

The following incomplete list of off-label uses of lupron/leuprolide is an excerpt from within Millican's 03-27-03 Congressional Testimony:

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“GnRH and its analogs have led to exciting new avenues of therapy in virtually every subspecialty of internal medicine as well as in gynecology, pediatrics, and urology ... virtually every subspecialty of medicine will be touched by the GnRH analogues ...” (Conn, Crowley; 1994).

The following is a fairly comprehensive, alphabetical list of clinical uses, case reports, or studies involving Lupron's use in unapproved and off-label indications. These uses were mostly found within published medical literature, although some were noted within patents, or advertisements for clinical trials, and one was a personal clinical observation. Citations have been omitted for brevity, but are available upon request.

A: adjuncts for IVF; adjunct to fibroid surgery; anovulation; autism [management of sexual behaviors]; acute intermittent porphyria; Alzheimer; adenomyosis; severe adenomyosis; adhesions; amenorrhea [functional]; angiomyxoma of vulva; autoimmune disease; autonomic neuropathies; ‘add-back’ regimen [estrogen/progestin with lupron]; advanced breast cancer.

B: before hysterectomy for leiomyomas; benign prostatic hyperplasia; benign prostatic hypertrophy; birth control; breast cancer; breast cancer prevention; bioavailability following nasal and inhalation delivery to healthy humans.

C: catamenial insulin reaction; catamenial pneumothorax; chronic intestinal pseudo obstruction [in patient with heart-lung transplant]; cluster headaches; colorectal cancer, congenital adrenal hyperplasia with oligomenorrhea; contraception; cryptorchidism; controlled ovarian hyperstimulation in normal, abnormal and poor responders; combination therapy with flutamide and castration; colonic endometriosis; comparison of suppressive capacity of different GnRHa's in women; comparison of hCG versus lupron for releasing oocytes.

D: dysfunctional uterine bleeding prior to hysterectomy, dyspepsia.

E: egg donation; endometrial ablation; endometrial cancer, endometrial glandular hyperplasia; endometrial hyperplasia without atypia; endometrial cancer; endometrial stromal sarcoma; epithelial ovarian cancer; exhibitionism; effect of very high dose in prostate cancer; effects in animal and man; effect on embryos (“accelerated development”); endometrial preparation for transfer of frozen-thawed pre-embryos in patients with anovulatory or irregular cycles; effects on follicular fluid hormone composition at oocyte retrieval for IVF; effect on hair growth and hormone levels in hirsute women; effects on glucose metabolism in a diabetic patient; equivalency of hMG and FSH stimulation following suppression; effect on LH surge ; effect on adrenocorticotropin and cortisol secretion in premenopausal women; effect on seminal vesicles; effects of lupron on luteal-phase hyperprolactinemia during ovarian stimulation.

F: fallopian tube obstruction; functional ovarian hyperandrogenism, functional abdominal pain from functional bowel disease; fibrocystic breast disease; first cycles of IVF/GIFT;

follicular development and oocyte maturation.

G: GIFT.

H: Headache, Huntington's Disease (for exhibitionism), hyperandrogenism, hysteroscopic surgery; hilus cell hyperplasia within ovarian cyst wall; hypermenorrhea in premenopausal women with acute leukemia; hypermenorrhea with severe thrombocytopenia; hypogonadotrophic hypogonadism; hypergonadotrophic hypogonadism; hypergonadotrophic amenorrhea; hypothalamic-pituitary axis disease; hypothalamic hamartomas and sexual precocity; hirsutism; moderate and severe hirsutism; hysteroscopic surgery; benign symptomatic hyperandrogenism in a postmenopausal woman; hidradenitis suppurativa.

I: infertility; IUI; IVF; IVF-ET in insulin-dependent diabetics; irritable bowel syndrome; intravenous leiomyomatosis with cardiac extension; intranasal lupron for endometriosis; intranasal/sc lupron for fibroids.

K: Kallmann syndrome.

L: leuprolide flare regime for IVF/GIFT & embryo cryopreservation; lupron screening test for IVF; luteal phase lupron flare protocol; luteinized unruptured follicle syndrome; leiomyosarcoma; leiomyomatosis peritonealis disseminata.

M: male contraception; \*male\* factor infertility (female is treated - male is not); Meniere's Disease; menstrual migraines; motility disorders.

O: ovarian cysts; ovarian cysts after ovarian transposition; ovarian epithelial tumors; ovarian granulosa cell tumor; ovarian hyperthecosis; advanced epithelial ovarian carcinoma; ovulation induction; ovarian stimulation; ovarian stimulation with lupron and norethindrone in IVF/GIFT; ovarian hyperstimulation; oocyte release; ovarian hyperstimulation syndrome; severe ovarian hyperstimulation; oocyte donation, oocyte donation [post-menopausal]; operable breast cancer; ovarian carcinoma [refractory]; ovarian remnant syndrome [diagnostic].

P: pancreatic cancer; paraphilias; Parkinson's Disease symptoms, pedophilia, pelvic pain not associated with endometriosis; pituitary metastatic mass; polycystic ovarian disease; PMS; protection against chemotherapy-induced testicular damage; postpartum depression; premenopausal breast cancer; post-menopausal breast cancer [advanced]; pre-implantation [embryonic] diagnosis; prevention of hypermenorrhea in premenopausal women undergoing bone marrow transplantation; prostate cancer (Stage C adenocarcinoma); endometroid adenocarcinoma of prostate; pseudo intestinal blockage, psychosis in PMS, resistant paraphilia, pulmonary endometriosis; pulmonary tuberous sclerosis; pulmonary delivery of leuprolide in health male volunteers; pre-myomectomy; poor prognosis patients for IVF/poor responders ; preservation of fertility in a woman with menorrhagia; pharmacokinetic studies in humans [iv and sc]; preoperative treatment of complicated myomata; pre-surgical treatment of fibroids.

R: resectoscopic endometrial ablation; rectal endometriosis; routine pituitary suppression before ovarian stimulation.

S: sexual offenders; sexual precocity; Sickle-cell anemia associated priapism; surrogacy, SUZI; steroid-cell tumor (advanced); systemic lupus erythematosus; submucous myomas; sexual behavior disorders; syndrome of familial virilization, insulin resistance, and acanthosis nigricans; stimulation test in Tourette's syndrome; small cell carcinoma of prostate.

T: transgender adjunct, testicular function effects; transdermal vs. subcutaneous leuprolide - a comparison; triggering follicular maturation.

U: urinary retention in prostate cancer; ureteral obstruction caused by endometriosis; urinary retention due to benign prostatic hyperplasia.

W: with or without medroxyprogesterone in treatment of fibroids.

Z: ZIFT