


90 mm

240 mm



Degaris™
Degarelix Acetate INN for Injection

DESCRIPTION
Degaris™ is a preparation of Degarelix Acetate. Degarelix is a GnRH receptor antagonist. It binds reversibly to the pituitary GnRH receptors, thereby reducing the release of gonadotropins and consequently testosterone.

INDICATIONS
For treatment of patients with advanced prostate cancer.

DOSAGE AND ADMINISTRATION
Degaris™ is for subcutaneous administration only. Treatment is started with a dose of 240 mg given as two injections of 120 mg each. The starting dose is followed by maintenance doses of 80 mg administered as a single injection every 28 days.

Instruction for Reconstitution:
The following information is intended for healthcare professionals only.

NOTE:

- Reconstituted drug **MUST** be administered within one hour after addition of Sterile Water for Injection USP.
- Do not shake the vials

Degaris™ 120 for Injection – Starting Dose

RECONSTITUTION:

- Take the disposable syringe, remove the peel-off pack and attach the 23G needle to the syringe.
- Break the ampoule and take 3 mL Water for Injection from ampoule using the syringe.
- Transfer the 3 mL Sterile Water for Injection from syringe to vial.
- With the syringe still attached to the vial, swirl gently until the liquid looks clear and free of powder or particles. If the powder adheres to the side of the vial above the liquid surface, the vial can be tilted slightly. Avoid shaking to prevent foam formation. A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure may take, in some cases, up to 15 minutes, but usually takes a few minutes.

ADMINISTRATION:

- Turn the vial upside down and draw 3 mL liquid in the syringe.
- IMMEDIATELY** after reconstitution, inject 3 mL of Degaris 120 mg slowly. Perform a deep subcutaneous injection. To do so: pinch the skin of the abdomen, elevate the subcutaneous tissue and insert the needle at a 45-degree angle. Do not inject into a vein or muscle. Gently pull back the plunger to check if blood is aspirated. If blood appears in the syringe, the product can no longer be used. Discontinue the injection and discard the syringe and the needle (reconstitute a new dose for the patient). No injections should be given in areas where the patient will be exposed to pressure, e.g., around the belt or waistband or close to the ribs.
- Repeat the reconstitution procedure for the second 120 mg vial to complete the 240 mg starting dose and choose a different injection site for the second dose.

Degaris™ 80 for Injection – Maintenance Dose

RECONSTITUTION:

- Take the disposable syringe, remove the peel-off pack and attach the 23G needle to the syringe.
- Break the ampoule and take 4.2 mL Water for Injection from ampoule using the syringe.
- Transfer the 4.2 mL Sterile Water for Injection from syringe to vial.
- With the syringe still attached to the vial, swirl gently until the liquid looks clear and free of powder or particles. If the powder adheres to the side of the vial above the liquid surface, the vial can be tilted slightly. Avoid shaking to prevent foam formation. A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure may take, in some cases, up to 15 minutes, but usually takes a few minutes.

ADMINISTRATION:

- Turn the vial upside down and draw 4 mL liquid in the syringe.
- IMMEDIATELY** after reconstitution, inject 4 mL of Degaris 80 mg slowly. Perform a deep subcutaneous injection. To do so: pinch the skin of the

abdomen, elevate the subcutaneous tissue and insert the needle at a 45-degree angle. Do not inject into a vein or muscle. Gently pull back the plunger to check if blood is aspirated. If blood appears in the syringe, the product can no longer be used. Discontinue the injection and discard the syringe and the needle (reconstitute a new dose for the patient). No injections should be given in areas where the patient will be exposed to pressure, e.g., around the belt or waistband or close to the ribs.

CONTRAINDICATIONS

- Patients with previous hypersensitivity reactions to Degarelix.
- Pregnancy Category X. Fetal harm can occur when administered to pregnant women.

SIDE EFFECTS

- Pain, erythema, swelling or induration
- Hot flashes
- Increased weight
- Increases in serum levels of transaminases and gammaglutamyltransferase (GGT)

WARNING AND PRECAUTION

- Hypersensitivity: Anaphylaxis, urticaria and angioedema have been reported. Discontinue Degarelix if a serious hypersensitivity reaction occurs, and manage as clinically indicated.
- Effect on QT/QTc Interval: Androgen deprivation therapy may prolong the QT interval. Consider risks and benefits.

USE IN PREGNANCY AND LACTATION
Pregnancy Category X. Contraindicated during pregnancy. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential of serious adverse reactions in nursing infants from Degarelix, a decision should be made whether to discontinue nursing or discontinue the drug taking into account the importance of the drug to the mother.

Pediatric Use:
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:
There is no need to adjust the dose for the elderly or in patients with mild or moderate liver or kidney function impairment.

DRUG INTERACTION
Clinically significant CYP450 pharmacokinetic drug-drug interactions are unlikely.

OVERDOSE
There have been no reports of overdose with Degarelix. In the case of overdose, however, discontinue Degarelix, treat the patient symptomatically, and institute supportive measures. As with all prescription drugs, this medicine should be kept out of the reach of children.

PHARMACEUTICAL PRECAUTION
Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PRESENTATION
Degaris™ 120 for Injection: Each box contains:

- One 5 mL ampoule containing Water for Injection USP
- One vial of Degarelix Acetate INN equivalent to Degarelix 120 mg
- One alcohol pad
- One disposable syringe with 23G needle



Degaris™ 80 for Injection: Each box contains:

- One 5 mL ampoule containing Water for Injection USP
- One vial of Degarelix Acetate INN equivalent to Degarelix 80 mg
- One alcohol pad
- One disposable syringe with 23G needle

SK+F ONCOLOGY
Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM2367 V01

PM SPECIFICATION

Creative ID: CSD_02

Job Name: Degaris Insert		Size: L - 90 mm, W - 240 mm		Paper: 60 gsm Offset Paper	
No. of Color: 2 Extra	Pantone Color Code	 2745 C	 2347 C		

	Creative Service Department	Marketing Department	PD/QC/Contract Customer	Approved By
Comments				
Signature & Date				