

OncoTICE® powder for suspension

2-8 X 10⁸ CFU Tice® BCG

Information for the patient

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Oncotice is and what it is used for

Oncotice contains something called 'BCG' ('Bacillus Calmette-Guérin'). This is a bacteria which has been specially altered, so that it can be used as a medicine.

Oncotice is used to:

- treat bladder cancer
- prevent bladder cancer from coming back after bladder surgery.

It comes as a powder which is mixed with saline (salt water). It is then run into your bladder through a tube. BCG is also used as a vaccine for TB (tuberculosis). Oncotice is a much stronger sort of BCG that can't be used as a vaccine.

2. Before you are given Oncotice

Oncotice should not be given if:

- You have a urinary tract infection (UTI) or cystitis (inflammation of the bladder). This must be treated first.
- You have blood in your urine.
- You have or think you have TB (tuberculosis). Before you have Oncotice, your doctor may do a skin reaction test, to see if you have TB. This is called a Tuberculin Test. If you have had Oncotice before, this may give you a positive result in this test.
- You are HIV-positive. You may need to have a blood test for HIV.

Tell your doctor if any of the following apply to you:

- you have been a drug user and have shared a needle
- you have had unsafe sex
- you have had a blood transfusion.
- you have problems with your immune system. This could be something which runs in the family or is caused by an illness or other medicines you are taking. Do not have Oncotice if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before being given Oncotice.

Take special care with Oncotice

Check with your doctor or pharmacist before being given the medicine if:

- Your bladder wall or the tube that goes into your bladder from your kidneys (called the ureter) have been damaged during previous treatment. Treatment with Oncotice will not be given until this has healed.

If you are not sure if any of the above apply to you talk to your doctor or pharmacist before being given Oncotice.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine. This includes medicines obtained without a prescription, including herbal medicines.

Do not have Oncotice and talk to your doctor straight away if:

- You are taking medicines for TB.

The following can lower the effect of Oncotice:

- antibiotics
- medicines which affect the immune system (immuno-suppressants)
- medicines which affect the production of bone marrow cells (bone marrow suppressants)
- radiation treatment.

If you are having any of these medicines or are having radiation treatment, your doctor will probably delay giving you Oncotice.

Using Oncotice with food and drink

- Do not drink any liquid for 4 hours **before** you are given Oncotice.
- Do not drink any liquid for 2 hours **after** you have been given Oncotice.

Pregnancy and breast-feeding

Do not have Oncotice if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Oncotice will not affect your being able to drive or use any tools or machines.

Important information about some of the ingredients of Oncotice

- Oncotice contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before being given this medicine.
- This medicine contains a very small amount of potassium (less than 1mmol or 39 mg per dose). This means it is essentially 'potassium-free'.

3. How Oncotice is given

You will always be given Oncotice by a doctor or nurse.

Before it is given

- Do not drink any liquid the 4 hours before Oncotice is given to you.
- You will be asked to urinate 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.
- During this time you should move around a little. This makes sure that the Oncotice is spread around your entire bladder wall.
- Do not drink any liquid for 2 hours after you have been given Oncotice.
- After 2 hours you will be asked to urinate, 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 urinate again, also do this while sitting down.
- Every time you urinate, add two cups of household bleach to the toilet.
- Leave the bleach and urine to stand in the toilet for 15 minutes before flushing.

How often Oncotice is given

Oncotice is usually given once a week for 6 weeks. After this some people have 'maintenance therapy', where you may be given more doses. Your doctor will talk to you about this.

Having sex in the week after having Oncotice

If you have sexual intercourse during the week after being given the medicine, you must use a condom. This will lower the chance of the BCG bacteria being passed to your partner.

If you have more Oncotice than you should

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 TB.

4. Possible side effects

Like all medicines, Oncotice can cause side effects, although not everybody gets them.

If you notice the following side effects, see your doctor straight away:

- a high temperature (fever) above 39 °C that lasts for more than 12 hours, even after taking medicines like paracetamol to lower your temperature.
- signs of a BCG or TB infection:
- cough or bronchitis
- chest pain or shortness of breath
- sweating
- sore throat
- runny nose
- swelling of your lymph glands.

See your doctor straight away if you notice any of these side effects.

The following side effects have been reported but the frequency cannot be estimated from the available information (frequency not known):

- allergic reactions that can range from mild to severe. Symptoms may include rash, itching, or more severe skin reactions.
- BCG infection in the blood (sepsis). Severe condition with multiple symptoms that may include fever, malaise, chills, sweats, weight loss and shortness of breath.
- abnormal arterial dilation for bacterial infection (infective aneurysm). Severe condition with symptoms that may include abdominal and/or back pain and fever.
- inflammation of the blood vessels. Severe condition with multiple symptoms that may include fever, headache, fatigue, weight loss, and general aches and pains.

Other side effects include:

Very common

(affects more than 1 in 10 people)

- bladder inflammation, pain when urinating, having to urinate often, and bloody urine. Usually this goes away within two days.
- flu-like symptoms such as fever, fatigue and feeling off-colour and tired (malaise). This usually happens about 4 hours after treatment and lasts for 24 to 48 hours.

Common

(affects less than 1 in 10 people)

- painful joints or arthritis
- muscle pain or stiffness
- nausea and vomiting
- abdominal pain or diarrhoea
- anaemia
- problems urinating
- shivering with a high temperature (fever)
- lung inflammation
- urinary tract infection
- urge to urinate
- abnormal urine lab test

Uncommon

(affects less than 1 in 100 people)

- skin rash
- jaundice (yellow colour of your skin or eyes)
- pus in your urine
- difficulty urinating
- decreased amount of red blood cells or platelets possibly associated with symptoms such as fatigue and / or bruises
- decrease of white blood cells
- abnormal liver function test
- bladder constriction and blocked urine flow
- tuberculosis infections

Rare

(affects less than 1 in every 1,000 people)

- inflammation of the epididymis (tube at the back of the testicles)
- cough.

Very Rare

(affects less than 1 in every 10,000 people)

- headache
- back pain

- increased muscle tension
- swollen legs or arms
- low blood pressure
- flatulence or discomfort following meals
- loss of appetite or weight loss
- hair loss
- prickling, burning, pins and needles or itching skin
- eye infection
- feeling confused, sleepy or dizziness (spinning sensation)
- kidney problems
- increased perspiration
- bronchitis
- shortness of breath
- sore throat
- runny nose
- swelling of the lymph glands
- granuloma (nodule in an organ)
- inflammation of the glans
- inflammation of the testicles
- inflammation of the prostate
- Reiter's syndrome (inflammation of the eyes, joints and genitourinary system)
- Lupus vulgaris (tuberculosis of the skin)
- elevation of Prostatic specific antigen (PSA) (prostate laboratory test)
- burning, itching and soreness in the female genital area
- chest pain

Tell your doctor if any side effect is severe or lasts longer than 48 hours. If you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oncotice

Keep Oncotice out of the reach and sight of children. Oncotice will be stored in the hospital according to the instructions given by the manufacturer on the packaging. Store at 2 °C to 8 °C (in a refrigerator). Do not use Oncotice after the expiry date which is stated on the carton and label.

6. Further information

What Oncotice contains

- The active substance is Bacillus Calmette-Guérin (BCG). It is a specially treated bacteria to be used as a medicine.
- The other ingredients are: lactose, asparagine, citric acid (E330), potassium phosphate, magnesium sulfate, iron ammonium citrate, glycerol (E422), ammonium hydroxide (E527), zinc formate.

What Oncotice looks like and contents of the pack

Oncotice is a freeze-dried powder, packed in 2 ml glass vials (available in packs of 1 or 3), each containing 1 dose of 12.5 mg (equivalent to 2 to 8 x 10⁸ CFU) of BCG.

Marketing Authorisation Holder:

Merck Sharp & Dohme (UK) Limited
120 Moorgate
London
EC2M 6UR
UK

Manufacturer is:

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

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To listen to or request a copy of this leaflet in braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: Oncotice

Reference Number: PL 53095/0003

This is a service provided by the Royal National Institute for Blind People

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