

PART III: CONSUMER INFORMATION

OncoTICE[®],
Bacillus Calmette-Guérin (BCG), strain TICE[®]

This leaflet is part III of a three-part "Product Monograph" published when OncoTICE[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OncoTICE[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is 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.

What it does:

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

When it should not be used:

- If you are hypersensitive (allergic) to Bacillus Calmette-Guérin (BCG) strain TICE[®] or any of the other ingredients of OncoTICE[®].
- If you have invasive bladder cancer.
- If you suffer from active tuberculosis.
- If you are being treated with anti-tuberculosis drugs.
- If you are HIV-positive.
- If you suffer from an impaired immune system (reduced immunity against infectious diseases), irrespective of the cause.
- If you are pregnant or breastfeeding.
- If you have blood in your urine.
- If you have a urinary tract infection. If you suffer from a cystitis, 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.

What the medicinal ingredient is:

The medicinal ingredient in OncoTICE[®], is Bacillus Calmette-Guérin (BCG), strain TICE[®].

What the important nonmedicinal ingredients are:

Nonmedicinal ingredients are lactose 150 grams and Sauton medium (lactose, asparagine, citric acid (E330), potassium phosphate, magnesium sulfate, iron ammonium citrate, glycerol (E422), ammonium hydroxide (E527), zinc formate).

What dosage forms it comes in:

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.

WARNINGS AND PRECAUTIONS

BEFORE you use OncoTICE[®] talk to your doctor or pharmacist:

Before the first intravesical instillation of OncoTICE[®], your doctor 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 is 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 doctor 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. OncoTICE[®] should not be given during pregnancy.
- If you are breastfeeding. OncoTICE[®] should not be given to breastfeeding mothers.

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

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with OncoTICE[®] include:

- 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 doctor will probably postpone the treatment until you have stopped this treatment.

PROPER USE OF THIS MEDICATION

OncoTICE[®] will always be given by a healthcare professional.

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 doctor will talk to you about this.

Before it is given

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

IMPORTANT: PLEASE READ

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

Being 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 doctor, pharmacist or nurse. It is unlikely that you will receive too much OncoTICE[®]. If you do have too much, your doctor will check carefully to see whether you have BCG infection. If necessary you will need to have treatment for tuberculosis.

Missed Dose:

No data established

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You should be attentive to side effects, such as fever, chills, malaise, flu-like symptoms, or increased fatigue.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

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

- Severe urinary side effects such as burning or pain on urination, urgency, frequency of urination, blood in urine
- An increase in urinary symptoms (such as urgency, frequency of urination, blood in urine)
- Joint pain
- Cough

- Skin rash
- Eye complaints (such as pain, irritation or redness)
- Jaundice
- Nausea or vomiting

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

HOW TO STORE IT

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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found or by contacting the sponsor Merck Canada Inc.

This leaflet was prepared by Merck Canada Inc.

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