OncoTICE®

Mycobacterium bovis (Bacillus Calmette and Guerin [BCG, strain Tice™])

New Zealand Consumer Medicine Information

Before administration of this medicine please read this leaflet carefully. In this leaflet you will find information about OncoTICE as well as some general advice on using medicines. If you have any questions or worries, ask your doctor or pharmacist.

What is in this leaflet

This information has been provided to help understand how this product works and to answer some common questions about OncoTICE. If you need more information please ask your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given OncoTICE against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What OncoTICE is used for

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.

Ask your doctor if you have any questions about why OncoTICE has been prescribed for you.

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

Before you are given OncoTICE

When you must not take it

Do not take OncoTICE if:

- 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 is commenced.
- you have blood in your urine
- you have active tuberculosis.

  Your doctor will probably do a skin reaction test (Mantoux) to assist in making this diagnosis.
- you are being treated with anti-tuberculosis drugs.
- 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

Before you start to take it

Take special care with OncoTICE in the following situations:

- Before the first intravesical instillation of OncoTICE, your doctor will probably perform a skin reaction test (Mantoux) to investigate if you have an active tuberculosis infection.
- When the bladder wall or ureter 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 doctor may 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. The use of a condom may protect your partner provided it is used correctly and does not tear.
- If a skin test (Mantoux test) is performed after treatment with OncoTICE, it may be positive.
- Driving and using machines: There is no warning that your ability to drive or operate machines will be affected.

OncoTICE should not be administered to children.

Taking other medicines

Tell your doctor if you are taking any other medication.

The following medicines/therapies can reduce the effect of OncoTICE:

- 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 doctor will postpone treatment with OncoTICE.

How OncoTICE is given

OncoTICE will be introduced into the bladder by a doctor or nurse.

The contents of one vial will be dissolved in 50mL of saline solution. A sterile tube 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.

Things you must do

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.

Things to be careful of

For cancer of the bladder, any lesions should have been given time to heal, before OncoTICE is administered following biopsy or traumatic catheterisation. The treatment schedule comprises a weekly instillation for the first 6 weeks, followed by a maintenance treatment of weekly instillations for 3 consecutive weeks starting at months 3, 6 and 12 after the first treatment. If necessary, the 3-weekly treatment may be repeated every 6 months thereafter.

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

If you have had bladder surgery, your doctor will start using OncoTICE between 10 and 15 days later. Treatment should not be started until lesions have healed. The treatment regimen will be the same as for bladder cancer.

In case of overdose

If you are given too much (overdose)

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.

While you are using OncoTICE

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.

Side effects

OncoTICE is generally well tolerated.

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

After treatment with OncoTICE you may suffer from one or more of the common (in more than 10% patients) side effects:

- 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.

The following side effects occur less frequently (1% - 10% of patients):

- 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

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

- Skin rashes or eruptions
- Hepatitis associated with jaundice (yellow colouration of the skin or eyes)
- Abnormal liver function test
- Pus in the urine
- Decreased amount of white blood cells, red blood cells, and/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

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

- Cough
- Inflammation of the epididymis

The following side effects occur very rarely (less than 0.01% patients):

- 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 gentiourinary system)
- 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 observed side effects are

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

In case your symptoms are severe or last longer than 48 hours, you are advised to contact your doctor. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

After using OncoTICE

Storage

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.

Product description

Ingredients

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) (Tice™ BCG) in sealed glass vials. This is a specially adapted bacterium. In addition to the active ingredient, BCG, OncoTICE contains the following additives: lactose, asparagine, citric acid (E330), potassium phosphate (dibasic), magnesium sulphate, iron ammonium citrate, glycerin (E422), zinc formate and ammonium hydroxide (E527).

Sponsor Details

OncoTICE is supplied in New Zealand by:

Merck Sharp & Dohme
(New Zealand) Limited

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0800 500 673

Date of Preparation

24 August 2023

RCN000024939