

# A guide for patients starting **OncoTICE<sup>®</sup>** treatment

(Bacillus Calmette and Guerin)



Hypothetical Patients



## Why you've been given this guide

This booklet is designed to give you information about OncoTICE<sup>®</sup> treatment and should be read together with the OncoTICE<sup>®</sup> Consumer Medicine Information leaflet, which is available from your healthcare professional.

This booklet does not take place of advice provided to you by your doctor. Please ask your doctor if you have any additional questions about your condition or treatment.

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## What is OncoTICE®?

OncoTICE® treatment is used to:<sup>1,2</sup>

- treat bladder cancer
- help prevent bladder cancer from coming back after bladder surgery.

Your treatment contains a substance called 'BCG' ('Bacillus Calmette-Guérin').<sup>1,2</sup> This is a bacterium which has been modified, so that it can be used as a treatment. OncoTICE® treatment works by stimulating your body's natural ability to fight bladder cancer.<sup>2</sup>

OncoTICE® will be introduced into your bladder by a doctor or nurse. It comes as a powder which is mixed with saline (salt water). It is then run into your bladder through a catheter (tube).<sup>2</sup>

## Your treatment schedule

About one to two weeks after your biopsy or procedure you will begin your treatment.<sup>1</sup> Your treatment is usually given once a week for 6 weeks.<sup>2</sup> After this period some people have 'maintenance treatment' where you may be given more doses.<sup>2</sup> Your doctor will talk to you about the duration and frequency of treatment that is right for you.

## Treatment timings

### Initial treatment (removal of tumours)

The first stage of treatment involves the removal of the tumour. This is referred to as "TUR" (transurethral resection) and is done using a device placed in the bladder. This is normally performed under a general anaesthetic. Approximately 10–15 days after the TUR procedure, OncoTICE® treatment is started. This is normally given once a week for the first 6 weeks.<sup>2</sup>

After initial treatment you will have a follow up cystoscopy, where a tube with a camera is inserted into your bladder. Following this, you will be able to have a further discussion with your doctor whether further maintenance treatment is required.

### Maintenance treatment

To reduce the risk of the tumour returning, maintenance treatment is often given after the initial 6 weeks.

The maintenance treatment schedule comprises of:

- **After biopsy or catheterisation:** monthly instillations over a period of 12 months.<sup>1</sup>
- **After bladder surgery:** an instillation in the 8th and 12th week and thereafter monthly instillations for months 4 through 12 after initiation of treatment.<sup>1</sup>

Your doctor will decide on the duration and frequency of your treatment.

You should make a note of any questions you have for your doctor regarding your treatment and ask them at your next appointment.

Now that you have started on your OncoTICE® treatment, it is important that you complete the treatment schedule. The table below will help you manage appointment times and dates for your treatment schedule.

<b>Start of treatment: OncoTICE® induction</b>			
	Date	Time	Notes
1st week			
2nd week			
3rd week			
4th week			
5th week			
6th week			
Next follow up:			

If you feel unwell, or unable to make the appointment please let your doctor know as soon as possible.

<b>Treatment schedule: OncoTICE® maintenance</b>			
	Date	Time	Notes
8th week			
12th week			
4 months			
5 months			
6 months			
7 months			
8 months			
9 months			
10 months			
11 months			
12 months			

Talk with your doctor or nurse to set up your appointment schedule. Please bring this schedule to all of your appointments.

Specialist Nurse	
Telephone Number	

## How does your treatment work?

The information below together with the diagram helps explain how your treatment works.

The bladder is a hollow structure which sits in the lower abdomen. It holds the urine produced by the two kidneys and releases this through the urethra when we 'pass urine.'

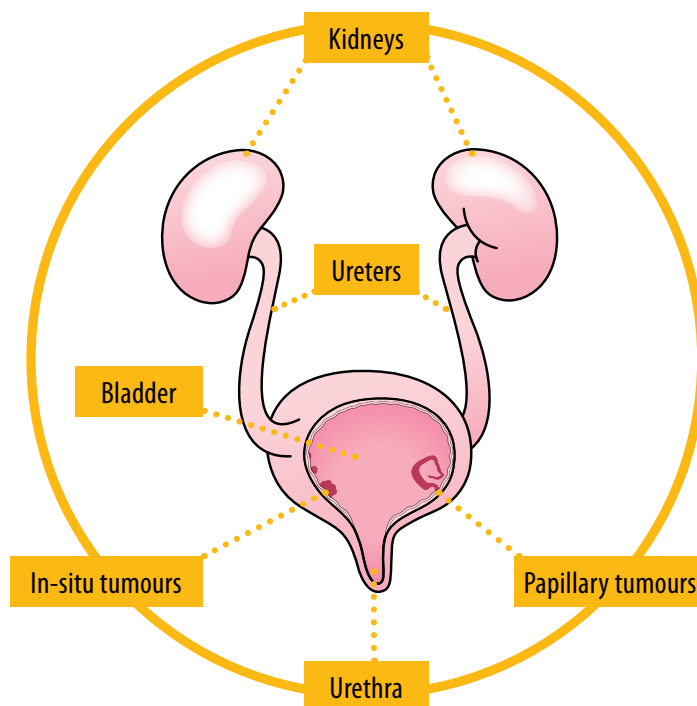
Superficial bladder cancer is treated with immunotherapy, which helps your body produce a natural defence against the bladder tumours.<sup>3</sup> BCG stimulates the immune system to fight the tumours of which there are 3 types:<sup>3</sup>

- The three main types of bladder cancer: urothelial carcinoma, squamous cell carcinoma and adenocarcinoma.
- The most common of these (80-90%) is urothelial carcinoma. This type of bladder cancer is divided into two subgroups: papillary urothelial carcinoma and flat urothelial carcinoma.
  - Papillary, which looks like a mushroom and grows from the bladder wall
  - Carcinoma in situ, which is a flat tumour that lies flat against the bladder wall.

It is not completely understood how your treatment works against bladder cancer. However, it appears to produce an inflammation in the lining of the bladder that destroys cancer cells, and it also seems to trigger the immune system, the body's defence system against disease.<sup>1</sup>

In order for your treatment to work, it must be in direct contact with the tumour cells.<sup>3</sup> That is why it is instilled – administered directly into the bladder – instead of given by injection.<sup>1</sup>

To help ensure your treatment is successful, it is important to follow your doctor or nurse's instructions.



## Before you are given your treatment

Before the first treatment is given you will be asked questions about any previous illnesses, operations or medication you may be taking. It would be useful to bring a list of current medications with you (some medicines may interfere with the way BCG works).

### Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicine, especially antibiotics or steroids. This includes medicines obtained without a prescription, including herbal medicines.

### Do not have your treatment and talk to your doctor straight away if you are on the following medicines/therapies:<sup>1,2</sup>

- Antibiotics
- Medicines that suppress the immune system such as anticancer drugs
- Medicines that suppress the production of bone marrow cells
- Radiation therapy

### Throughout your treatment period please let your doctor know if:<sup>2</sup>

- You have a urinary tract infection (UTI). This must be treated first.
- You have visible blood in your urine.
- You have or think you have TB (tuberculosis).
- You are being treated with anti-tuberculosis drugs.
- You suffer from an impaired immune system against infections irrespective of the cause.
- You are HIV positive.

### Pregnancy and breast-feeding<sup>2</sup>

Do not take your treatment if you are pregnant or breast-feeding. Ask your doctor for advice before taking any medicine if you are pregnant or breast-feeding.

## Before you are given your treatment

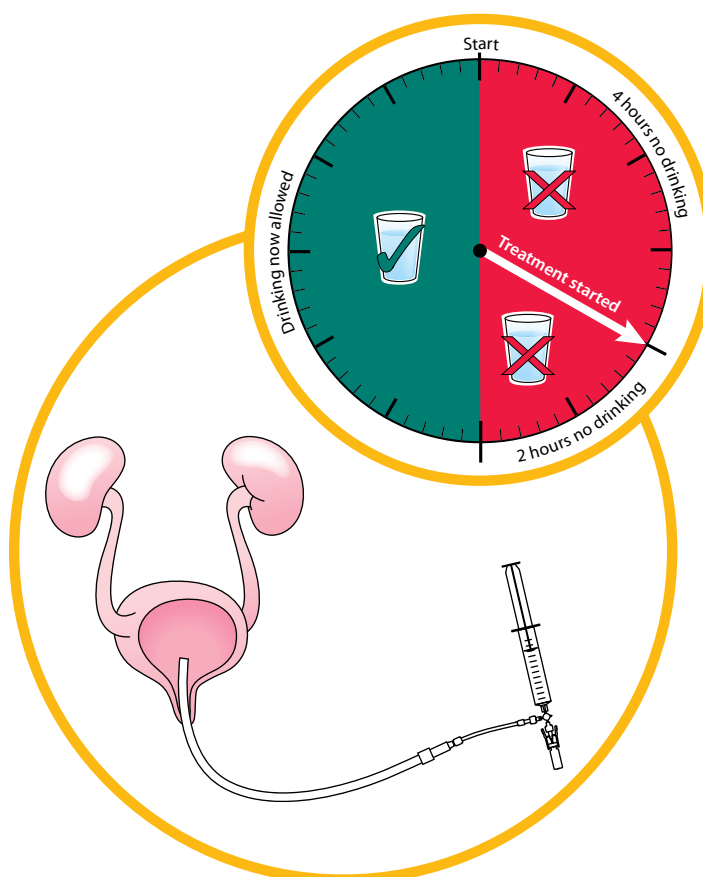
You will always be given your treatment by a doctor or nurse.

### Before it is given

- Do not drink any liquid in the 4 hours before your treatment is given to you.<sup>2</sup>
- You will be asked to pass urine immediately before your treatment is given to you.

### Being given your treatment

- First your genital area will be cleaned with a sterile solution.
- A nurse or doctor will then pass a small flexible tube (catheter) into your bladder through the normal urine passage.
- Your treatment is then run into your bladder through this tube. This will only take a few minutes.
- The small flexible tube will then be removed.
- Now OncoTICE® treatment has been put into your bladder:
  - Do not pass urine for 2 hours or drink any fluid during this period.<sup>2</sup>
  - It is important you try to move around.<sup>2</sup>



## Side effects

Like all medicines, OncoTICE® treatment can cause side effects, although not everybody gets them. If you do experience unusual symptoms or feel unwell after receiving this medication, please inform your doctor.

### If you notice the following side effects, see your doctor straight away:<sup>2</sup>

- A high temperature (fever) above 39°C that lasts for more than 12 hours, even after taking medicines like paracetamol to lower your temperature.
- BCG or TB infection - signs may include:
  - cough or bronchitis
  - chest pain or tightness
  - sweating
  - sore throat
  - cold in the nose
  - swelling of your lymph glands.

### Other side effects include:

#### **Very common** (affects more than 1 in 10 people):<sup>2</sup>

- Bladder infection, painful urination, urinary frequency, urgency and blood in the urine. In general, these symptoms disappear within within two days.
- Flu-like symptoms such as fever and a feeling of discomfort. These symptoms usually occur as soon as 4 hours after treatment and last for 24 to 48 hours.

#### **Common** (affects between 1 in 10 and 1 in a 100 people):<sup>2</sup>

- painful joints or arthritis
- muscle pain
- feeling sick (nausea) and being sick (vomiting)
- abdominal pain or diarrhoea
- airway infection
- anaemia
- loss of urine
- a large amount of blood in your urine
- feverish shivers

#### **Tell your doctor if:**

- you experience any unusual symptoms
- you feel unwell
- any side effect is severe or lasts longer than 48 hours



### After the treatment has been given<sup>1,2</sup>

- Your treatment will be left in your bladder for 2 hours.
- Do not drink any liquid for 2 hours after you have been given your treatment.
- 2 hours after your treatment began you will be asked to empty your bladder. You should do this while sitting down to avoid splashing your urine around the toilet.

### During the next 6 hours<sup>1,2</sup>

- Every time you need to urinate, also do this while sitting down.
- Every time you urinate, add two cups of household bleach to the toilet.
- Leave the bleach and urine to stand in the toilet for 15 minutes before flushing.
- Wash your hands with soap and water when you finish urinating.
- If you have two toilets, consider using one for your personal use on the day of your treatment.



## Effect of treatment on home life and work

Try to talk to your family, friends and colleagues as openly as possible about your illness and your course of treatment. This will allow them to help you and may address any concerns they have about how the treatment will affect you and them. You can also always talk to your doctor or nurse about any concerns or issues that you have.

### At home<sup>1,2</sup>

- As your treatment is potentially infectious there are one or two steps that you need to take at home to avoid family members accidentally being infected with BCG bacteria:
  - Wherever possible, your family should avoid using the same toilet with you on treatment days
  - Men should remember to sit down to urinate in the 6 hours after treatment (to avoid splashing urine around the toilet)
  - For 6 hours after treatment, disinfect the toilet with undiluted bleach each time it is used
  - It is advisable to refrain from sexual intercourse during the week following OncoTICE® treatment. The use of a condom may protect your partner provided it is used correctly and does not tear. Women should use additional birth control to avoid becoming pregnant during treatment.<sup>2</sup>

### At work

- You will need to talk to your employers so that they know that you will need time off for treatment – it's probably a good idea to do this as soon as possible.



**Use this section to make notes at/after your consultation to help you remember later**

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**GP details**

Name .....

Address .....

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Telephone .....

**References:** 1. OncoTICE® Product Information, 3 November 2014. 2. OncoTICE® Consumer Medicine Information, November 2014. 3. Cancer Council. Understanding Bladder Cancer, February 2016. Available at: <http://www.cancervic.org.au/downloads/resources/booklets/Understanding-Bladder-Cancer.pdf> (accessed 03/11/16).

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