

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S2****VesiCulture freeze-dried powder for reconstitution*****Mycobacterium bovis* BCG****Sugar free****Read all of this leaflet carefully before you receive VesiCulture**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VesiCulture has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VesiCulture is and what it is used for
2. What you need to know before you receive VesiCulture
3. How to receive VesiCulture
4. Possible side effects
5. How to store VesiCulture
6. Contents of the pack and other information

1. What VesiCulture is and what it is used for

VesiCulture contains *Mycobacterium bovis* BCG. This is a bacteria which has been specially altered, so that it can be used as a medicine.

VesiCulture is used to treat bladder cancer or to prevent bladder cancer from coming back after bladder surgery.

2. What you need to know before you receive VesiCulture

VesiCulture should not be administered to you if:

- you are allergic (hypersensitive) to *Mycobacterium bovis* BCG or any of the other ingredients of VesiCulture (listed in section 6).
- 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.
- you have TB (tuberculosis). Before you receive VesiCulture, your doctor may do a skin reaction test, to see if you have TB.
- you are receiving medical treatment against TB.
- you are HIV-positive. You may need to have a blood test for HIV.
- you are pregnant or breastfeeding your baby.
- you have had radiation therapy of the bladder.

Warnings and precautions

Special care with VesiCulture will be taken:

- If you have a urinary tract infection (UTI) or cystitis (inflammation of the bladder). This must be treated first.
- If you have blood in your urine.
- If you are HIV-positive. In order to protect your partner, it is recommended that you either abstain from intercourse for one week after bladder irrigation or use a condom.
- 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 VesiCulture will not be given until this has healed.

Other medicines and VesiCulture

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not receive VesiCulture and talk to your doctor straight away if:

- you are taking medicines for TB, such as isoniazid, rifampicin and ethambutol

The following can lower the effect of VesiCulture:

- 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 VesiCulture.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive VesiCulture.

The use of VesiCulture is not recommended during pregnancy or breastfeeding.

Driving and using machines

VesiCulture has no or a minor influence on the ability to drive and use machines

3. How to receive VesiCulture

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself VesiCulture. It will be given to you by a person who is qualified to do so.

Before VesiCulture is given

- Do not drink any liquid before VesiCulture is given to you.
- You will be asked to urinate immediately before VesiCulture is given to you.

When given VesiCulture

- 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.
- VesiCulture is then run into your bladder through this tube. This will only take a few minutes.
- The tube will then be removed.

After VesiCulture has been given

- VesiCulture will be left in your bladder for 2 hours.
- During this time you should move around a little. This makes sure that the VesiCulture is spread around your entire bladder wall.
- Do not drink any liquid for 2 hours after you have been given VesiCulture.

How often VesiCulture is given

VesiCulture 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.

If you receive more VesiCulture than you should

Since a health care provider will administer VesiCulture, he/ she will control the dosage. However, in the event of overdose your doctor will manage the overdose. If you receive too much, your doctor will check carefully to see whether you have BCG infection. If necessary, you will need to have treatment for TB.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist

4. Possible side effects

VesiCulture can have side effects.

Not all side effects reported for VesiCulture ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving VesiCulture, please consult your health care provider for advice.

If any of the following happens, stop receiving VesiCulture and tell your doctor or nurse immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had an allergic reaction to VesiCulture. You may need urgent attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following: 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;
- BCG infection in the blood (sepsis). Severe condition with multiple symptoms that may include fever, malaise, chills, sweats, weight loss and shortness of breath.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Very common (affects more than 1 in 10 people)

- abnormally frequent urination.

Common (affects less than 1 in 10 people)

- painful urination, inflammation of the bladder,
- general feeling of discomfort, illness or unease,
- slight rise in body temperature,
- flu-like symptoms.

Uncommon (affects less than 1 in 100 people)

- shivering with a high temperature (fever).

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

- painful joints or arthritis,
- muscle pain or stiffness,
- inflammation of the testicles,
- skin rash,
- inflammation of the prostate,
- temporary obstruction/narrowing of the urethra,
- blood in the urine.

Very rare (affects less than 1 in every 10 000 people)

- bladder contraction.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of VesiCulture.

5. How to store VesiCulture

Store all medicines out of reach of children.

- Store in a refrigerator (2 °C – 8 °C).
- Store in the original package in order to protect from light.
- Do not use after the expiry date stated on the label.
- The resuspended solution may be kept for 4 hours at room temperature, protected from light. VesiCulture will deteriorate when exposed even for short periods to direct sunlight and diffuse daylight (also indoors).

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VesiCulture contains

- The active substance is *Mycobacterium bovis* BCG.

Each vial of live VesiCulture contains a semi-dry mass of 30 mg *Mycobacterium bovis* BCG, Danish strain 1331 with approximately $2,5 \times 10^8$ CFU. There is no bactericidal or bacteriostatic agent present.

- The other ingredient is:

Monosodium glutamate.

What VesiCulture looks like and contents of the pack

Brown glass vials containing a white to off-white freeze-dried powder.

Reconstituted product: slightly opaque and colourless suspension.

Contents of the pack

Packs of four 4 ml brown glass vials closed with grey rubber stoppers capped with an aluminium overseal, each containing 30 mg of VesiCulture.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To be confirmed.