

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

OncoTICE®

Bacillus Calmette-Guérin (BCG), Strain TICE®

Read this carefully before you start taking **OncoTICE®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **OncoTICE®**.

What is **OncoTICE®** used for?

- **OncoTICE®** contains something called 'BCG' ('Bacillus Calmette-Guérin' Strain TICE®). This is a bacterium which has been specially altered so that it can be used as a medicine.
- **OncoTICE®** is used to treat bladder cancer. It is also used to prevent bladder cancer from coming back after bladder surgery.

How does **OncoTICE®** work?

OncoTICE® belongs to a group of medicines called immunostimulants. These medicines stimulate certain parts of the immune system and thereby invoke a local inflammatory response.

What are the ingredients in **OncoTICE®**?

Medicinal ingredients: Bacillus Calmette-Guérin (BCG), Strain TICE®

Non-medicinal ingredients: Lactose 150 grams, Sauton medium (lactose, asparagine, citric acid (E330), potassium phosphate, magnesium sulfate, iron ammonium citrate, glycerol (E422), ammonium hydroxide (E527), zinc formate).

OncoTICE® comes in the following dosage forms:

OncoTICE® is supplied as a freeze-dried preparation in 2 mL vials; each vial contains 1 to 8 x 10⁸ CFU of TICE® BCG which is equivalent to approximately 50 mg wet weight. It is supplied in boxes containing 1 vial per box.

Do not use **OncoTICE®** if:

- You are hypersensitive (allergic) to Bacillus Calmette-Guérin (BCG) Strain TICE® or any of the other ingredients of **OncoTICE®**.
- You suffer from active tuberculosis.
- You are being treated with anti-tuberculosis drugs.
- You are HIV-positive.
- You suffer from an impaired immune system (reduced immunity against infectious diseases), irrespective of the cause.
- You have blood in your urine.
- You have a urinary tract infection. If you suffer from cystitis (inflammation of the bladder), you will first receive a course of antibiotics before treatment with **OncoTICE®** starts. Treatment with antibiotics needs to be finished before treatment with **OncoTICE®** is started.

To help avoid side effects and ensure proper use, talk to your healthcare professional before starting treatment with OncoTICE®. Talk about any health conditions or problems you may have, including if you have :

- active tuberculosis infection

Other warnings you should know about:

BEFORE you use OncoTICE® talk to your healthcare professional:

Before the first intravesical instillation of OncoTICE®, your healthcare professional will probably perform a skin test (Mantoux test) to investigate if you have an active tuberculosis infection.

- If a skin test (Mantoux test) is performed after treatment with OncoTICE®, it may be positive.
- When the bladder wall or ureter is damaged during catheterization, treatment will need to be postponed until the lesion is healed.
- It is important that infection with the HIV virus is excluded. It may be necessary that a blood sample is taken to test for HIV. Your healthcare professional might also ask if there are any risk factors, such as unsafe sex, use of dirty needles if you are a drug user and blood transfusions.
- To protect your partner from transmission of the BCG bacteria, it is advisable to refrain from sexual intercourse during the week following treatment with OncoTICE®. If you use a condom you can have intercourse, on condition that the condom is used correctly, and does not tear.
- If you are pregnant, talk to your healthcare professional.
- If you are breastfeeding, talk to your healthcare professional.

There is no warning that your ability to drive or operate machines will be affected.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with OncoTICE®:

- Antibiotics
- Medicines for tuberculosis
- Medicines which suppress the immune system (immune suppressants)
- Medicines which suppress the production of bone marrow cells (bone marrow suppressants)
- Radiation therapy

If you are using any of these medicines or are undergoing one of these therapies, your healthcare professional will probably postpone treatment with OncoTICE® until you have stopped these other treatments.

How to take OncoTICE®:

- OncoTICE® will be given to you by a healthcare professional in a healthcare setting.

Usual dose:

OncoTICE® is usually given once a week for 6 weeks followed by additional doses of OncoTICE® as part of your 'maintenance treatment'. Your healthcare professional will talk to you about this.

Before it is given

- Do not drink any liquid 4 hours before OncoTICE® is given to you.

- You will be asked to pass water immediately before OncoTICE® is given to you.

When given your medicine

- First your genital area will be cleaned with a sterile solution.
- A nurse will then pass a small flexible tube into your bladder. This will remove any urine that is still in your bladder.
- OncoTICE® is then run into your bladder through this tube. This will only take a few minutes.
- The tube will then be removed.

After it has been given

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

During the next 6 hours

- If you need to pass water again, also do this while sitting down.
- Every time you pass water, add two cups of household bleach to the toilet.
- Leave the bleach and urine to stand in the toilet for 15 minutes before flushing.

Overdose:

OncoTICE® is made up from a standard bottle by your healthcare professional, pharmacist or nurse. It is unlikely that you will receive too much OncoTICE®. If you do have too much, your healthcare professional will check carefully to see whether you have BCG infection. If necessary you will need to have treatment for tuberculosis.

If you think you, or a person you are caring for, have taken too much OncoTICE®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using OncoTICE®?

These are not all the possible side effects you may have when taking OncoTICE®. If you experience any side effects not listed here, tell your healthcare professional. You should be attentive to side effects, such as fever, chills, malaise, flu-like symptoms, or increased fatigue.

If you experience any of the following side effects, your physician should be notified:

- An increase in urinary symptoms (such as burning, or pain upon urination, urgency, frequency of urination, blood in urine)
- Decreased urination or failure to urinate
- Joint or muscle pain
- Cough and/or shortness of breath
- Skin rash
- Eye complaints (such as pain, visual impairment, irritation or redness)
- Jaundice (yellow colouration of the skin or eyes)
- Nausea or vomiting
- Allergic reactions

- BCG infection in the blood (sepsis)
- Abnormal arterial dilation for bacterial infection (infective aneurysm)
- Inflammation of the blood vessels

This is not a complete list of side effects. If you notice any side effects not mentioned in this patient information, please notify your treating physician.

Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
UNCOMMON		
Tuberculous infections		X
RARE		
Cough		X
Epididymitis		X
VERY RARE		
Pharyngitis, orchitis, Reiter's syndrome, Lupus vulgaris		X
Lymphadenopathy		X
Anorexia		X
Confusional state		X
Dizziness, dysaesthesia ¹ , hyperaesthesia ¹ , paresthesia, somnolence, headache, hypertonia, neuralgia ¹		X
Conjunctivitis		X
Vertigo		X
Hypotension		X
Bronchitis, dyspnea, rhinitis		X
Dyspepsia ¹ , flatulence ¹		X
Alopecia, hyperhidrosis		X
NOT KNOWN (cannot be estimated from the available data)		
Back pain		X
Renal failure acute		X
Balanoposthitis, prostatitis, vulvovaginal discomfort ¹		X
Chest pain, edema peripheral, granuloma ²		X
Prostatic specific antigen increased, weight decreased		X
endophthalmitis		
UNKNOWN		
Increase in urinary symptoms (examples: burning, pain upon urination, urgency, frequency of urination, blood in urine)		X
Decreased urination or failure to urinate		X
Joint or muscle pain		X

Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
Cough and/or shortness of breath		X
Skin rash		X
Eye complaints (examples: pain, visual impairment, irritation or redness)		X
Jaundice (yellow colouration of the skin or eyes)		X
Nausea or vomiting		X
Allergic reactions		X
BCG infection in the blood (sepsis)		X
Abnormal arterial dilation for bacterial infection (infective aneurysm)		X
Inflammation of the blood vessel		X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep OncoTICE[®] out of the reach and site of children.

OncoTICE[®] will be stored in the hospital according to the instruction given by the manufacturer on the packaging.

Store at 2°C – 8°C (in a refrigerator).

Do not use OncoTICE[®] after the expiry date which is stated on the carton and label.

If you want more information about OncoTICE[®]:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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