

Consumer Medicine Information

OncoTICE®

Bacillus Calmette and Guerin (BCG, strain Tice)

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. Keep this leaflet. You may need to read it again.

What OncoTICE is used for

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.

Before you use OncoTICE

Do not use OncoTICE if:

- you have a urinary tract infection. If you have cystitis, 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

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 should 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.

OncoTICE should not be administered to children.

Before you are given OncoTICE

Tell your doctor if you are taking any other medication. The following medicines/therapies can reduce the effects of OncoTICE:

- Antibiotics
- Treatment for tuberculosis
- 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.

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.

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.

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. Spills or splashes should be covered by bleach soaked paper towels for at least 10 minutes then disposed of with rest of urine.

For cancer of the bladder, before BCG is administered following biopsy or traumatic catheterisation any lesions should have been given time to heal. 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 and 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.

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.

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 infection
- Painful urination, urinary frequency, urgency and blood in the urine. In general these symptoms disappear 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. If fever above 39°C persists longer than 12 hours even after taking anti-fever medication, see your doctor.
- Tiredness

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

- Painful joints
 - Arthritis
 - Muscular pain
 - Nausea and vomiting
 - Abdominal pain
 - Diarrhoea
 - Airway infection
 - Anemia
 - Loss of urine
 - A large amount of blood in urine
 - Feverish shivers
- Uncommon side effects (0.1% - 1% of patients)
- Skin rash
 - Hepatitis associated with jaundice (yellow colouration of the skin or eyes)
 - Pus in the urine
 - Decreased amount of red blood cells or platelets possibly associated with symptoms such as fatigue and/or bruises
 - Difficult urination
 - BCG infection in the blood

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

- Cough
- Inflammation of the epididymis

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

- Hair loss
- Increased perspiration
- Dizziness
- Headache
- Increased muscle tension
- Abnormal sensation such as prickling or itching
- Conjunctivitis
- Loss of appetite
- Confusion
- Weight loss
- Low blood pressure
- Bronchitis
- Tightness of the chest
- Sore throat
- Cold in the nose
- Swelling of lymph glands
- Insufficient function of the kidney
- Inflammation of the glands
- Inflammation of the testicles
- Inflammation of the prostate

- Back pain
- Chest pain
- Fluid retention in the limbs

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 $2-8 \times 10^8$ Colony Forming Units of Calmette and Guerin (BCG strain Tice) in sealed glass vials. In addition to the active ingredient, BCG, OncoTICE contains the following additives: lactose, asparagine, citric acid monohydrate, potassium phosphate (dibasic), magnesium sulphate, ferric ammonium citrate, glycerol, ammonium hydroxide, zinc

formate.

Sponsor

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