

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VERITY-BCG

Bacillus Calmette-Guérin (BCG), Freeze-dried Powder

Read this carefully before you start taking **VERITY-BCG** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VERITY-BCG**.

Serious Warnings and Precautions

- After the surgery to remove the cancer in your bladder you must wait two or three weeks, to give time for the bladder to heal, before treatment with VERITY-BCG can be started.
- If the bladder is injured when the tube in the urethra (catheter) is inserted on the day of treatment, then the treatment must be postponed until the bladder heals. Treatment with VERITY-BCG when the bladder is injured could cause a serious infection.
- If you have blood in your urine, you must have it evaluated and treated before VERITY-BCG can be given.
- If you have a fever, you must have it evaluated and treated before VERITY-BCG can be given.
- If you have a urinary tract infection or if you suffer from cystitis (inflammation of the bladder), you must have antibiotics before treatment with VERITY-BCG starts. Treatment with antibiotics needs to be finished before VERITY-BCG can be given.
- Before you start VERITY-BCG, your doctor will do a tuberculin skin test (also called a 'Mantoux' test) to see if you have ever been exposed to tuberculosis (TB). A small amount of TB protein is injected into the top layer of the skin in your lower arm. If you have ever been exposed to TB, your skin will react with a firm red bump in 2 or 3 days. If your skin does react, then you will need a medical evaluation and chest x-ray to make sure you do not have active TB disease. VERITY-BCG treatment cannot be given to you, if you have active TB disease.

What is VERITY-BCG used for?

VERITY-BCG contains something called 'BCG' ('Bacillus Calmette-Guérin'). This bacteria has been weakened, so that it can be used as a safe medicine.

VERITY-BCG is used to treat early bladder cancer that has not invaded the muscle wall of the bladder. It is used after bladder surgery – to prevent or delay bladder cancers from growing back or spreading into the deeper layers of the bladder.

For the following indication(s) VERITY-BCG has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- Adjuvant therapy after transurethral resection (TUR) of a primary or relapsing superficial papillary urothelial cell carcinoma of the bladder stage Ta (grade 2 or 3) or T1 (grade 1, 2, or 3), without concomitant carcinoma in situ. It is only recommended for stage Ta grade 1 papillary tumors, when there is judged to be a high risk (>50%) of tumor recurrence.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does VERITY-BCG work?

VERITY-BCG belongs to the group of medicines called immunostimulants. These medicines stimulate your immune system to fight the cancer in the bladder.

What are the ingredients in VERITY-BCG?

Medicinal ingredients: Bacillus Calmette-Guérin (BCG): Strain Russian BCG-I.

Non-medicinal ingredients: Monosodium glutamate.

VERITY-BCG comes in the following dosage forms:

Each vial contains 40 mg ($1 - 8 \times 10^8$ CFU) of VERITY-BCG in freeze-dried powder form.

Each instillation in the bladder contains 80 mg of VERITY-BCG (2 vials) which is diluted in 50 mL of saline.

Do not use VERITY-BCG if:

- If you are hypersensitive (allergic) to Bacillus Calmette-Guérin (BCG) or any of the other ingredients of VERITY-BCG.
- If you have invasive bladder cancer.
- If you have any disease that impairs your immune system (and reduces your immunity against infectious diseases).
- If you take medicines that make your immune system weak.
- If you have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS).
- If you are pregnant or breastfeeding.
- If you have active tuberculosis.
- If you are being treated with anti-tuberculosis drugs.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VERITY-BCG. Talk about any health conditions or problems you may have, including if you:

- If your bladder wall or ureter is damaged, treatment will need to be postponed until the lesion has healed.

Other warnings you should know about:

- Treatment with VERITY-BCG may cause a positive reaction to the Tuberculin Skin Test.
- Your doctor might ask about activities that can put you at risk for HIV, such as having unsafe sex or

sharing needles or syringes, if you use drugs. It may be necessary to take a blood test for HIV before starting treatment with VERITY-BCG. You cannot be treated with VERITY-BCG if you have HIV infection.

- You might pass on the BCG bacteria to your partner when you have sex during the first week after treatment. It is recommended that you avoid having sex during this time but if you do, then use a condom with intercourse throughout the entire treatment period and during the first week after treatment.
- If you are pregnant, VERITY-BCG should not be given.
- If you are breastfeeding, VERITY-BCG should not be given.
- There is no warning that your ability to drive or operate machines will be affected.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VERITY-BCG:

- Antibiotics
- Medicines for tuberculosis
- Medicines which suppress the immune system (immune suppressants)
- Medicines which suppress the production of bone marrow cells (bone marrow suppressants)
- Radiation therapy
- If you are using any of these medicines or are undergoing one of these therapies, your doctor will probably postpone the treatment until you have stopped this treatment.

How to take VERITY-BCG:

- VERITY-BCG will always be given by a healthcare professional in a healthcare setting.

Usual dose:

The recommended dose per instillation is 80 mg (2 vials) of VERITY-BCG.

VERITY-BCG is usually given once a week for 6 weeks followed by additional doses of VERITY-BCG as part of your 'maintenance treatment'. Maintenance treatments will be given every few months for as long as one or three years, depending on the chances of your cancer coming back. Your doctor will talk to you about this.

Before it is given

- Do not drink any liquid the 4 hours before VERITY-BCG is given to you.
- You will be asked to pass urine immediately before VERITY-BCG is given to you.

Being given your medicine

- 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.
- Next, the doctor or nurse will attach a container of VERITY-BCG solution to the tube. VERITY-BCG will 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

- VERITY-BCG will be left in your bladder for 2 hours.
- Do not drink any liquid for 2 hours after you have been given VERITY-BCG.
- You will be asked to change positions every 15 minutes during the 2 hours VERITY-BCG is in your bladder. This will make sure that VERITY-BCG comes into contact with your bladder wall during treatment.
- After 2 hours, you will be asked to pass urine, 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 pass urine again, also do this while sitting down.
- Every time you pass urine, add two cups of household bleach to the toilet.
- Leave the bleach and urine to stand in the toilet for 15 minutes before flushing. If clothing has been soiled, it should be laundered and dried separately at a high temperature. Incontinence pads should be soaked in bleach, wrapped separately in a plastic bag and thrown in the garbage.

Overdose:

VERITY-BCG is made up from a standard bottle by your doctor, pharmacist, or nurse. It is unlikely that you will receive too much VERITY-BCG.

If you think you, or a person you are caring for, have taken too much VERITY-BCG, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is very important to go to all your appointments for treatment. If you miss an appointment, call your doctor to make another one as soon as you can. If doses are missed, they may be replaced later. Your doctor will talk to you about this.

What are possible side effects from using VERITY-BCG?

These are not all the possible side effects you may have when taking VERITY-BCG. If you experience any side effects not listed here, tell your healthcare professional.

- You may feel unwell and have fever, chills, muscle aches or tiredness.
- You may have burning or pain when you urinate.

- You may urinate more often than usual.
- You may have sudden urges to urinate immediately.
- You may have blood in your urine.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Blood in the Urine		✓	
Painful or difficult urination	✓		
Fever less than 39°C	✓		
Flu-like symptoms, fatigue	✓		
COMMON			
Urinary Frequency or Urgency	✓		
Fever greater than 39°C		✓	
Any Fever Lasting longer than 24-48 hours		✓	
Allergic reactions		✓	
RARE			
Burning during urination	✓		
Skin rash		✓	
Joint pain		✓	
Cough	✓		
Eye pain or irritation/redness	✓		
Nausea or vomiting	✓		
Jaundice		✓	
BCG infection in the blood (sepsis)		✓	
Abnormal arterial dilation due to bacterial infection (infective aneurysm)		✓	
Inability to urinate			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

VERITY-BCG will be stored in the hospital. Vials of VERITY-BCG are stable for up to 24 months when stored at 2 to 8°C and protected from light.

Do not use VERITY-BCG after the expiry date which is stated on the carton and label.

Keep out of reach and sight of children.

If you want more information about VERITY-BCG:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.veritypharma.com, or by calling 1-800-977-9778.

This leaflet was prepared by Verity Pharmaceuticals.

Last Revised: January 5, 2021