CLINICAL STUDIES

These studies provided no evidence of a mutagenic potential.

In two open-label, non-comparative trials of patients with prostate cancer treated with Viadur® and eval ed for up to two years. Five of the patients had died or lost their disease after 12 months. The eighth patient was admitted to the hospital for an intercurrent illness and died at 49 months. A further five patients died in the study population at 6 months.

Sixty-eight percent of 131 patients (see Insertion and Removal Procedures for correct implant placement).

Leuprolide (free base) (5-Oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysyl) is a synthetic, non-mutagenic analog of naturally occurring luteinizing hormone-releasing hormone (LH-RH). The analog was synthesized in the early 1970s and is highly specific for the LH-RH receptor. It is histidine and lysine (NH2-COOG) at positions 5 and 10. The amino acid residues are separated by five additional amino acids. Leuprolide binds selectively to the cytoplasmic domain of the LH-RH receptor. This leads to a decrease in the secretion of gonadotropins, the pituitary hormones that control sex hormone production by the ovary and testis. The net effect of these hormones is to lower the amount of testosterone in the body. Testosterone appears to be needed by prostate cancer cells. Usually prostate cancer shrinks or stops growing when the body’s supply of testosterone is lowered.

In these two clinical trials, four patients had local infection/inflammations that resolved after treatment with oral antibiotics. In one patient, a local infection/inflammation was noted at the testicles and resolved after discontinuation of the drug. In two other patients, local infection/inflammations were noted at the testicles and resolved after discontinuation of the drug. In one patient, a local infection/inflammation was noted at the testicles and resolved after discontinuation of the drug.

In the patients studied (80 Caucasian, 23 Black, 3 Hispanic), mean serum leuprolide concentrations were maintained at 0.9 mg/L (0.3 to 3.1 mg/L; SD = ±0.4) for 12 months. Upon removal and insertion of a new Viadur® implant, stable serum leuprolide concentrations were maintained.

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After Viadur® implantation, mean serum leuprolide concentrations were 10 ng/mL at 4 hours and 2.4 ng/mL at 24 hours. Thereafter, leuprolide was released at a constant rate. Mean serum leuprolide concentrations were maintained.

In a study comparing one Viadur® implant to two Viadur® implants, mean serum leuprolide concentrations were proportional to dose.

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INSERTION AND REMOVAL PROCEDURES

Viadur® is supplied in a box containing one sterile Viadur® implant in a sealed vial, one sterile Viadur® sterile implanter, and one sterile Viadur® Kit. The Viadur® Kit is designed to provide a sterile field and supplies to facilitate the insertion and subsequent removal of the implant.

In addition to the Viadur® Kit, sterile gloves are required for the insertion procedure and subsequent removal of the implant.

INSERTION PROCEDURE

Under aseptic conditions, an implanter is placed to implant the under the skin.

1. Using aseptic technique, cleanse the insertion site, then administer local anesthetic to the patient’s arm. After administering the local anesthetic, remove the protective cap from the actuator and inflating the air into the needle handle, leaving the tip of the needle exposed. Do not pull back on the implanter barrel handle while inflating the track. As the needle tip, the tip may lead to incorrect positioning of the implant and subsequent migration. The needle tip should not enter the muscle tissue, but be well within the subcutaneous space. Advance the implanter to the depth indicated on the cannula, which indicates the recommended implant length.

2. Insert the implant under the skin with the implanter. The implant is inserted using the procedure outlined below.

3. Using aseptic technique, cleanse the removal area. Press the edges of the incision or incisions together to close the incision with one or two surgical closure strips. Cover with an adhesive bandage. If inserting a new Viadur® implant may be placed through the same incision site. Alternatively, the contralateral arm may be used.

4. Open the vial, remove the metal band from the vial, and remove the protective cap from the actuator handle. Slide the actuator slowly back until it stops. (This retracts the actuator cannula into the handle, leaving the implant beneath the skin). Do not pull back on the implanter barrel handle while inflating the air into the needle handle, leaving the tip of the needle exposed. Do not pull back on the implanter barrel handle while inflating the track. As the needle tip, the tip may lead to incorrect positioning of the implant and subsequent migration. The needle tip should not enter the muscle tissue, but be well within the subcutaneous space. Advance the implanter to the depth indicated on the cannula, which indicates the recommended implant length.

5. Continue to apply pressure to the end of the implant to encourage expulsion. Push the implant gently toward the incision with the fingers. When the tip is visible or near the incision, grasp it with a clamp and remove.

6. Apply one or two surgical closure strips. Cover with an adhesive bandage. Note that the implant is not a removable device. For more information call 1-800-288-8371 or visit www.VIADUR.com.

PREPARING THE SITE

1. Place the patient near the back of the examination table, with his left arm (if the patient is left-handed, the right arm) flexed at the elbow and externally rotated so that his hand is out to his side.

2. If necessary, cut through any fibrous encapsulation with the scalpel to free the implant.

3. Properly dispose of removed implant immediately, before opening the vial containing the implant.

4. Before opening the vial containing the implant, visually inspect the vial for any defects. Do not use the Viadur® Kit or the following materials if they appear damaged. (NDC 528-811-01) For more information call 1-800-288-8371 or visit www.VIADUR.com.

HOW SUPPLIED

Viadur® is supplied in a box containing 3 vial packages. One vial contains a sterile Viadur® implant in a sealed vial and a sterile Viadur® implanter. The other contains the sterile implanter and sterile Viadur® Kit.

REFERENCES


PREPARING THE SITE

1. Inspect the site, palpating the location of the implant to keep the patient’s arm. After determining the absence of known allergies to the anesthetic agent, apply a small amount of local anesthetic under the skin and round the area with a fenestrated drape.

2. After determining the absence of known allergies to the anesthetic agent, apply a small amount of local anesthetic under the skin and round the area with a fenestrated drape. Drape the area with a fenestrated drape.

Suggestion:

If unable to palpate by palpation, radiological imaging may be helpful.
Contents: One sterile Viadur ® (leuprolide acetate implant) contains 65 mg of leuprolide dissolved in 104 mg dimethyl sulfoxide. The 4 mm by 45 mm titanium alloy reservoir houses a polyurethane rate-controlling membrane, an elastomeric piston, and a polyethylene diffusion moderator. The reservoir also contains the osmotic tablets composed of sodium chloride, sodium carboxymethyl cellulose, povidone, magnesium stearate, and sterile water for injection. Polyethylene glycol fills the space between the osmotic tablets and the reservoir. A minute amount of silicone medical fluid is used during manufacture as a lubricant.

One sterile Viadur ® Implanter for single use with Viadur ® (leuprolide acetate implant).

One sterile Viadur ® Kit which includes: 1 scalpel, 1 forceps, 1 syringe, povidone-iodine swabs, 1 package wound closure strips, 1-22 Ga x 1.5" needle, 1-25 Ga x 1.5" needle, 1 ampule lidocaine HCI USP 2% (10 mL), 6 gauze sponges, 2 alcohol prep pads, 1 package skin protectant, 1 bandage, 1 fenestrated drape, 1 marking pen, 1 ruler, and 1 mosquito clamp. A physician insert, patient information, and insertion and removal instructions are also provided in the box.

The Viadur ® implant must be removed after 1 year of use.

Store at 25 °C (77 °F); excursions permitted to 15 °C –30 °C (59 °F – 86 °F). (See USP Controlled Room Temperature.)

NOTE: DO NOT USE IF SEAL ON KIT OR VIADUR ® IMPLANT OR VIADUR ® IMPLANTER IS BROKEN.

Read Enclosed Full Prescribing Information.
Important Safety Considerations:

Viadur® is contraindicated in patients with hypersensitivity to GnRH, GnRH agonist analogs, or any of the components in Viadur®.

Viadur® is contraindicated in women and pediatric patients and was not studied in women or children.

Viadur®, like other LH-RH agonists, causes a transient increase in serum concentrations of testosterone during the first week of treatment. Patients may experience worsening of symptoms or onset of new symptoms including bone pain, neuropathy, hematuria, or ureteral or bladder outlet obstruction, and spinal cord compression.

The most common systemic side effects were hot flashes (67.9%), asthenia (7.6%), gynecomastia (6.9%), depression (5.3%), and sweating (5.3%). The most common local side effects were bruising (34.6%) and burning (5.6%).

Please see accompanying prescribing information.

For additional product information, please contact Bayer Clinical Communications at 1-800-288-8371 or visit our Web site at viadur.com.
This review provides information on the insertion procedure for Viadur® (leuprolide acetate implant) to ensure its optimal placement and functioning. In addition, the review describes how to remove the implant when appropriate.

Viadur® is a cylindrical titanium alloy drug reservoir that is implanted subcutaneously in the inner aspect of the upper arm. The leuprolide-containing cylinder measures 4 mm by 45 mm and houses a polyurethane rate-controlling membrane, an elastomeric piston, and a polyethylene diffusion moderator. See Figure 1 below (implant shown larger than actual size).

**Fig. 1**

2. If necessary, cut through any fibrous encapsulation with the scalpel to free the implant.

3. Properly dispose of removed implant immediately, before opening the vial containing the new implant. If inserting a new Viadur® implant, return to section describing INSERTION PROCEDURE. The new Viadur® implant may be placed through the same incision site. Alternatively, the contralateral arm may be used.

4. Cleanse insertion site area. Apply pressure to each end of the incision to close the wound. Apply 1 or 2 surgical closure strips to close the wound tightly, and cover with an adhesive bandage. Observe the patient for a few minutes for signs of bleeding from the incision before he is discharged. Instruct the patient to keep the area clean and dry for 24 hours, and to avoid strenuous physical activity for 48 hours.

*Please see accompanying prescribing information.*
PREPARING THE SITE

1. Inspect the site, palpating the location of the implant. Mark the position of the implant with marking pen. Cleanse with povidone-iodine swab. Drape the area with a fenestrated drape.

Suggestion:
If unable to locate by palpation, radiological imaging may be helpful.

2. After determining the absence of known allergies to the anesthetic agent, apply a small amount of local anesthetic under the end of the implant nearest the original incision site. Then advance the needle to infiltrate the tissue along the track.

REMOVING THE IMPLANT

1. Determine that anesthesia is adequate. Apply pressure to one end of the implant to elevate the other end. Make an incision of approximately 5 mm at the elevated end of the implant. Do not make a large incision.

Continue to apply pressure to the end of the implant to encourage expulsion. Push the implant gently toward the incision with the fingers. When the tip is visible or near the incision, grasp it with a clamp and remove.

In the full description of the procedures described below, the following points should be particularly noted to prevent damage to the implant at the time of insertion and to avoid its extrusion:

1. In Step 2 under “Preparing the Sterile Field,” note that when removing the protective cap from the implant, you should pull the cap straight off. DO NOT TWIST CAP OFF AS IT MAY UNSCREW THE DIFFUSION MODERATOR, CAUSE ITS REMOVAL, OR OTHERWISE DAMAGE THE IMPLANT. SHOULD DAMAGE OCCUR, DO NOT INSERT THE IMPLANT AS PRODUCT FUNCTION CAN BE IMPAIRED.

2. In Step 3 under “Inserting the Implant,” note that the implanter should not enter muscle tissue, but be well within the subcutaneous space.

3. In Step 4 under “Inserting the Implant,” care should be taken not to pull back on the implanter handle while sliding the actuator back, as this may lead to subsequent extrusion of the implant.

By observing the proper insertion and removal procedures, you can achieve the best possible treatment result with Viadur®. In this regard, periodic monitoring of serum testosterone and PSA concentrations also is recommended, especially if the anticipated clinical or biochemical response to treatment has not been achieved.

If you have clinical questions concerning Viadur®, please contact Bayer Clinical Communications at 1-800-288-8371.

Please see accompanying prescribing information.
REMOVAL PROCEDURE

Viadur® must be removed following 12 months of therapy. The position of the patient and the sterile technique are the same as for insertion. To remove Viadur®, use the Viadur® Kit or the following sterile items:

- 1 scalpel
- 1 forceps
- 1 syringe
- 1 package povidone-iodine swabs
- 1 package wound closure strips
- 1-22 Ga x 1.5" needle
- 1-25 Ga x 1.5" needle
- 1 ampule Lidocaine Hydrochloride USP 2%, 10 mL
- 6 gauze sponges
- 2 alcohol prep pads
- 1 package skin protectant
- 1 bandage
- 1 fenestrated drape
- 1 marking pen
- 1 ruler
- 1 mosquito clamp

Please see accompanying prescribing information.
**INSERTING THE IMPLANT (Cont.)**

5. Cleanse the insertion area. Press the edges of the incision together, and tightly close the incision with 1 or 2 surgical closure strips. Cover with an adhesive bandage. Observe the patient for a few minutes for signs of bleeding from the incision before he is discharged. Instruct the patient to keep the area clean and dry for 24 hours, and to avoid heavy lifting and strenuous physical activity for 48 hours. The surgical closure strip can be removed as soon as the incision has healed, normally in 3 days.

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If diffusion moderator is pulled off or should damage occur, DO NOT INSERT THE IMPLANT AS PRODUCT FUNCTION CAN BE IMPAIRED. Please contact Bayer Clinical Communications at 1-800-288-8371.

Please see accompanying prescribing information.
Viadur® is supplied in a box containing 1 sterile Viadur® implant in a sealed vial, 1 Viadur® sterile implanter, and 1 sterile Viadur® Kit. The Viadur® Kit is designed to provide a sterile field and supplies to facilitate the insertion and/or subsequent removal of the implant. In addition to the Viadur® Kit, sterile gloves are required for the insertion procedure and subsequent removal of the implant.

**INSERTION PROCEDURE**

Under aseptic conditions, an implanter is used to place the implant under the skin. The implant is inserted using the procedure that follows.

3. Grasp the handle of the implanter and extend the index finger to rest on the back of the actuator as shown. Insert the cannula tip into the incision with the bevel up and advance it subcutaneously along the intended track. To ensure subcutaneous placement, the Viadur® implanter should visibly raise the skin at all times during insertion. The implanter should not enter muscle tissue, but be well within the subcutaneous space. Advance the implanter to the depth indicator on the cannula, which indicates the recommended insertion length.

4. Holding the implanter handle in position, use the index finger to slide the actuator slowly back until it stops. (This retracts the actuator cannula into the handle, leaving the implant beneath the skin.) Do not pull back on the implanter handle while sliding the actuator back, as this may lead to incorrect positioning of the implant and subsequent extrusion. Withdraw the implanter from the incision. Release of the implant can be checked by palpation. It is important to keep the implanter steady and not to push the implant into the tissue. After placement, sterile gauze may be used to apply pressure briefly to the insertion site to ensure hemostasis.

Please see accompanying prescribing information.
IDENTIFYING THE INSERTION SITE

1. Have the patient lie on his back on the examination table, with his left arm (if the patient is left-handed, the right arm) flexed at the elbow and externally rotated so that his hand is out to his side.

2. Using a pen and ruler, mark a site on the inner, upper arm approximately 8 to 10 cm above the elbow crease in the groove between the biceps and triceps muscles. Make sure that the site is unaffected by movement of the muscles.

INSERTING THE IMPLANT

1. Using aseptic technique, cleanse the insertion site, then drape the patient’s arm. After determining the absence of known allergies to the anesthetic agent, infiltrate the site with lidocaine. Advance the needle to infiltrate the intended 5 cm track for the implant insertion.

2. Determine that anesthesia is adequate. Make an incision of approximately 5 mm with the scalpel, just through the dermis.
PREPARING THE STERILE FIELD

1. To establish a sterile field, carefully open the sterile Viadur® Kit. The sterile kit contains:

- 1 scalpel
- 1 forceps
- 1 syringe
- 1 package povidone-iodine swabs
- 1 package wound closure strips
- 1-22 Ga x 1.5" needle
- 1-25 Ga x 1.5" needle
- 1 ampule Lidocaine Hydrochloride USP 2%, 10 mL
- 6 gauze sponges
- 2 alcohol prep pads
- 1 package skin protectant
- 1 bandage
- 1 fenestrated drape
- 1 marking pen
- 1 ruler
- 1 mosquito clamp

2. The implant tray contains:
   - 1 sealed vial, which contains the Viadur® implant
   - 1 sterile implanter

To open the vial, remove the metal band from the bottle and pull up the stopper. Carefully drop the implant from the bottle onto the sterile field. Then, carefully drop the implanter onto the sterile field.

Using sterile technique, remove the protective cap from the implant by pulling the cap straight off. **DO NOT TWIST CAP OFF AS IT MAY UNSCREW THE DIFFUSION MODERATOR, CAUSE ITS REMOVAL, OR OTHERWISE DAMAGE THE IMPLANT. SHOULD DAMAGE OCCUR, DO NOT INSERT THE IMPLANT AS PRODUCT FUNCTION CAN BE IMPAIRED.**

LOADING THE IMPLANTER

1. The implanter is packaged in the correct configuration for implant loading and insertion. Make sure the cannula is fully extended as shown, and the actuator is in its most forward position.

2. Using sterile forceps, slide the implant into the end of the cannula and push until it stops. When properly loaded, the implant should not protrude more than 1 mm past the bottom of the beveled edge.

Please see accompanying prescribing information.
Each implant contains 65 mg leuprolide dissolved in 104 mg dimethyl sulfoxide.

It is enclosed in one sterile implant. Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature] Do not use if seal is broken. See full prescribing information.
VIADUR® IMPLANTER
For use with Viadur®
(leuprolide acetate implant)

Sterile
For single use only

Contains:
One Sterile Implanter

Read enclosed full
prescribing information.
Do not use if seal is broken.
Disposable. Single Use.
Do Not Resterilize.

Lot:
Expires:

Rx Only

Bayer

Distributed by:
Bayer Corporation
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516 USA

Viadur® is a registered trademark of ALZA
Corporation under license to Bayer Corporation.

Lot:
Expires:

100%
VIADUR® KIT
Kit for use with Viadur® (leuprolide acetate implant)

Sterile for single use only. Do not use if seal is broken.
Store at controlled room temperature.

Viadur® is a registered trademark of ALZA Corporation under license to Bayer Corporation.

Distributed by:
Bayer Corporation
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516 USA

Kit PN: 08724655
Lot: 08720714
Expires: 4/02

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It is Only
Read enclosed full prescribing information.
Do not use if seal is broken.
Store at 25°C (77°F); excursions permitted to
15-30°C (59-86°F). [See USP Controlled Room Temperature].

Contents:
1 - Scalpel
1 - Forceps
1 - Syringe
1 - Package Povidone-Iodine Swabs
1 - Package Wound Closure Strips
1 - 22 Ga x 1 1/2” Needle
1 - 25 Ga x 1 1/2” Needle
1 - Lidocaine Hydrochloride USP, 2%, 10 mL
6 - Gauze Sponges
2 - Alcohol Prep Pads
1 - Package Skin Protectant
1 - Bandage
1 - Fenestrated Drape
1 - Marking Pen
1 - Ruler
1 - Mosquito Clamp
IMPORTANT VIADUR® IMPLANT REMINDER

Implant shown with diffusion moderator.

Carefully pull the protective cap straight off.
DO NOT TWIST CAP OFF AS IT MAY UNSCREW THE DIFFUSION MODERATOR, CAUSE ITS REMOVAL, OR OTHERWISE DAMAGE THE IMPLANT.

Implant shown without diffusion moderator.

If diffusion moderator is pulled off or should damage occur, DO NOT INSERT THE IMPLANT AS PRODUCT FUNCTION CAN BE IMPAIRED. Please contact Bayer Clinical Communications at 1-800-288-8371.

Please see accompanying prescribing information.
Important Safety Considerations:

Viadur® (leuprolide acetate implant) is contraindicated in patients with hypersensitivity to GnRH, GnRH agonist analogs, or any of the components in Viadur®.

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