

PROSTATE CANCER & YOU

A GUIDE FOR PATIENTS
AND CAREGIVERS



Eligard[®]

(leuprolide acetate) for injectable suspension

Personal Information

My Contact Information

Name: _____

Address: _____

Phone: _____

Email: _____

Emergency Contact Information

Name: _____

Address: _____

Phone: _____

Email: _____

Use: ELIGARD® is a prescription drug, given by injection, for the management of advanced prostate cancer. However, there is no known cure for advanced prostate cancer. **Please see full Important Safety Information on page 20 and enclosed full Prescribing Information in back pocket.**

Table of Contents

Welcome

You Are Not Alone.....	1
Facts About Prostate Cancer.....	2

Understanding Prostate Cancer

About the Prostate.....	5
Risks and Causes of Prostate Cancer.....	6
Symptoms of Prostate Cancer.....	6
Diagnosis of Prostate Cancer.....	7
Grading and Staging of Prostate Cancer.....	9
The Gleason Grading System.....	10
Staging – How Far the Cancer has Spread.....	11


Treating Prostate Cancer

ELIGARD® (leuprolide acetate) for injectable suspension.....	13
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LHRH Agonist Drugs.....	14
How ELIGARD Works.....	15
How ELIGARD's extended-release delivery system works.....	16
ELIGARD Dosing Options.....	16
Your ELIGARD Injection.....	17
Common Side Effects and Tips for Managing Symptoms.....	18
Important Safety Information for ELIGARD® (leuprolide acetate) for injectable suspension.....	20

Get the Support You Need

Advocacy.....	21
Financial Assistance.....	23
Education.....	24
Track Your Healthcare Visits.....	25



If you have prostate cancer,
knowing what to expect
can help you cope.

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Welcome

You have been prescribed ELIGARD® (leuprolide acetate) for injectable suspension to treat your prostate cancer.

To maximize the benefits of your treatment, it is important that your medication is administered as prescribed by your doctor. This guide contains information about prostate cancer and your treatment with ELIGARD. It also includes practical tools to help you on your journey with ELIGARD.

This guide should not be used as a substitute for advice from your doctor. If you have any questions or concerns regarding ELIGARD, your other medications, your condition or overall health, talk to your healthcare professional.

You Are Not Alone

Being diagnosed with prostate cancer is a life altering experience, but it is important to remember you are not alone. Prostate cancer affects millions of men every year.¹ This guide is designed to help you navigate your way through your treatment.

2021 STATISTICS

Facts About Prostate Cancer¹⁻³

Other than skin cancer, prostate cancer is the most common cancer in American men.

Annually, an Estimated



248,530

American men will be diagnosed with prostate cancer.

34,130

will die from the disease.

About

1 in 41

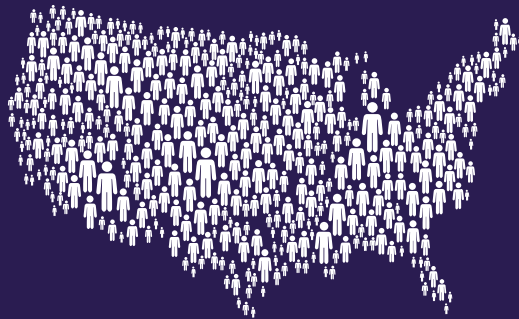
men in the U.S. will die of prostate cancer.

About **1 in 8** men will be diagnosed with prostate cancer during their lifetime.



Prostate cancer can be a serious disease, but most men diagnosed with prostate cancer do not die from it.

There are approximately **3.1 million** American Prostate Cancer Survivors





About
6 in 10
cases

are diagnosed in
men 65 or older.
Prostate cancer is rare
in men younger than 40.

Prostate cancer occurs more often in African American men and in Caribbean men of African ancestry than in men of other races.

Having a father or brother
with prostate cancer
**more than
doubles
the risk**
of developing prostate cancer.



Can prostate cancer be prevented?

You may not be able to prevent prostate cancer, but here are lifestyle habits that **may help lower your risk:**



Eating at least 2½ cups of a wide variety of vegetables and fruits each day



Being physically active



Staying at a healthy weight

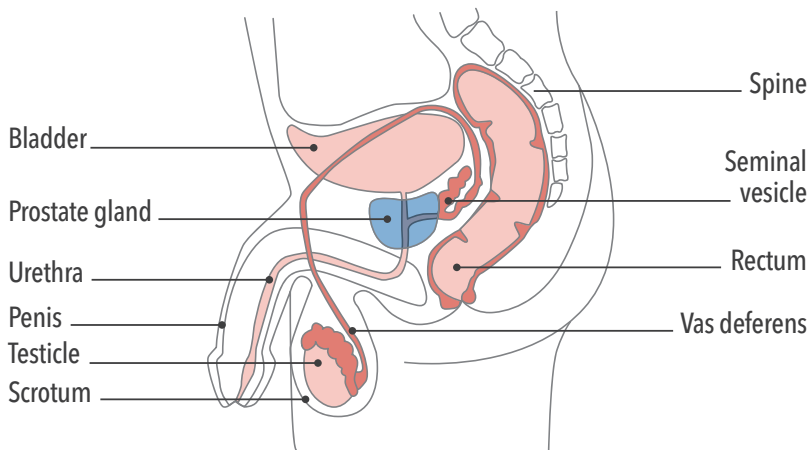


Understanding Prostate Cancer

About the Prostate²

The prostate is a small gland found in the male reproductive system. It produces some of the fluid found in semen.

The prostate is about the size of a walnut in younger men, but can grow in size as men age. It is found just below the bladder, directly in front of the rectum. The urethra, which is the tube that carries urine and semen out of the body through the penis, goes through the center of the prostate.²



About Prostate Cancer

Cancer is a disease where cells, which are the building blocks of the tissues in the body, become abnormal. These abnormal cells multiply and can spread throughout the body.²

Cancer can grow in the prostate as a number of small tumors scattered throughout the prostate gland.⁴

- Tumors usually develop in older men and grow slowly.²
- Prostate cancer can develop in younger men, especially African American men and those with a family history of prostate cancer.²

- Some prostate cancer tumors are slow growing, do not spread and do not lead to death. However, some grow quickly and spread to other parts of the body, which may result in death.²

Today's methods of finding and treating prostate cancer have led to improvements in survival rates for this disease.¹

Risks and Causes of Prostate Cancer^{1-3,5}

Like many cancers, the exact cause of prostate cancer is unknown. There are, however, a few known risk factors that have been linked to an increase in the likelihood of developing prostate cancer.

Age

- The risk of prostate cancer increases with age.
- The average age at diagnosis is 66.

Family history (genetics)

- The risk of developing prostate cancer increases in men who have a first-degree relative (father or brother) with prostate cancer.
- A family history of breast or ovarian cancer is also a risk factor for prostate cancer.

Symptoms of Prostate Cancer

During the early stages, prostate cancer usually causes no symptoms. As the cancer progresses, symptoms may include:^{1,5}

- Difficulties with starting and stopping urination
- The need to urinate more often than usual, particularly at night
- Sudden urges to urinate
- Dribbling urine
- Pain or a burning sensation when passing urine
- Blood in the urine or semen
- Pain during ejaculation
- Pain in the lower back, upper thighs or hips

Diagnosis of Prostate Cancer

Prostate cancer is diagnosed using a combination of tests, which may include:^{2,5}

Digital Rectal Exam (DRE): The doctor feels for any bumps or hard areas on the prostate by inserting a gloved finger into the rectum.

Prostate-Specific Antigen (PSA) Blood Test: Higher levels of PSA, detectable with a blood test, can occur in men with prostate cancer. They also occur in men with a benign enlargement or an inflammation of the prostate.

Transrectal Ultrasound (TRUS): Ultrasound waves are used to visualize the prostate.

Biopsy: If either the DRE or PSA tests are abnormal, a biopsy may be taken. Small pieces of the prostate are sampled and examined under a microscope for cancer cells. A biopsy is a definitive way of diagnosing prostate cancer.





Men over the age of 50, or who are over the age of 40 and have a family history of prostate cancer should talk to their doctor about testing for prostate cancer as part of their annual health examination.¹

Grading and Staging of Prostate Cancer

There are tests that help your doctor determine the best treatment option for you.²

When prostate cancer has been diagnosed, doctors will determine the grade of the cancer (its aggressiveness) by examining biopsied cells under a microscope. Determining the grade of the cancer helps doctors choose the best treatment option for you.

Other tests are often ordered, which may include magnetic resonance imaging (MRI), computed tomography (CT) scans, bone scans and prostate-specific membrane antigen (PSMA) or positron emission tomography (PET) scans to determine the stage of the cancer.

Grading - a system doctors use to determine how quickly the cancer is likely to spread.²

Prostate cancer is usually graded using a Gleason Score⁶ or the grade group,⁷ a system that was developed by the International Society of Urological Pathology (ISUP). The higher the score, the more aggressive the cancer. Here's how the grading system works:²

- Samples from two areas of the prostate are each graded into a Gleason Grading System pattern from 1 to 5.

- The numbers are added together to get a Gleason score between 2 and 10.
- A lower Gleason score means the cells look more like normal prostate cells.
- A higher Gleason score means the cells look more abnormal, and the cancer is likely to grow and spread more quickly.

The Gleason Grading System

The Gleason Grading System describes the five distinct patterns where prostate cells change from normal cells to cancerous cells.⁶

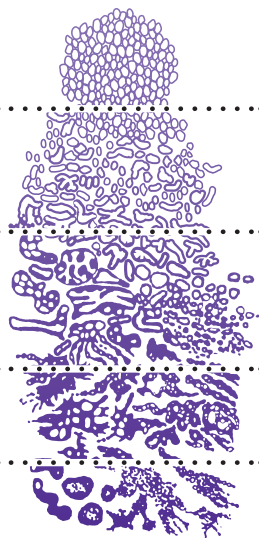
1 Small, identical cells that are close together

2 Cells in various shapes and sizes, loosely packed

3 Increased cell size with irregular shapes; cells are closer together

4 Large, irregular, fused cells

5 Irregular, fused cells that have invaded surrounding connective tissue cells



GLEASON PATTERNS ⁷	GLEASON SCORE ⁷	GRADE GROUP ⁷
1-3	≤6	1
3-4	3+4=7	2
3-4	4+3=7	3
3-5	8	4
4-5	9-10	5

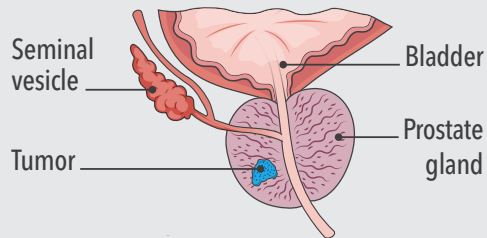
Staging - How Far the Cancer has Spread²

If a biopsy reveals cancer, additional tests are used to help determine if the cancer has spread outside the prostate. This is called staging.^{2,5} The American Joint Committee on Cancer TNM Staging System is used.¹

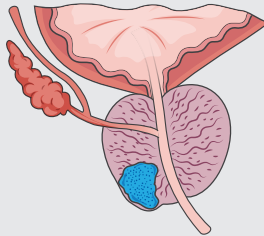
T Categories describe the local extent of a prostate tumor, ranging from T1 to T4. **N Categories** describe whether the cancer has spread to nearby lymph nodes. **M Categories** describe whether the cancer has spread to distant parts of the body.

T Categories

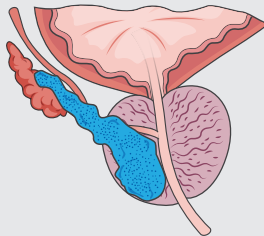
T1: The tumor is not felt during a DRE, but a biopsy found cancer cells.



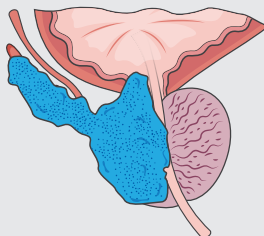
T2: The tumor is felt during a DRE, but the cancer remains within the prostate gland.



T3: The tumor has spread beyond the outer rim of the prostate and may have grown into the seminal vesicles.



T4: The tumor has spread to tissues and structures next to the prostate such as the bladder, rectum or pelvic wall.



N Categories

N0: The cancer has not spread to any nearby lymph nodes.

N1: The cancer has spread to one or more nearby lymph nodes.

M Categories

M0: The cancer has not spread beyond nearby lymph nodes.

M1: The cancer has spread beyond nearby lymph nodes.



When choosing the right treatment option, it is important to ask your cancer care team questions. They can help you make an informed decision.

Even when your cancer is advanced, you should know about an important therapy option.

ELIGARD[®] (leuprolide acetate) for injectable suspension

ELIGARD is proven to reduce testosterone below castrate levels and to maintain those low levels over time.³



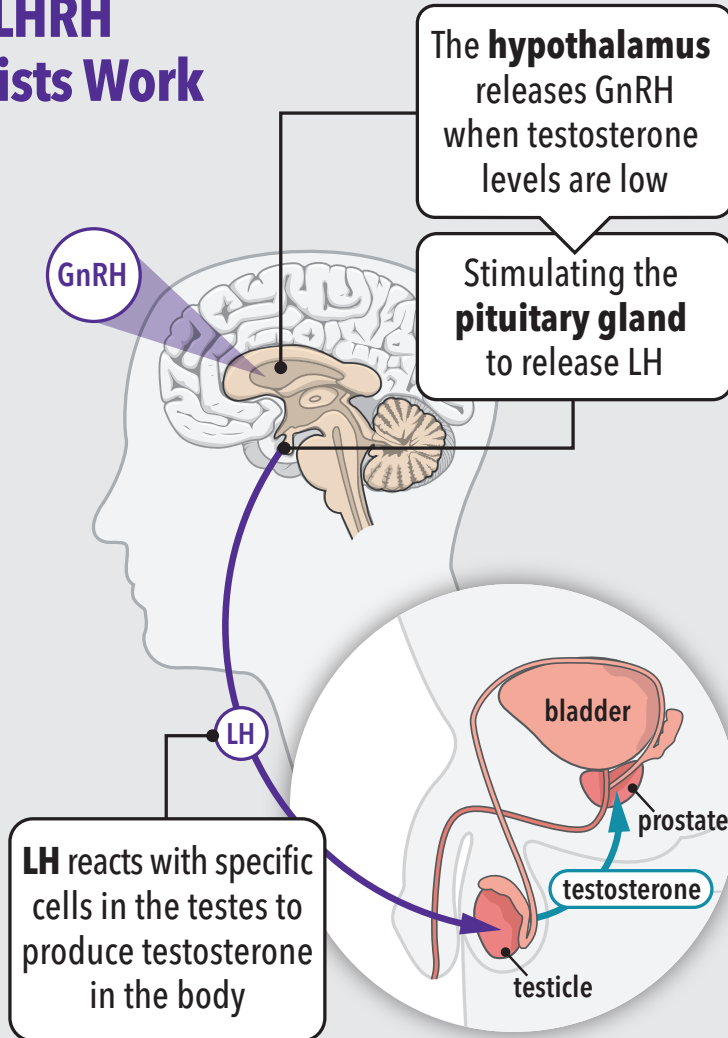
Use: ELIGARD[®] is a prescription drug, given by injection, for the management of advanced prostate cancer. However, there is no known cure for advanced prostate cancer.

Please see full Important Safety Information on page 20 and enclosed full Prescribing Information in the back pocket.

LHRH Agonist Drugs

There are several different types of hormone therapies, and they are grouped based on how they work to manage testosterone.¹ *Luteinizing hormone-releasing hormone* (LHRH) agonists are drugs that work by stopping testosterone production in the testicles.

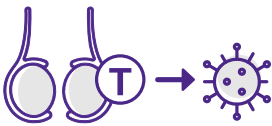
How LHRH Agonists Work



How ELIGARD® (leuprolide acetate) for injectable suspension Works^{1,4,8-10}

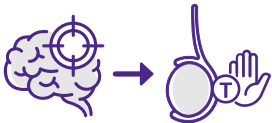
ELIGARD works by lowering your testosterone (T) levels.

Prostate cancer cells need hormones called androgens to replicate. In men, the main androgen is testosterone. The goal of hormone therapy is to keep your body from making testosterone, which can slow down tumor growth, at least for a period of time.²



1 Testosterone “stimulates” cancer cells

Most of the body’s testosterone is made by the testicles. Testosterone stimulates the growth of prostate cancer cells.



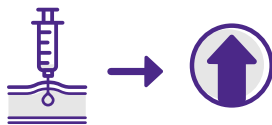
2 ELIGARD targets the source of testosterone production

ELIGARD suppresses testosterone produced by the testicles. This has the effect of inhibiting the growth of the tumor, which relies on testosterone to grow.



3 Testosterone hormone levels fall

Within 3 weeks, ELIGARD causes male hormone levels including testosterone to fall. This can slow down tumor growth, at least for a period of time.²



4 A temporary rise in testosterone levels is common

The first injection of ELIGARD makes testosterone levels rise for a short period of time. This rise is called a “surge” and is common. Your response to ELIGARD should be monitored by your doctor to evaluate if the product is working for you.

IMPORTANT SAFETY INFORMATION

ELIGARD® is used for the palliative treatment of advanced prostate Cancer. ELIGARD is a prescription medication that must be administered by a health care professional.

- ELIGARD should not be used by anyone who is allergic to any of the ingredients in ELIGARD or to any similar drugs.

**Please see next page for additional Important Safety Information.
See enclosed full Prescribing and Safety Information in back pocket**

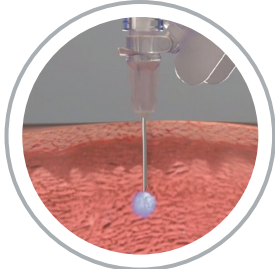
ELIGARD is a proven LHRH agonist treatment with the unique, polymeric gel extended-release technology for controlled drug delivery.⁹ It is designed to deliver a continuous dose of medicine to your body until your next ELIGARD injection — no matter which dose your doctor prescribes.



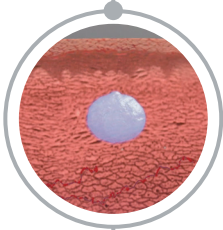
ELIGARD Dosing Options

Every month, every 3 months, every 4 months or every 6 months. Allowing you more freedom from your LHRH treatment with as little as 2 injections a year

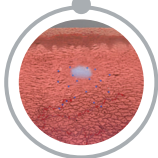
How ELIGARD's[®] extended-release delivery system works²



ELIGARD is injected into the fat or “subcutaneous” layer under the skin. This means it's not injected into muscle. ELIGARD can be injected at one of several injection sites, like the abdomen, arm or upper buttocks.



The liquid solidifies into a pea-sized pearl. You may feel a tiny bump immediately after injection, which goes away over time.



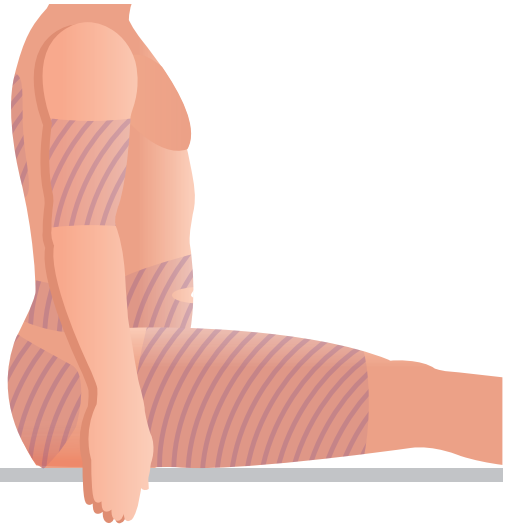
The ELIGARD pearl dissolves slowly, continuously releasing medicine over the dosing period.

Your ELIGARD® Injection

ELIGARD is given by subcutaneous injection by your doctor or nurse. Subcutaneous means under the skin. In this type of injection, a short needle is used to inject the drug into the tissue layer between the skin and the muscle.



Possible Injection Site Areas¹⁰



 **Eligard**[®]
(leuprolide acetate) for injectable suspension

IMPORTANT SAFETY INFORMATION

- ELIGARD causes an increase in testosterone during the first few weeks of therapy and some men may experience new or worsening symptoms of prostate cancer e.g., bone pain, urinary symptoms, or nerve problems such as numbness, during this period. If your cancer has spread to the urinary tract or spine, urinary blockage or pressure on the spine that can lead to paralysis may occur. Your doctor will discuss with you the benefits and risks of taking ELIGARD.
- Increased risk of heart attack, sudden death due to heart problems and stroke have also been reported in men taking ELIGARD. ELIGARD may also affect electrical activity in the heart that can cause an irregular heartbeat. Your doctor will monitor you for heart conditions.

**Please see next page for additional Important Safety Information.
See enclosed full Prescribing and Safety Information in back pocket**

Common Side Effects with Hormonal Therapies and Tips for Managing Symptoms^{4,8}

Many men experience side effects during hormonal therapies. It is important to understand these side effects and how to help manage them. This information does not replace the advice of your doctor; be sure to talk to your doctor about any side effects you have or lifestyle changes you make during treatment.

Side effects¹⁰

Tips for managing side effects¹¹

Hot flashes

Hot flashes may feel like a sudden rush of warmth in the face, neck, chest and back. They may last a few seconds to an hour or more.

- Avoid coffee, alcohol and spicy foods.
- Wear lightweight cotton clothes.
- Talk to your doctor if you have hot flashes. He or she may be able to help.

Fatigue

Fatigue can feel like extreme tiredness, exhaustion, depression or difficulty concentrating. There are many causes of fatigue including inactivity, poor sleep and side effects from drugs.

Simple things you can do to minimize fatigue:

- Talk to your doctor to determine the cause.
- Get enough rest.
- Don't push yourself.
- Take short walks and exercise, if possible.
- Eat nutritious foods that help with energy.
- Try stress-relieving activities.

Dizziness

If blood vessels in the brain dilate, or expand, you may become lightheaded or dizzy. Alcohol, excitement, high temperatures, hyperventilation (breathing too fast) and certain medicines can cause dizziness.

Call your doctor if you feel any of the following, which may be a side effect or possibly something more serious:

- Faint
- Giddy or erratic
- Light headed

You may experience some temporary discomfort during and after your ELIGARD® injections. Common side effects related to the injection are:¹⁰

- Burning and stinging
- Pain
- Bruising
- Redness

Other side effects related to hormonal therapies include osteoporosis, hyperglycemia, diabetes and cardiovascular disease. Please notify your doctor if you experience any symptoms related to these diseases. You may experience other side effects and should always tell your doctor about how you are feeling when receiving hormonal therapy. Additional side effects have been reported with ELIGARD. Please see additional Important Safety Information for ELIGARD on page 20 of this booklet.



IMPORTANT SAFETY INFORMATION

- Elevated blood sugar and an increased risk of developing diabetes have been reported in men receiving ELIGARD. Your doctor will monitor blood sugar levels.
- Convulsions have been observed in patients taking leuprolide acetate, including patients who have a history of seizures, epilepsy, or brain disorders (related to blood vessels, nerves, or tumors), and in those taking medications associated with convulsions. Convulsions have also been reported in patients without any of these conditions.
- ELIGARD may cause fetal harm when administered to a pregnant woman. Expected hormonal changes that occur with ELIGARD treatment increase the risk for pregnancy loss.
- ELIGARD may impair fertility in males of reproductive potential.

**Please see next page for additional Important Safety Information.
See enclosed full Prescribing and Safety Information in back pocket**

Important Safety Information for ELIGARD® (leuprolide acetate) for injectable suspension

ELIGARD® is used for the palliative treatment of advanced prostate Cancer. ELIGARD is a prescription medication that must be administered by a health care professional.

- ELIGARD should not be used by anyone who is allergic to any of the ingredients in ELIGARD or to any similar drugs.
- ELIGARD causes an increase in testosterone during the first few weeks of therapy and some men may experience new or worsening symptoms of prostate cancer e.g., bone pain, urinary symptoms, or nerve problems such as numbness, during this period. If your cancer has spread to the urinary tract or spine, urinary blockage or pressure on the spine that can lead to paralysis may occur. Your doctor will discuss with you the benefits and risks of taking ELIGARD.
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- ELIGARD may cause fetal harm when administered to a pregnant woman. Expected hormonal changes that occur with ELIGARD treatment increase the risk for pregnancy loss.
- ELIGARD may impair fertility in males of reproductive potential.

The most common injection site reactions are transient burning and stinging, pain, bruising, and redness. The most common side effects include hot flashes/sweats, fatigue, weakness, muscle pain, dizziness, clamminess, testicular shrinkage, decreased erections and enlargement of breasts.

Other side effects, including thinning of bones that may lead to fracture, and rare but serious problems with the pituitary gland in the brain, have been reported with ELIGARD.

See enclosed package insert for full Prescribing and Safety Information in back pocket.

Get the Support You Need

No one should fight a cancer diagnosis alone. It is important to build a support team that includes your medical professionals, family, friends and caregivers. You may also want to include others who have been touched by this disease.

Advocacy

Prostate cancer advocacy groups help you and your loved ones navigate the cancer landscape. They can connect you with medical professionals, support groups and financial assistance. Advocacy groups also raise funds for advancing treatment options.

Patient Advocates for Advanced Cancer Treatments, Inc. (PAACT)

www.paact.help
1-616-453-1477

Prostate Cancer Foundation

www.pcf.org
1-800-757-CURE (2873)

Prostate Cancer Research Institute

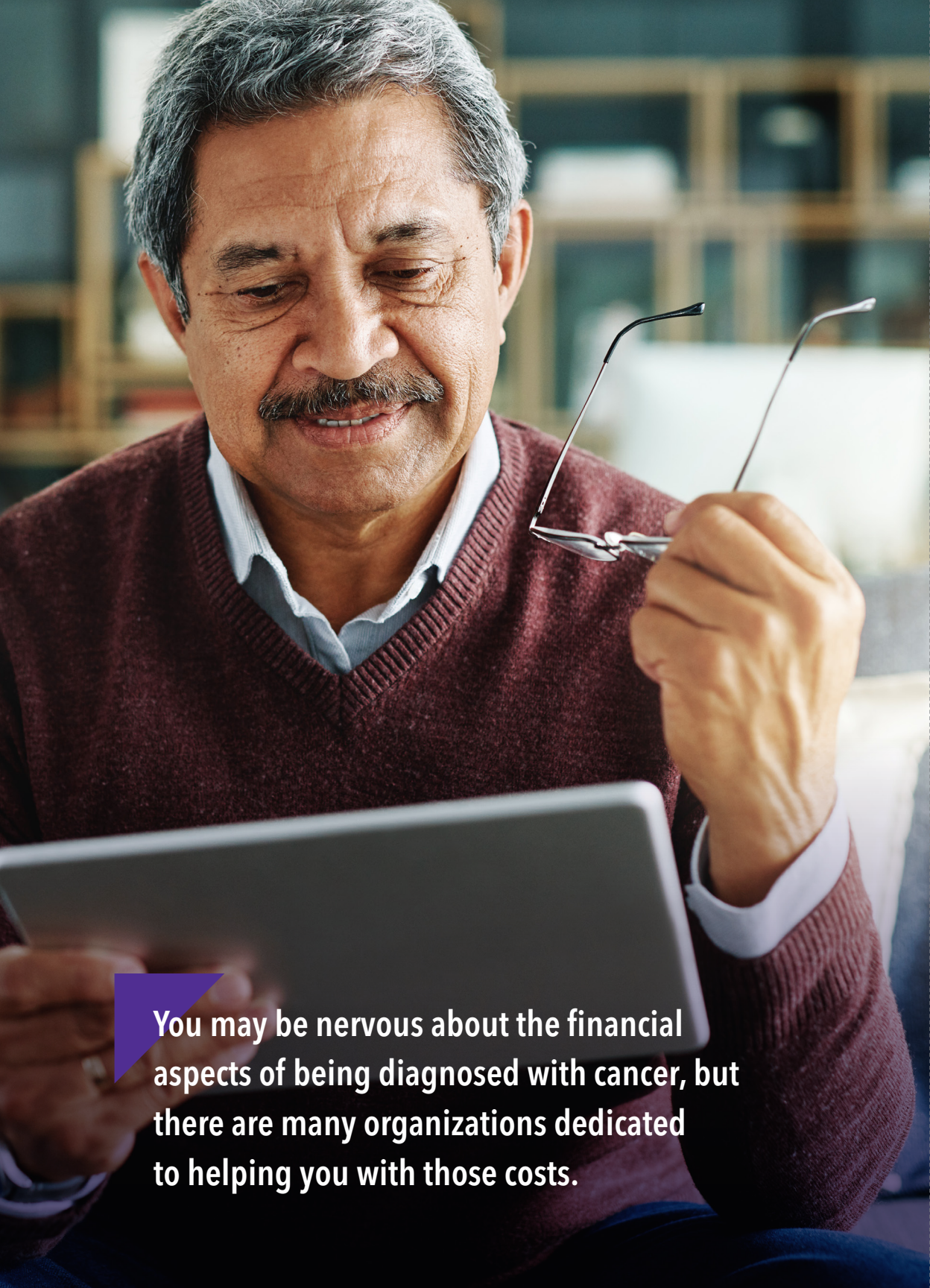
www.pcri.org
1-800-641-PCRI (7274)

US Too

www.ustoo.org
1-800-808-7866

ZERO – The End of Prostate Cancer

www.zerocancer.org
1-888-245-9455



You may be nervous about the financial aspects of being diagnosed with cancer, but there are many organizations dedicated to helping you with those costs.

Financial Assistance

You may be nervous about the financial aspects of being diagnosed with cancer, but there are many organizations dedicated to helping you with those costs. Speak with the organizations below to see what type of assistance they may be able to offer. You should also check with your doctor's office to see if other assistance is available.

BenefitsCheckUp®

www.benefitscheckup.org

CFAC: Cancer Financial Assistance Coalition

www.cancerfac.org

CancerCare® Co-Payment Assistance Foundation

www.cancercarecopay.org

1-866-55-COPAY (2-6729) or

1-212-601-9750

Health Well Foundation®

www.healthwellfoundation.org

1-800-675-8416

Medicine Assistance Tool

www.medicineassistancetool.org

Patient Advocate Foundation

www.copays.org

1-866-512-3861

Education

Becoming your own advocate means learning as much as you can about prostate cancer. The following organizations will help you learn about your condition, treatment options and how you can support your medical care through healthy lifestyle choices.

Men's Health Network™

www.menshealthnetwork.org
1-202-543-MHN-1 (6461) ext.101

Urology Care Foundation™

www.urologyhealth.org
1-800-828-7866

American Cancer Society®

www.cancer.org (see "Learn About Cancer")
1-800-227-2345

Blue Cure®

www.bluecure.org

Prostate Health Education Network, Inc.

www.prostatehealthed.org
1-617-481-4020



Track Your Healthcare Visits

Name of Physician:

Office Visit Date: Injection Due: Yes No

Injection Location:

Notes / Questions for your Doctor:

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Office Visit Date: Injection Due: Yes No

Injection Location:

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REFERENCES:

1. American Cancer Society, Prostate Cancer website. <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>. Accessed June 2021.
2. National Comprehensive Cancer Network, NCCN Guidelines for Patients: Prostate Cancer, Version 1.2016: National Comprehensive Cancer Network website. <https://www.nccn.org/patients/guidelines/content/PDF/prostate-advanced-patient.pdf>. Accessed June 2021.
3. Center for Disease Control, Prostate Cancer website. https://www.cdc.gov/cancer/prostate/basic_info/index.htm. Accessed June 2021.
4. Carroll PR, Carducci MA, Zeitman AL, Rothenberger JM. *Report to the Nation on Prostate Cancer: A Guide for Men and Their Families*. Santa Monica, CA: Prostate Cancer Foundation; 2005 1-108.
5. NIH, National Cancer Institute, Prostate Cancer Patient website. https://www.cancer.gov/types/prostate/patient/prostate-treatment-pdq#link/_120; <https://www.cancer.gov/about-cancer/coping>. Accessed June 2021.
6. Gleason DF, Mellinger GT. Prediction of prognosis for prostatic adenocarcinoma by combined histological grading and clinical staging. *J Urol*.1974 111:58-64.
7. Epstein JI, Zelefsky MJ, Sjoberg DD, et al. A contemporary prostate cancer grading system: A validated alternative to the Gleason score. *Eur Urol*. 2016 69(3): 428-435.
8. Prostate Cancer Foundation website. <https://www.pcf.org/understanding-prostate-cancer>. Accessed June 2021.
9. Sartor O. Eligard® 6: A new form of treatment for prostate cancer. *Eur Urol*. 2006 (suppl 5):905-910.
10. ELIGARD® (leuprolide acetate) for injectable suspension, Highlights of Prescribing Information: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b78d1919-9dee-44fa-90f9-e0a26d32481d>. Accessed June 2021
11. ELIGARD® (leuprolide acetate) for injectable suspension, Side Effects. <https://eligard.com/about-eligard/>. Accessed June 2021.

For more information
about ELIGARD[®] visit
www.ELIGARD.com

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(leuprolide acetate) for injectable suspension