

# PROSTATE CANCER CARE GUIDEDBYILLUMINATION

#### INDICATIONS AND USAGE

Illuccix<sup>®</sup>, after radiolabeling with gallium-68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

### **Important Safety Information**

#### WARNINGS AND PRECAUTIONS

#### Risk for Misdiagnosis

Image interpretation errors can occur with gallium-68 gozetotide PET. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of gallium-68 gozetotide for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of gallium-68 gozetotide for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score.

Please see additional <u>Important Safety Information</u> throughout. Please see full <u>Prescribing Information</u>.

# How Illuccix<sup>®</sup> Works

# Illuccix can help your doctor get a more precise picture of your prostate cancer

Illuccix is an advanced imaging tracer that is used with a **positron emission tomography (PET) scan** to detect cancer cells in your body.

When you have rising **prostate-specific antigen** (**PSA**) **levels**, a PET scan with Illuccix can give your care team the information they need to determine the appropriate treatment plan for you.

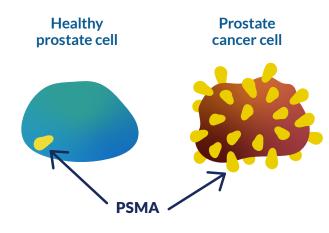
# What rising PSA means

**PSA is a protein produced by both healthy and cancerous cells of the prostate gland.** PSA levels are useful as an early sign of prostate cancer or to indicate that prostate cancer has come back or spread.

Actor portrayal.

However, PSA levels can go up or down for a variety of outside factors, such as particular forms of exercise, recent sexual activity, and certain medications. Because of this variability, more reliable screening tools may be necessary. That is why your doctor may order imaging tests.

# PSMA is a precise imaging target that can help detect prostate cancer



- **PSMA**, which stands for **prostate-specific membrane antigen**, is a protein that is abundant on the surface of prostate cancer cells. This is what makes PSMA a good target for prostate cancer imaging
- PSMA is also found on cancer cells that have spread to other parts of the body, such as the lymph nodes or bones
- PSMA imaging may be able to detect tumors that are undetectable with conventional imaging, which relies on size and shape of tumor

# **Important Safety Information**

### WARNINGS AND PRECAUTIONS

### Risk for Misdiagnosis (continued)

Gallium-68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Please see additional <u>Important Safety Information</u> throughout. Please see full <u>Prescribing Information</u>.



# Illuccix binds to PSMA to illuminate prostate cancer

What's important about Illuccix as a tracer is that it is able to attach to PSMA proteins on cancerous cells. During the PET scan, Illuccix lights up these proteins wherever they are in the body.

This advanced imaging tracer can help your care team make more informed decisions about your treatment path forward.



# The Illuccix<sup>®</sup> Difference



# How Illuccix is different from conventional imaging technology

Depending on your prostate cancer, your doctor may recommend different kinds of imaging, such as:

- Computed tomography (CT): Uses x-rays to show size and shape of organs, and is often used to see if tumors have grown, spread, or returned
- Magnetic resonance imaging (MRI): Uses radio waves and strong magnets to create images of soft tissue, including tumors
- Bone scans: Uses an imaging tracer to locate cancer that has spread to the bones

A PET scan with Illuccix: Uses an imaging tracer to target the specific PSMA protein on cancer cells throughout the body. A PET scan with Illuccix may be able to detect cancer when PSA levels are low and when tumors are small or conventional imaging results are uncertain.

# Understanding more about radiation

The use of radiation in medical imaging is quite common.

The Illuccix imaging tracer uses a small amount of radiation that is in the body for a short amount of time. Your care team is trained to use safe handling practices to help minimize any risk.

You can help by making sure to drink plenty of water after scan appointments and to empty your bladder frequently.

If you have any concerns, talk to your doctor or a member of your care team.





# The benefits of a PET scan with Illuccix



Can give doctors greater clarity regarding the extent of your prostate cancer.



A better understanding of your prostate cancer can help you and your doctors make more informed decisions about your treatment plan.



## Important Safety Information WARNINGS AND PRECAUTIONS

#### **Radiation Risks**

Gallium-68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to hydrate before and after administration and to void frequently after administration.

Please see additional <u>Important Safety Information</u> throughout. Please see full <u>Prescribing Information</u>.





The Illuccix tracer can be prepared on demand, which can provide greater flexibility in scheduling an appointment.



The Illuccix tracer reduces to minimal levels after 6 hours.

# A PET Scan With Illuccix®

# Preparing for your scan with Illuccix

If you are scheduled to have a scan, your doctor or a member of your care team will review specific preparation instructions with you, which may include:



Drink plenty of water: Make sure to hydrate adequately before your scan appointment. Continue to drink water and urinate frequently after you receive the injection for your scan

 $\checkmark$ 

- Avoid exercise: Try not to do strenuous exercise for at least 24 hours before your scan
- Diet: Ask your doctor or care team about any foods or beverages you should avoid before your scan

# What to expect with Illuccix during your imaging appointment

When you arrive for your appointment, your doctor or a member of your care team will prepare you for the scan.

## Below are some of the steps you can expect during your visit.



You will receive an intravenous or IV injection.



You will be asked to wait about an hour for the solution to make its way through your body and attach itself to any PSMA cells.



You will likely be asked to urinate right before the scan.



You will be instructed to lie still for the scan and breathe normally. Someone from the care team will be there to assist you.

You will be positioned on your

back with your arms above your

head for the scan.



The scan time can vary, but usually takes about 30 minutes.

# What to expect after your scan with Illuccix



You should continue to drink water and empty your bladder for several hours after the appointment.



Your doctor will contact you as soon as possible to discuss your scan results.

# **Important Safety Information**

### **INDICATIONS AND USAGE**

Illuccix<sup>®</sup>, after radiolabeling with gallium-68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

### WARNINGS AND PRECAUTIONS

#### **Risk for Misdiagnosis**

Image interpretation errors can occur with gallium-68 gozetotide PET. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of gallium-68 gozetotide for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of gallium-68 gozetotide for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score. Gallium-68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site. is recommended.

### **Radiation Risks**

Gallium-68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an

increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to hydrate before and after administration and to void frequently after administration.

of < 1%.





#### **ADVERSE REACTIONS**

The safety of gallium-68 gozetotide was evaluated in 960 patients, each receiving one dose of gallium-68 gozetotide. The average injected activity was 188.7 ± 40.7 MBg (5.1  $\pm$  1.1 mCi). No serious adverse reactions were attributed to gallium-68 gozetotide. The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate

#### **DRUG INTERACTIONS**

Androgen deprivation therapy and other therapies targeting the androgen pathway

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium-68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium-68 gozetotide PET has not been established.

#### You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.

You may also report adverse reactions to Telix by calling 1-844-455-8638 or emailing pharmacovigilance@telixpharma.com.

#### Please see full Prescribing Information.

# Print this page and bring it to your next appointment Talk To Your Doctor About Illuccix®



A PET scan with Illuccix can give your care team the information they need to determine a treatment plan that's right for you. Here are some questions you can ask your doctor during your next appointment.

- I had a negative MRI scan, CT scan, and/or bone scan but I have rising PSA levels. Can Illuccix help identify if my cancer has come back?
- Can a PET scan with Illuccix see if my cancer has spread?
- How safe is a PET scan with Illuccix?

# Illuccix scan appointment reminder and follow-up visit

Keep track of your scheduled appointments by filling out the below fields.

### SCHEDULED ILLUCCIX SCAN

Date:	
Time:	
Imaging Center:	
Address:	
Phone number:	

### **FOLLOW-UP VISIT**

Date: _		
Time: _		



If you need assistance or have any questions about Illuccix, please call 844-455-8638 or visit www.illuccix.com.

Please see additional <u>Important Safety Information</u> on throughout. Please see full <u>Prescribing Information</u>.



The Telix Pharmaceuticals and the Illuccix® name and logo are trademarks of Telix Pharmaceuticals Limited and its affiliates. © 2022 Telix Pharmaceuticals (US) Inc. All rights reserved. US-2100015 03/2022