Direct Healthcare Professional Communication (DHPC)

Dhai Taiba Pharmaceutical Company
Date: 17/09/2025

Subject: Important Safety Information Regarding Lectrum Acetate 7.5 mg Injection (Eriochem) – Absence of English Package Leaflet

Dear Healthcare Professional,

Dhai Taiba Pharmaceutical Company, in agreement with the Saudi Food and Drug Authority (SFDA), would like to notify you of an important safety concern regarding Lectrum Acetate 7.5 mg Injection (Eriochem).

Summary of the Safety Concern

- Certain batches of Lectrum Acetate 7.5 mg Injection were distributed in Saudi Arabia without an English-language package leaflet.
- The absence of the leaflet may limit access to essential information related to safe use, dosage, precautions, contraindications, and possible adverse reactions.

Recommendations for Healthcare Professionals

- Ensure patients receive the necessary medical guidance and counseling in the absence of the English leaflet.
- Refer to the approved English product information provided by the company for full details on indications, dosing, contraindications, warnings, and safety profile.
- Report any suspected adverse reactions related to Lectrum Acetate promptly to the National Pharmacovigilance Center.

Background on the Safety Concern

- The package leaflet is a key reference for healthcare professionals and patients.
- Its absence may increase the risk of inappropriate use, lack of awareness of contraindications, and under-reporting of adverse events.
- Corrective actions are currently being implemented to ensure all future batches distributed in Saudi Arabia will contain the English package leaflet.

Call for Reporting
Healthcare professionals are strongly encouraged to report any suspected adverse reactions associated with Lectrum Acetate to the National Pharmacovigilance Center via:
- Phone: +966-11-2038222 Ext. 2350-2354
- Fax: +966-11-2057662
- Email: npc.drug@sfda.gov.sa
- Online: https://ade.sfda.gov.sa

Contact Information
For any inquiries regarding this communication, please contact:
Email: pharmacovigilance@dhaitaiba.com

Phone: 0504815709

Sincerely,
Dr. Nourah Fahd ElSaqr
PharmacoVigilance Director
On behalf of Dhai Taiba Pharmaceutical Company

190mm

390mm

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Lectrum ®7.5mg

Leuprolide acetate
Freeze-dried injectable
Argentine Industry - Prescription sales

Read the entire leaflet carefully before you start using the medicine.
- Keep this leaflet, as you may need to read it again.
- If you have any questions,**Consult your doctor or pharmacist.**
- If you consider that any of the adverse effects you suffer are serious or if appreciate any side effects not mentioned in this leaflet,
tell your doctor or pharmacist.
- This medicine has been prescribed for you and**should not give it to others people**, even if they have the same symptoms, since it can harm them.

Leaflet content:

1. WHAT IS LECTRUM7.5mg AND WHAT IT IS USED FOR
Lectrum 7.5 mg is a medicine that belongs to the group of analogues of gonadotropin-releasing hormone.
Lectrum 7.5 mg is used for the palliative treatment of carcinoma of the advanced prostate.
It is also indicated in the treatment of central precocious puberty, diagnosed clinically by the appearance of secondary sexual characteristics before the age of eight in girls and nine in boys.

2. BEFORE USING LECTRUM7.5mg Do not use Lectrum7.5mg if
- is hypersensitive to leuprolide acetate or similar nonapeptides or to any of the other ingredients of this medicine,
- you are pregnant or think you might become pregnant during treatment,
- is breastfeeding.

Precautions and warnings *Take special care with Lectrum 7.5 mg*
- Generally there is an increase in the blood of the sex hormone male (testosterone) and female sex steroids during the first week of treatment. This can lead to a temporary worsening of symptoms related to the disease and also the appearance of new symptoms that had not been experienced until then. These symptoms especially include bone pain, problems with urination, or pressure on the spinal cord. These symptoms normally subside as treatment continues. If the symptoms do not

If symptoms subside or worsen, you should contact your doctor immediately.
- If you experience obstruction of the urinary tract, presence of blood in the urine or metastatic spinal and/or brain lesions. In these cases your
Your doctor should monitor you during the first weeks of treatment.
- Cases of hyperglycemia and increased risk of
If you develop diabetes, your doctor will need to monitor you periodically.
- It can cause loss of bone mineral density with risk of osteoporosis fractures.
- May increase the risk of cardiovascular disease if you have other
Tell your doctor about cardiovascular risk factors.
- If you have a history of QT prolongation in the electrocardiogram (recording of the electrical activity of the heart), salt imbalance in the blood or taking medications that can cause changes in the electrocardiogram (see Use of Lectrum 7.5 mg and other medications), tell your doctor.
- Seizures have been observed in patients with or without a history of
predisposing factors, your doctor will tell you what you should do in that case.
- Leuprolide may cause fetal harm.

Central precocious puberty:
- follow the doctor's instructions as failure to do so may mean death.
return of signs of puberty.
- worsening of clinical symptoms may be observed during first phase of treatment.
- the doctor may carry out tests to correctly establish
the dose.
- know that it is the parents who must accept the treatment scheme for the therapy to be successful.
- psychiatric events such as changes in mental status have been reported mood (crying, irritability, impatience, anger and aggression). Your doctor should monitor the development or worsening of symptoms.

Use of Lectrum 7.5mg and other medications
No interactions with other medications have been described.
Tell your doctor if you take medications to treat cardiac arrhythmias.
heart, some antibiotics, some antidepressants or others medications that can cause changes in the electrocardiogram. Tell your doctor or pharmacist if you are using or have used
recently other medications, even those purchased without a prescription.

3. APPROPRIATE USE OF LECTRUM7.5mg
Follow the instructions for administration of Lectrum7.5 mg exactly. indicated by your doctor. Consult your doctor or pharmacist if you have doubts.
The normal dose for the treatment of prostate carcinoma is intramuscular injection once a month during the period stipulated by the doctor
In precocious puberty:
- the dose must be individualized for each child according to weight. The children
Younger people require higher doses.
- Initial dose: the recommended initial dose is 0.3 mg/kg of weight each four weeks (minimum 7.5 mg) administered intramuscularly, according to the following scheme:

WEIGHT	DOSE
<25kg	7.5mg
25 - 37.5kg	11.25mg
> 37.5kg	15mg

- Maintenance dose: the dose can be increased at intervals of 3.75 mg every 4 weeks until a maximum total dose of 15 mg is achieved. Your doctor will tell you the duration of treatment. Do not suspend the treatment sooner, since, even if you feel better, your illness could worsen or come back.

4. POSSIBLE ADVERSE EFFECTS
Like all medicines, Lectrum 7.5 mg can cause

adverse effects, although not all people suffer them.

prostate cancer
In clinical studies, the following adverse reactions occur in 5% or more of the patients who received leuprolide acetate:

- Cardiovascular system:	edema
- Digestive system:	nausea, vomiting
- Endocrine system:	decreased size of the testicles*, hot flashes*, sweating*, impotence*
- Central/peripheral nervous system:	generalized pain
- Respiratory system:	dyspnoea
- Miscellaneous:	asthenia

In these same studies, the following adverse reactions were reported in less than 5% of patients receiving leuprolide acetate:

- Cardiovascular system:	angina, cardiac arrhythmia
- Digestive system:	anorexia, diarrhea
- Endocrine system:	gynecomastia, decreased libido bone pain, myalgia
- Musculoskeletal system:	
- Central/peripheral nervous system:	paresthesia, insomnia
- Respiratory system:	hemoptysis
- Cutaneous system:	dermatitis, local skin reactions, hair growth
- Urogenital system:	dysuria, frequency, urinary urgency, testicular pain
- Miscellaneous:	diabetes, fever, chills, hard nodules in the oropharynx, increased serum calcium, weight gain, increased serum uric acid. Injection site reactions have been reported, including pain, swelling, sterile abscess, induration, and hematoma.

* Physiological effects of decreased testosterone

Additional adverse effects

Cardiovascular system:	congestive heart failure, hypertension, ECG changes/ischemia, myocardial infarction, murmur, phlebitis/thrombosis, pulmonary embolism, transient ischemic episode, QT prolongation, bradycardia, varicose veins
- Digestive system:	constipation, dysphagia, gastrointestinal disturbances and bleeding, liver dysfunction, peptic ulcer, rectal polyps, belching, elongated abdomen, duodenal ulcer, increased appetite, thirst/dry mouth
- Respiratory system:	cough, pleural rub, pulmonary fibrosis, pulmonary infiltration, respiratory changes, sinus congestion, emphysema, hemoptosis, pulmonary edema, increased sputum, epistaxis, pharyngitis, pneumonia, interstitial lung disease
- Hepatobiliary disorder	serious drug-induced liver injury breast
- Endocrine system:	pain or tenderness, increased libido, enlarged thyroid
- Blood and lymphatic system:	anemia, decreased number of white blood cells
- Musculoskeletal system:	tenosynovitis-like symptoms, ankylosing spondylitis, joint pain, pelvic fibrosis
- Central/peripheral nervous system:	anxiety, peripheral neuropathy, spinal fractures/paralysis, blurred vision, dizziness, disturbances in vision and taste, lethargy, memory disturbances, mood changes, slowness, syncope/loss of consciousness, agitation, neuromuscular disorders, hallucinations, hypoesthesia, nervousness, amblyopia, dry eyes, tinnitus
- Cutaneous system:	rash, urticaria, photosensitivity reactions, skin/ear carcinoma, dry skin, ecchymosis, hair loss, pruritus, lesions and skin pigmentation, hair disorders
- Urogenital system:	prostate pain, bladder spasms, incontinence, penis enlargement, urinary obstruction, urinary tract infection, urinary disorder, balanitis, breast enlargement, penis disorder, testicle disorder
- Miscellaneous:	Hypoglycemia, depression, infection/ inflammation, ophthalmological changes, tumors (temporal bone) and isolated cases of anaphylaxis, cellulitis, neoplasm, injection site reactions, lymphoedema, dehydration

precocious puberty
In general, the appearance of vaginal spotting with continued treatment (after possible withdrawal bleeding in the first month of treatment) should be evaluated as a sign of potential low dose.
Pituitary suppression should then be determined by LHRH testing.

Very rare side effects

- Immune system	General allergic reactions (fever, rash, itching, anaphylactic reactions

Additional adverse effects

- Cardiovascular system:	Vasodilation, bradycardia, hypertension, peripheral vascular disorder, syncope, hypotension, pallor
- Digestive system:	Constipation, dyspepsia, dysphagia, gingivitis, increased appetite
- Endocrine system:	acceleration of sexual maturity, feminization, gout
- Nervous system:	Depression, hyperkinesis, nervousness, drowsiness, mood disturbance, crying, dizziness, peripheral neuropathy, seizure, spinal fracture, paralysis
- Whole body	Generalized pain, aggravation of pre-existing tumor and decreased vision, allergic reaction, body odor, fever, flu-like syndrome, hypertrophy, infection
- Hematological and lymphatic system:	purple
- Metabolic and nutritional system:	Growth retardation, peripheral edema, weight gain, decreased appetite, obesity, diabetes mellitus
- Musculoskeletal system:	Arthralgia, joint disorder, myalgia, myopathy, musculoskeletal pain, pain in extremities, tenosynovitis-like symptoms Crying
- Psychiatric	
- Respiratory system:	Asthma, epistaxis, pharyngitis, rhinitis, sinusitis, cough
- Cutaneous system:	Seborrhea, rash including erythema multiforme, alopecia, hair disorder, hirsutism, leucoderma, nail disorder, skin hypertrophy, hyperhidrosis, redness
- Urogenital system:	Cervical disorder/neoplasm, dysmenorrhea, gynecomastia/breast disorders, menstrual disorder,

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Input: Prospectus Lectrum 7.5 Argentina
Language: Spanish
Master:MST PR 4261-00
Dimensions:190 x 390mm
Colors: Pantone Black
Material: Paper 53±10% g/m2

- General:	urinary incontinence, prostate pain Pain at the injection site, swelling at the injection site, asthenia, gait disorder, sterile abscess, hematoma, hardening and/or warmth at the injection site, irritability, chest pain Decreased white
- Investigations	blood cell count, weight gain
- Laboratory	Presence of antinuclear antibodies and increased erythrocyte sedimentation rate

A reduction in bone mass may occur with the use of agonists GnRH.
Pituitary apoplexy: During post-marketing surveillance,
Rare cases of pituitary apoplexy (clinical syndrome secondary to infarction of the pituitary gland) have been reported after administration of gonadotropin-releasing hormone agonists. In the majority of these cases, a pituitary adenoma was diagnosed, with a majority of cases of pituitary apoplexy occurring within 2 weeks of the first dose, and some within the first hour. In these cases, pituitary apoplexy has presented as sudden headache, vomiting, visual changes, ophthalmoplegia, altered mental status, and sometimes
cardiovascular collapse. Immediate medical attention is required.
If you consider that any of the side effects you suffer are serious or if
If you notice any side effects not mentioned in this leaflet, tell your doctor or pharmacist.

If you took more medication than indicated
There is no clinical experience of the effects of an acute overdose of leuprolide acetate. In animal studies, doses 125 to 250 times and 250 to 500 times higher than recommended for use in children and adults resulted in dyspnea (shortness of breath), decreased activity, and irritation. locally at the injection site. In case of overdose the patient must be monitored and accompanied.

In the event of an overdose, go to the nearest hospital.
nearby or contact the Poison Centers of: Ricardo Gutiérrez
Pediatric Hospital: (011) 4962-6666/2247 A. Posadas Hospital:
(011) 4654-6648/4658-7777

5. CONSERVATION OF LECTRUM7.5mg
Do not use Lectrum 7.5 mg after the expiration date shown
in the packaging.
Store at a temperature below 25°C. Protected from light and do not freeze.
Keep this product in its packaging until use.
Because lyophilized leuprolide and the solvent do not contain preservatives, the reconstituted suspension should be used immediately after preparation and any unused portion should be discarded. Stored in accordance with these recommendations, the product is
will remain suitable for use until the indicated expiration date
in the box.
Medications should not be disposed of down drains or in the trash. In
If in doubt, ask your pharmacist how to dispose of packaging and medicines you no longer need. In this way, you will help protect the environment.

6. ADDITIONAL INFORMATION
Formula:
Each vial of Lectrum 7.5 mg contains: Leuprolide
acetate..... 7.5 mg.
Excipients: Gelatin 1.30 mg; PLGA 66.20 mg; mannitol 13.20 mg.

Each ampoule of solvent contains:
Carboxymethyl cellulose sodium 7.50 mg; mannitol 75.0 mg; polysorbate 80 1.5 mg; water for injections csp 1.5 ml.

Presentations:
Lectrum 7.5 mg containing 1 vial plus 1 vial of
solvent, 1 disposable syringe and 2 22G 1½ needles.

"If there is any problem with the product, the patient can fill the file that is on the ANMAT Website: http://
www.anmat.gov.ar/farmacovigilancia/Notify.asp or call
ANMAT and answer 0800-333-1234"

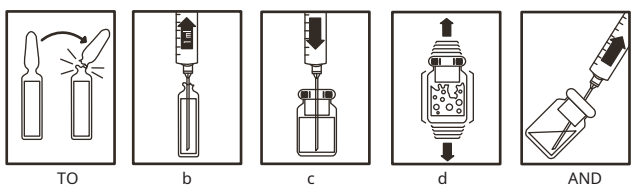
KEEP OUT OF THE REACH OF CHILDREN

Medicinal Specialty Authorized by the Ministry of Health.
Certificate No. 48,819

Made in:
ERIOCHEM SA, National Route 12, Km 452, (3107) Colonia Avellaneda,
Paraná, Entre Ríos, Argentina
Technical Director: Dr. Marisa I. Motura – Pharmacist and PhD in Chemistry.

ADDITIONAL INFORMATION FOR THE HEALTH CARE PROFESSIONAL
Method of administration:
Each vial of lyophilized Lectrum 7.5 mg microspheres is
Reconstitute with 1 ml of solvent. Shake well until suspension
homogeneous with a milky appearance.
Use a 22G 1½ (40/70) needle.

Instructions for use:
1- Verify that all the contents of the solvent ampoule are in the body of the ampoule. Press until breaking the neck of the ampoule. (A) 2- With the needle and syringe provided in the kit, extract 1 ml of solvent. Discard the rest.(B)
3- Remove the plastic cap from the ampoule bottle and inject the solvent inside the jar. (C)
4- Shake the vial bottle to obtain a uniform suspension
milky in appearance. (D)
5- Extract all the contents of the vial bottle by slightly tilting the vial vial and placing the bevel of the needle at the bottom of it. No invert the vial bottle. (AND)
6- Disinfect the skin where the injection is going to be applied and inject the contents of the syringe using the second needle provided in the kit.



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