finasteride or placebo.
Digital rectal examinations as well as other evaluations for prostate cancer are recommended prior to initiating therapy with finasteride and periodically thereafter. Serum PSA is also used for prostate cancer detection. Generally a baseline PSA >10 ng/mL (Hybritech) prompts further evaluation and consideration of biopsy; for PSA levels between 4 and 10 ng/mL, further evaluation is advisable. There is considerable overlap in PSA levels among men with and without prostate cancer. Therefore, in men with BPH, PSA values within the normal reference range do not rule out prostate cancer regardless of treatment with finasteride. A baseline PSA <4 ng/mL does not exclude prostate cancer.
Finasteride causes a decrease in serum PSA concentrations by approximately 50% in patients with BPH even in the presence of prostate cancer. This decrease in serum PSA levels in patients with BPH treated with finasteride should be considered when evaluating PSA data and does not rule out concomitant prostate cancer. This decrease is predictable over the entire range of PSA values, although it may vary in individual patients. In patients treated with finasteride for six months or more, PSA values should be doubled for comparison with normal ranges in untreated men. This adjustment preserves the sensitivity and specificity of the PSA assay and maintains its ability to detect prostate cancer.
Any sustained increase in PSA levels of patients treated with finasteride 5mg should be carefully evaluated, including consideration of non-compliance to finasteride therapy.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT:
No drug interactions of clinical importance have been identified. Finasteride is metabolized primarily via, but does not appear to affect significantly the cytochrome P450 3A4 system. Although the risk for finasteride to affect the pharmacokinetics of other drugs is estimated to be small, it is probable that inhibitors and inducers of cytochrome P450 3A4 will affect the plasma concentration of finasteride. However, based on established safety margins, any increase due to concomitant use of such inhibitors is unlikely to be of clinical significance.
Compounds which have been tested in man have included doxazosin, propranolol, digoxin, glibenclamide, omeprazole, warfarin, theophylline, and phenazone and no clinically meaningful interactions were found.

PREGNACY AND LACTATION:
Pregnancy
Finasteride is contraindicated in women when they are or may potentially be pregnant.
Because of the ability of Type II 5 α-reductase inhibitors to inhibit conversion of testosterone to dihydrotestosterone, these drugs, including finasteride, may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant woman
Breast-feeding
FINLESTA-5 Tablets are not indicated for use in women.
It is not known whether finasteride is excreted in human milk.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
There are no data to suggest that FINLESTA-5 Tablets affect the ability to drive or use machines.

UNDESIRABLE EFFECT:
The most frequent adverse reactions are impotence and decreased libido. These adverse reactions occur early in the course of therapy and resolve with continued treatment in the majority of patients.
The adverse reactions reported during clinical trials and/or post-marketing use are listed in the table below.
Frequency of adverse reactions is determined as follows:
Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000), not known (cannot be estimated from the available data).

- **Immune system disorders**
  Unknown: hypersensitivity reactions including swelling of the lips and face
- **Psychiatric disorders**
  Common: decreased libido
  Unknown: decreased libido that may continue after discontinuation of therapy, depression
- **Cardiac disorders**
  Unknown: palpitation
- **Hepatobiliary disorders**
  Unknown: increased hepatic enzymes
- Skin and subcutaneous tissue disorders
  Uncommon: rash
  Unknown: pruritus, urticaria
- **Reproductive system and breast disorders**
  Common: impotence
  Uncommon: ejaculation disorder, breast tenderness, breast enlargement
  Unknown: testicular pain, sexual dysfunction (erectile dysfunction and ejaculation disorder) which may continue after discontinuation of treatment; male infertility and/or poor seminal quality. Normalization or improvement of seminal quality has been reported after discontinuation of finasteride.

OVERDOSE:
No specific treatment of overdosage with finasteride is recommended. Patients have received single doses of finasteride up to 400 mg and multiple doses of up to 80 mg/day for up to three months without any adverse effects.

INCOMPATIBILITY:
Not Applicable

SHELF LIFE:
36 months

PACKAGING:
10 tablets are packed in Alu- Alu blister and such 5 blisters are packed in a monocarton along with pack insert.

STORAGE CONDITION:
Store in dry place below 30°C.
Keep out of reach of children.

MARKETED BY:
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