Decreased testicular size* 7 11
Anorexia 65
Nausea 52
Vomiting 52
Frequency/urgency 68
Bone pain 52
Integumentary System
Dyspnea 28
Myalgia 39
Arthralgia 28
Joint pain 28
Rashes 28
Dermatitis 28
Dermographism 28
Pain 28
Pain, extremity 28
Pain, back 28
Integumentary System
Gastrointestinal System
Mouth dryness 14
Abdominal distention 7
Abdominal pain 11
Dyspepsia 7
Nausea 11
Vomiting 7
Anorexia 11
Dysphagia 7
Hemic and Lymphatic System
Anemia 7
Myocardial infarction 11
Pulmonary emboli 11
Cerebrovascular accident 11
Surgical site complications 11
Cardiovascular System
Hypertension 11
Dizziness 11
Hypotension 11
Rhinitis 11
Dry skin 11
Tremor 11
Sneezing 11
Cough 11
Sneezing, rhinorrhea 11
Sinusitis 11
Integumentary System
Diabetes mellitus 11
Migraine 11
Itching 11
Weight loss 11
Weight gain 11
Blurred disc margins 11
Bone fracture 11
Muscle stiffness 11
Muscle tenderness 11
Pelvic fibrosis 11
Spasms/cramps 11
Carcinoma of skin/ear 14
Dry skin 14
Mole 14
Shingles 14
Spiders 14
Rales/rhonchi 14
Rhinitis 14
Strep throat 14
Wheezing/bronchitis 14

dosage and administration:

Leuprolide acetate injection is chemically similar to gonadotropin releasing hormone (GnRH or LH-RH) a hormone that makes testosterone again. This effect is reversible. Patients receiving a GnRH ago -

lide acetate for up to three years with doses as high as 10

PSA. In the majority of patients, testosterone levels

dence of a mutagenic potential. Clinical and pharmacologic

Pregnancy Category X:
with prostate cancer, 12 of whom had been treated previously.

function is usually restored within 4 to 12 weeks after treatment.

cell adenomas in males (highest incidence in the low dose

Nursing Mothers: creatic islet-cell adenomas in females and of testes interstitial

Pregnancy Category X:

CLINICAL PHARMACOLOGY: Pharmacokinetics:

Absorption: A two-year carcinogenicity study was conducted in rats

Distribution: In healthy adult male volunteers, a 1 mg bolus of leuprolide

Clearance was 7.6 L/h, with a terminal elimination half-life of

Approximately 3 hours based on a two compartment model.

Contraindications: The analog possesses greater potency than the nat -

sodium chloride, USP (6.3 mg/mL) for tonicity adjustment, ben -

Drug Interactions: anaphylactic reactions to GnRH agonist analogs have been

Carcinogenesis, Mutagenesis, Impairment of Fertility:

In those same studies, the following adverse reactions were

In children with central precocious puberty (CPP), stimulated

Baseline evaluation should also include:

- Computerized tomography of the head to rule out intracra-

Prophylactic administration of leuprolide, prior to gonadotropin surges, is recom-

Hypertrophy;

• Convulsion, Spinal fracture/paralysis, Hearing disorder;

• Height and weight measurements.

• Beta human chorionic gonadotropin level to rule out a

• Tanner staging to confirm downregulation.

• IR INJECTION

• Prepare aseptically the solution of leuprolide acetate.

• Dilute the solution to the appropriate volume, as indicated in the

• Mix gently but thoroughly with a sterile syringe without

• Tubing and extension set or other medical device in which

• Sterile syringe, 16G or larger:

• Syringe and needle:

• Sterile saline solution (10 mL):

• Needle:

• Alcohol swabs:

• Inserting the needle:

• The recommended starting dose is 50 mcg/kg/day adminis-

• When administering the injection to adult patients, the

• During postmarketing surveillance, which includes other

• The recommended starting dose is 50 mcg/kg/day adminis-

• The recommended starting dose is 50 mcg/kg/day adminis-

• The recommended starting dose is 50 mcg/kg/day adminis-

• Note:

• ADMINISTERING THE INJECTION

1. Discontinue all oral contraceptives, estrogen, or progestin


ADMINISTERING THE INJECTION

Leuprolide Acetate for Injection

Administering the Injection:
Read this booklet before injecting the medication. Read the complete instructions for injection.

Provided as an educational service by Sandoz Inc., Princeton, NJ 08540

ADMINISTERING THE INJECTION

1. Wash hands thoroughly.

2. Check the liquid in the container. It should look clear. DO NOT USE if it is not clear or if it has particles in it. If using a new bottle, flip off the plastic cover to expose the grey rubber stopper. Use an alcohol swab to cleanse the metal ring and rubber stopper on medication bottle every day, just before you use it.

3. Remove outer wrapping from one syringe.

4. Pull the syringe plunger back until its tip is at the proper mark.

5. Uncover needle. Do not touch the needle.

6. Place the bottle on a clean, flat surface and push the needle through the center of the rubber stopper on the bottle. Push the plunger all the way in to inject air into the bottle.

7. Keep the needle in the bottle. Lift the bottle and turn it straight upside down. Check to see that the needle tip is in the liquid.
8. With the needle tip in the liquid, slowly pull back the plunger until syringe fills to the proper mark. If any bubbles appear in the syringe, remove them by pushing the plunger up slowly. With the needle tip still in the liquid, pull the plunger until it is once more at the proper mark.

9. Choose a different injection site each day.

   Cleanse the injection site with a new alcohol swab.

   Hold the skin the way you were instructed.

   Slide the needle quickly all the way through the skin, into the subcutaneous tissue, at a 90° angle.

10. Push the plunger to inject the medication.

    Withdraw the needle at the same angle it was inserted (90°).

    Wipe the skin with an alcohol swab.

11. Dispose of the syringe and alcohol swabs as you were instructed. Remember: use the disposable syringe only once.