



TLX250-CDx patient brochure  
Intended for US patients

Expanded Access Program (EAP)  
for the identification of clear cell  
renal carcinoma (ccRCC) in adults,  
using TLX250-CDx\*



\*TLX250-CDx is an investigational product only intending to detect ccRCC lesions.

## What is an Expanded Access Program?

Where an investigational product addresses an unmet medical need, and where there is no comparable or satisfactory alternate option, a patient's treating physician can request access prior to regulatory approval as permitted under local applicable laws and regulations.

This expanded access program provides a pathway for patients to access TLX250-CDx, an investigational imaging agent being developed worldwide by Telix Pharmaceuticals for the diagnosis of kidney cancer.

TLX250-CDx has successfully completed a phase III global clinical study showing efficacy to diagnose a form of kidney cancer. It has not yet been approved in your country nor in any other jurisdiction.

### General information

#### What is nuclear medicine?

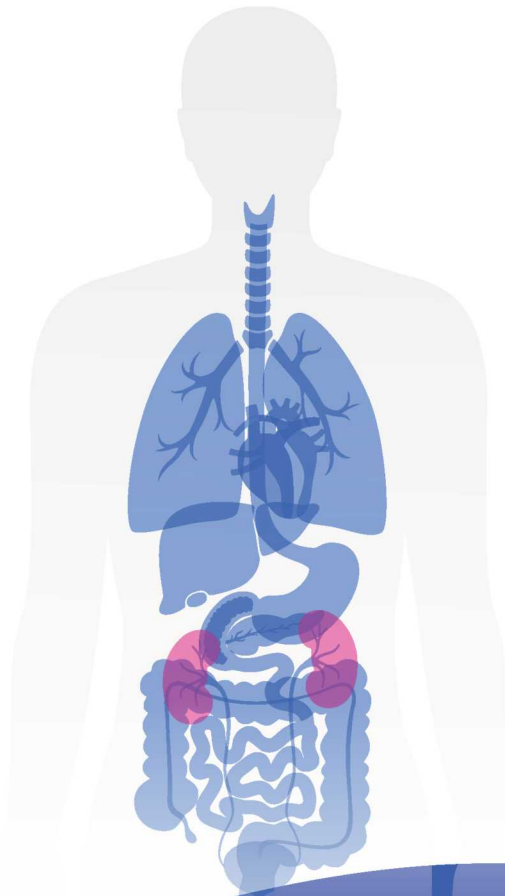
Nuclear medicine is a specialised area of radiology that uses very small amounts of radioactive material to identify and treat a variety of diseases.

When a radioactive material is injected, it travels through your bloodstream to specific organs, or area(s) of interest. Once the injected material reaches the specific area, your physician will use a diagnostic imaging tool, such as PET/CT, to take pictures inside your body and gather information on any potential changes.

## Why would I have a PET/CT scan?

PET/CT scans are used to detect or clarify different diseases including but not limited to cancer, inflammation, cardiac and brain lesions. This technique combines two types of imaging: PET (positron emission tomography) and CT (computed tomography).

PET/CT imaging of TLX250-CDx allows identification of tumour areas, more specifically clear cell renal cell carcinoma (ccRCC), a form of kidney cancer. This scan has potential to provide new information that may assist the medical team in making a diagnosis, guide treatment decisions or alleviate the need for invasive procedures and unnecessary surgery.



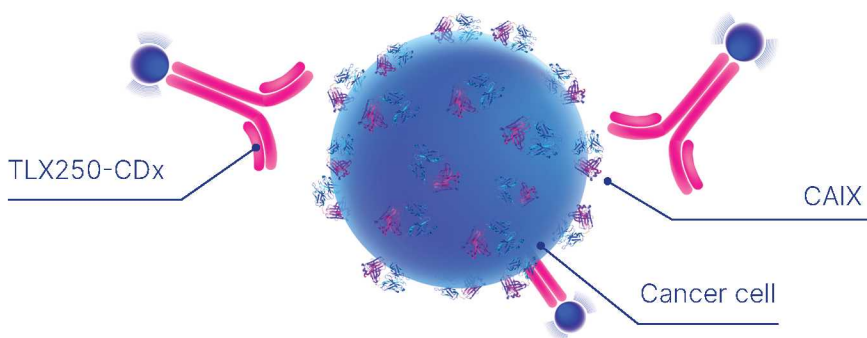
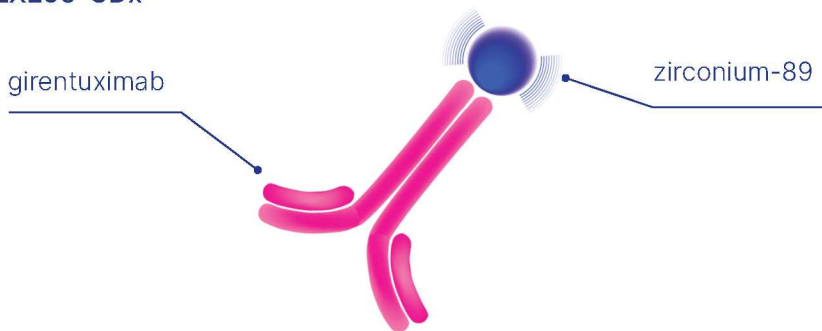
\*Illustrative image only - not in proportion.

## What will be used in my PET/CT scan?

TLX250-CDx contains a small amount of radioactive material known as zirconium-89 linked to an antibody known as girentuximab.

Girentuximab targets carbonic anhydrase IX (CAIX), which is a protein that is detected on the surface of ccRCC and many other hypoxic solid tumours, but not often found in normal, healthy tissue. The zirconium-89 linked to girentuximab provides a signal that is detected by the PET/CT scanner. These images will show if TLX250-CDx has accumulated anywhere in the body, which can be indicative of kidney cancer. Previous studies have shown that imaging with TLX250-CDx can differentiate kidney cancer from a benign (non-cancerous) kidney growth.

### TLX250-CDx

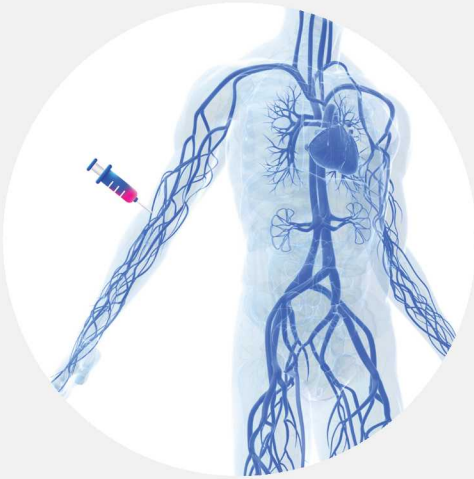




## How to prepare for the PET/CT scan?

Please inform your physician if you are breastfeeding or might be pregnant. Women of childbearing potential have to perform pregnancy tests. Please follow your physician's recommendations.

## What can I expect when I come in to the hospital?

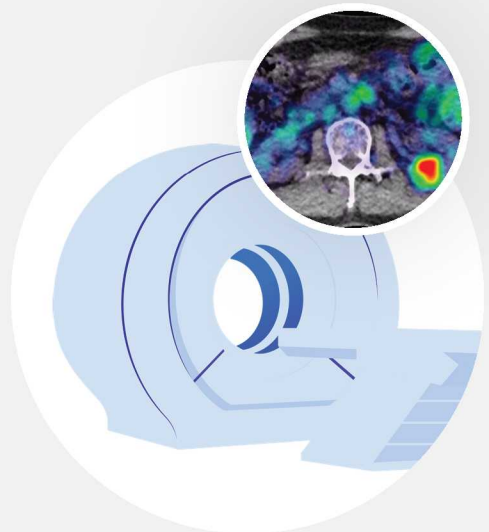


### Administration

You will receive a single dose of TLX250-CDx through an injection into a vein over a minimum of 3 minutes.

### PET/CT scan

Approximately 5 days after the TLX250-CDx injection you will return for the PET/CT scan. A PET/CT scanner can detect the distribution of TLX250-CDx within the body and areas where TLX250-CDx gathers, identifying potential tumours. These areas will appear brighter than normal tissue on the images.



\* Patient representative sample - individual results may vary.

Brochure is intended as education for the most frequent asked questions.  
Please talk to your physician for any personal medical advice.

## Site contacts & details of administration/scan (This section is to be completed by your physician)

Site name and address

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.....  
.....  
.....  
.....

Name of physician

.....  
.....

Emergency contacts

*Physician:*

.....  
.....

*Phone:*

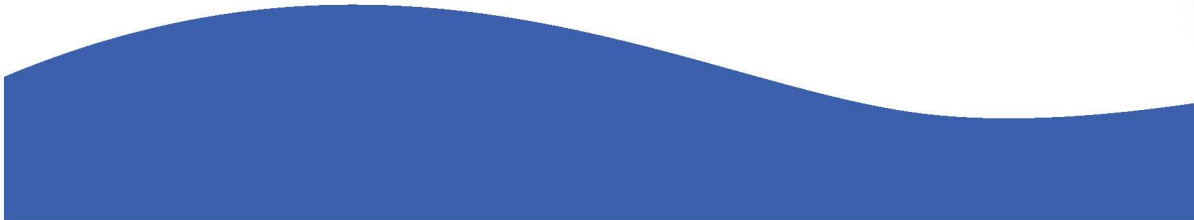
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Date and time of TLX250-CDx (89Zr-labelled girentuximab) administration

*Date:* ..... *Time:* .....

Date and time of PET/CT scan

*Date:* ..... *Time:* .....



## Will there be side effects?

Girentuximab has been used for the past 20 years in a number of clinical studies. Hundreds of patients worldwide have shown it has a favourable safety profile and can be used as an effective imaging agent, when labelled with a radioisotope.

Like other imaging exams, it will expose you briefly to a small amount of radiation. This is necessary to create an image of structures inside your body and for the detection of TLX250-CDx. Your treating physician will explain to you what are the most common side effects when using TLX250-CDx. Feel free to ask any questions you may have. Your physician will answer all of your questions.

Refer to safety measures on the following page for precautions to take after being dosed with TLX250-CDx. Once you have been administered with the investigational product, your medical team will also provide instructions on precautions to take for the next week. It is important you follow these instructions.

### Radiation exposure

The radiation dose you receive is about the same as exposure over several years from our natural environment. This small amount of additional radiation is very unlikely to have an effect on your health.



## Safety measures after TLX250-CDx administration

When you leave the hospital after administration of TLX250-CDx, you will emit a low level of radioactivity. Please follow the below guidelines on appropriate care for yourself and those around you. **These instructions need to be followed for one week after the injection.**

- When you leave the hospital, you should go directly home. If you travel by public transport, travelling time must not exceed 2 hours. You should limit any subsequent travel journeys during the week to no more than 30 minutes. In all cases, we recommend that you are accompanied by a person.
- You should avoid crowded public places.
- Limit close contact (less than 3 feet) with others, including your partner or primary carer, to 90 minutes per day.
- Do not sleep in the same bed as your partner for 1 week.
- Adults may approach you for a few minutes at a time, but for prolonged periods they should stay more than 6 feet away.
- Children and pregnant women may approach you for a few minutes at a time, but for prolonged periods they should stay more than 10 feet away.
- Observe rigorous hygiene to avoid the risk of contamination of others using the same toilet facility.
- A double toilet flush is recommended.
- You should wash your hands thoroughly every time after using the toilet.
- You are encouraged to increase fluid intake and to void frequently through the following day after the administration.
- Practice double-barrier contraception until a minimum of 42 days after TLX250-CDx administration.

### **Please inform your physician:**

- if you are using or going to use other medicines (even if these are homeopathic medicines, dietary supplements and / or vitamins);
- if you are admitted or treated in a hospital;
- if you suddenly have health complaints.