ESTRADURIN®
Polyestradiol Phosphate
For Treatment of Prostate Cancer\(^{(1)}\)
**ESTRADURIN® HAS AN ANTICANCER EFFICACY EQUAL TO COMBINED ANDROGEN DEPRIVATION (CAD)**

In The Scandinavian Prostatic Cancer Group (SPCG)-5 Trial it was found that there were no difference between the two treatment groups in relation to overall survival after a medium follow-up of 18.5 months. At the final evaluation, when 855 out of 910 patients had died, there was no difference between groups in relation to biochemical or clinical progression-free survival or in overall or disease-specific survival.

**Significantly fewer grave skeletal events in ESTRADURIN® vs. CAD treated patients**

In the same study the number of skeletal events was measured. There were 18 grave skeletal events in the CAD group but none in the ESTRADURIN® group (p=0.001). The groups consisted of 458 patients in the ESTRADURIN® arm and 457 patients in the CAD arm.

**Significantly lower incidence of hot flashes in ESTRADURIN® vs. CAD treated patients**

A prospective evaluation of hot flashes during treatment showed that the incidence in ESTRADURIN® treated patients was 30.1% vs. 74.3% (p<0.001) in CAD treated patients. There was a complete relief from hot flashes in 50% of men treated with ESTRADURIN® during follow-up vs. none in the CAD treated group.

**No difference in cardiovascular (CV) mortality in ESTRADURIN® vs. CAD treated patients**

The SPCG-5 study showed no difference in CV mortality between treatment groups, but a significant increase in non-fatal CV events in the ESTRADURIN® arm (p<0.05).

**Conclusion**

- Prostate cancer patients with metastasis get the same anticancer efficacy from treatment with ESTRADURIN® and CAD.
- It is feasible to use ESTRADURIN® in the primary or secondary endocrine treatment of patients without prominent cardiac risk factors and especially those with osteoporosis.
- Endocrine treatment with ESTRADURIN® induces fewer hot flashes than CAD treatment.
i.m. ESTRADURIN® 80 mg
polyestradiol. phosph.
Pulver til injektionsvæske /
Injektiokuiva-aine /
Pulver til injeksjonsvæske /
Pulver till injektionsvätska
ABBREVIATED PRESCRIBING INFORMATION FOR ESTRADURIN 80 mg POWDER AND SOLVENT FOR SOLUTION FOR INJECTION.

One vial contains: polyestradiolphosphate 80 mg and mepivacaine hydrochloride 5 mg. Holder of market authorization: Pharmanovia A/S, Jægersborg Allé 164, 2820 Gentofte, Denmark. Indication: Prostatic carcinoma. Contraindications: Active or recent arterial thromboembolic disease. Prior or current venous thromboembolism. Predisposition for thrombosis. Hyperlipoproteinemia. Acute or prior liver disease as long as the liver function have not been normalised. Porphyria. Hypersensitivity to estradiol, mepivacaine or any excipients. Warnings and rules of caution: These conditions can recur or be aggravated from treatment with Estradurin: Risk factors for thromboembolic disease, hypertension, liver disorders, diabetes mellitus with or without vascular involvement, gall stone disease, migraine or (severe) headache, systemic lupus erythematous (SLE), epilepsy, asthma, otosclerosis. Reasons to immediately cease treatment: The treatment should be ceased with the appearance of conditions that are found under the section: Contraindications and with: Jaundice (icterus) or deteriorating liver function, significant increase in blood pressure, debut of migraine-like headache. Interactions with other drugs and other interactions: The metabolism of oestrogens can increase with simultaneous treatment with substances that induce cytochrome P450 enzymes. For example anti-epileptics (e.g. phenobarbitol, phenytoin or carbamazepine) and certain drugs against infections (e.g. rifampicine, nevirapine or efavirenz). Ritonavir and nelfinavir display inducing properties when they are administered together with steroid hormones. St. John’s wort (Hypericum perforatum) can also induce the metabolism of oestrogens. Adverse effects: Common (≥1/100, <1/10) Gynecomastia, weight change, headache, abdominal pain, nausea, rash, itching, impotence. Dosage and method of administration: Estradurin is a depot preparation of estradiol and shall be administered deep intramuscularly. Dosage: 160-320 mg every fourth week for a three month. The dose can then be reduced to 80-160 mg every fourth week. Packaging type and contents: Colourless glass vial with rubber cork containing the freeze-dried substance. Colourless glass ampoule containing solvent. Packaging sizes: Powder and solvent for solution for injection. 1 x (bottle with powder + ampoule with solvent). Price 06/24/2013: DK: AUP 240.05 DKK, dispensing Group B, general subvention SE: AUP 258.00 SEK, to be sold only with a doctor’s prescription. Further information including full prescribing information is available from: Pharmanovia A/S, jægersborg Allé 164, 2820 Gentofte, Denmark. Tel: +45 33 33 76 33.