OncoTICE®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your healthcare provider.

1. Why am I using OncoTICE?

OncoTICE contains the active ingredient Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain). OncoTICE is used for the treatment of superficial bladder cancer by stimulating the body's natural ability to fight disease. It is also used to prevent the disease from recurring after bladder surgery.

For more information, see Section 1. Why am I using OncoTICE? in the full CMI.

2. What should I know before I use OncoTICE?

Do not use if you have ever had an allergic reaction to OncoTICE or any of the ingredients listed at the end of the CMI.

Talk to your healthcare provider if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use OncoTICE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OncoTICE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How am I given OncoTICE?

- OncoTICE will be instilled into the bladder via a sterile tube (catheter) by a healthcare provider.
- Your healthcare provider will decide on the duration and frequency of treatment for you.

More instructions can be found in Section 4. How am I given OncoTICE? in the full CMI.

5. What should I know while using OncoTICE?

Things you should do	• Remind any healthcare provider you visit that you are using OncoTICE. • Refrain from drinking any fluid in the four hours before receiving this product and during the two hours the OncoTICE remains in the bladder. • It is important you move around while OncoTICE is in the bladder. The solution must remain in the bladder for two hours and you should not empty your bladder during this period. After two hours the bladder should be emptied in a sitting position. For six hours after treatment the bladder should continue to be emptied in a sitting position. Two cups of household bleach should be added to the toilet containing the urine and left to stand for 15 minutes before flushing.

For more information, see Section 5. What should I know while using OncoTICE? in the full CMI.

6. Are there any side effects?

Like all medicines, OncoTICE can cause side effects, although not everybody gets them. Your healthcare provider will discuss these with you and will explain the risks and benefits of your treatment. When you get OncoTICE, you can have some serious side effects

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

OncoTICE

Active ingredient: Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)

Consumer Medicine Information (CMI)

This leaflet provides important information about using OncoTICE. **You should also speak to your healthcare provider if you would like further information or if you have any concerns or questions about using OncoTICE.**

Where to find information in this leaflet:

1. Why am I using OncoTICE?
2. What should I know before I use OncoTICE?
3. What if I am taking other medicines?
4. How do I use OncoTICE?
5. What should I know while using OncoTICE?
6. Are there any side effects?
7. Product details

1. Why am I using OncoTICE?

OncoTICE contains the active ingredient Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain).

OncoTICE belongs to the group of medicines called immunostimulants. These medicines stimulate certain parts of the immune system.

OncoTICE is used for the treatment of superficial bladder cancer by stimulating the body's natural ability to fight disease. It is also used to prevent the disease from recurring after bladder surgery.

2. What should I know before I use OncoTICE?

Warnings

Do not use OncoTICE if:

- you are allergic to Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have a urinary tract infection. If you have cystitis (inflammation of the bladder), you will receive a course of antibiotics before treatment with OncoTICE starts. The treatment with antibiotics needs to be finished before treatment with OncoTICE starts.
- you have blood in your urine
- you have active tuberculosis - your healthcare provider will probably do a skin reaction test (Mantoux) to assist in making this diagnosis.
- you are being treated with anti-tuberculosis medicines.
- you suffer from an impaired immune system (reduced immunity against infectious diseases), irrespective of the cause.
- you are HIV-positive
- you are pregnant or are breast feeding your baby

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your healthcare provider if you are pregnant or intend to become pregnant.

Talk to your healthcare provider if you are breastfeeding or intend to breastfeed.

Special Instructions

Take special care with OncoTICE in the following situations:

- Before the first time OncoTICE is instilled in your bladder, your healthcare provider will probably perform a skin reaction test (Mantoux) 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.
- If the bladder wall or urethra is damaged during catheterisation, 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 provider may also ask if there are any risk factors, such as unsafe sex, use of shared needles if you use intravenous drugs, or received 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. The use of a condom may protect your partner provided it is used correctly and does not tear.

3. What if I am taking other medicines?

Tell your healthcare provider if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with OncoTICE and affect how it works.

Medicines that may reduce the effect of OncoTICE include:

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

If you are using any of these medicines or undergoing one of these therapies, your healthcare provider will postpone treatment with OncoTICE.

Check with your healthcare provider if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OncoTICE.

4. How do I use OncoTICE?

How OncoTICE is used

OncoTICE will be introduced into the bladder by a healthcare provider.

The contents of one vial will be dissolved in 50mL of saline solution. A sterile tube (catheter) will be inserted into the bladder through the normal urine passage and the bladder will be emptied of urine. The OncoTICE solution will be instilled into the bladder via the tube.

For cancer of the bladder, 7 to 14 days should elapse before BCG is administered following biopsy or traumatic catheterisation. The treatment schedule comprises a weekly instillation for the first 6 weeks, followed by a monthly treatment for a period of 12 months.

If you have had bladder surgery, your healthcare provider will start using OncoTICE between 10 and 15 days later. It will generally be given once a week for 6 weeks, then an instillation in the 8th and 12th week followed by monthly instillations from month 4 through to month 12.

- Your healthcare provider will decide on the duration and frequency of treatment for you.

If you are given too much OncoTICE

In the unlikely event that more than one vial is administered, you will be monitored for signs of BCG infection, and if indicated, you may be treated with anti-tuberculosis medication.

5. What should I know while using OncoTICE?

Things you should do

- Refrain from drinking any fluid in the four hours prior to receiving this product and during the two hours the OncoTICE remains in the bladder.
- It is important you move around while OncoTICE is in the bladder. The solution must remain in the bladder for two hours and you should not empty your bladder during this period. After two hours the bladder should be emptied in a sitting position
- For six hours after treatment the bladder should continue to be emptied in a sitting position.
- Two cups of household bleach should be added to the toilet containing the urine and left to stand for 15 minutes before flushing.

Remind any healthcare provider you visit that you are using OncoTICE.

Driving or using machines

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

Looking after your medicine

- Store OncoTICE at 2°C to 8°C, protect from light and use before the expiry date on the product label. The product in solution can be stored for a maximum of 2 hours under these conditions.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

OncoTICE is generally well tolerated.

If you do experience unusual symptoms or feel unwell after receiving this medication, please inform your healthcare provider.

See the information below and, if you need to, ask your healthcare provider if you have any further questions about side effects.

Very Common side effects (in more than 10% patients)

Very Common side effects	What to do
• Bladder inflammation • Painful urination, urinary frequency, and blood in the urine. • In general, these symptoms disappear within two days. • Flu-like symptoms such as fever, fatigue and malaise (feeling of discomfort). • These symptoms usually occur as soon as 4 hours after treatment and last for 24 to 48 hours.	**Speak to your healthcare provider if you have any of these side effects**

Common side effects (1% -10% of patients)

Common side effects	What to do
• Painful joints • Arthritis • Muscular pain • Nausea and vomiting • Abdominal pain • Diarrhoea • Lung inflammation • Anaemia • Loss of urine • Urinary tract infection • Urge to urinate • Abnormal urine lab test • Feverish shivers	**Speak to your healthcare provider if you have any of these side effects.**

Uncommon side effects (0.1% - 1% of patients)

Uncommon side effects	What to do
• Skin rash • Hepatitis associated with jaundice (yellow colouration of the skin or eyes) • Abnormal liver function test • Pus in the urine • Decreased amount of red blood cells or platelets possibly associated with symptoms such as fatigue and/or bruises • Decrease of white blood cells • Difficult urination • Bladder constriction and blocked urine flow • Tuberculous infections	**Speak to your healthcare provider if you have any of these side effects.**

Rare side effects (0.01% - 0.1% of patients):

Rare side effects	What to do
• Cough • Inflammation of the epididymis	**Speak to your healthcare provider if you have any of these side effects.**

Very Rare side effects (less than 0.01% patients)

Very Rare side effects	What to do
• Hair loss • Increased perspiration • Dizziness (sensation of spinning) • Headache • Increased muscle tension • Abnormal sensation such as prickling, burning, pins and needles or itching • Conjunctivitis • Loss of appetite • Indigestion and gas • Confusion • Weight loss • Low blood pressure • Bronchitis • Shortness of breath • Sore throat • Runny nose • Swelling of lymph glands • Insufficient function of the kidney • Granuloma (nodule in an organ) • Inflammation of the glans • Inflammation of the testicles • Reiter's syndrome (inflammation of the eyes, joints and genitourinary system)	**Speak to your healthcare provider if you have any of these side effects.**
• Lupus vulgaris (tuberculosis of the skin) • Inflammation of the prostate • Elevation of Prostatic specific antigen (PSA) (prostate laboratory test) • Burning, itching and soreness in the female genital area • Back pain • Chest pain • Fluid retention in the limbs	

Other side effects

Other observed side effects	What to do
• Allergic reactions • BCG infection in the blood (sepsis) • Abnormal arterial dilation for bacterial infection (infective aneurysm) • Inflammation of the blood vessels	**Speak to your healthcare provider if you have any of these side effects.**

Side effects (Unknown frequency)	What to do
• Osteomyelitis (infection of bone) • Intervertebral discitis (infection in the spinal disc) • A serious and potentially life-threatening condition where the immune system becomes overactive and produces too many infection fighting cells, which can cause inflammation and damage to body's own tissues and organs (hemophagocytic lymphohistiocytosis). Symptoms may include fever that doesn't go away, feeling very tired or weak, looking pale, feeling lightheaded or short of breath, or easy bruising	**Speak to your doctor healthcare provider if you have any of these side effects.**

In case you develop these symptoms or any new or worsening symptoms, you are advised to contact your healthcare provider, immediately.

Tell your healthcare provider if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your healthcare provider before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What OncoTICE contains

Active ingredient (main ingredient)	Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)
Other ingredients (inactive ingredients)	lactose monohydrate asparagine citric acid monohydrate dibasic potassium phosphate magnesium sulfate heptahydrate ferric ammonium citrate glycerol zinc formate dihydrate strong ammonia solution.

Do not take this medicine if you are allergic to any of these ingredients.

What OncoTICE looks like

OncoTICE is a freeze-dried preparation containing two hundred million - eight hundred million Colony Forming Units of Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain) in sealed glass vials (Aust R 59912).

Who distributes OncoTICE

Merck Sharp & Dohme (Australia) Pty Limited

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Macquarie Park NSW 2113 Australia

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