

# ImmuCyst<sup>®</sup> (im-you-sist)

*BCG immunotherapeutic (BCG im-you-no-thera-pew-tick)*

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## Consumer Medicine Information (CMI)

### What is in this leaflet

This leaflet answers some common questions about ImmuCyst.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

### What ImmuCyst is used for

ImmuCyst is used to treat some types of cancer that occur on the inside surface of the urinary bladder.

The exact way that ImmuCyst works is still not completely known. When instilled into the bladder, ImmuCyst causes an immune reaction in the bladder which causes the body's own cells to help destroy any remaining cancer cells. As with any cancer treatment, ImmuCyst may not be effective in all patients and may not cure your cancer forever.

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

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

This medicine is not addictive.

### Before you are given it

#### **When you must not be given it**

**Do not receive ImmuCyst if you have:**

- tuberculosis
- current or history of severe reaction to BCG
- fever
- infection of your urinary tract or bladder
- blood in your urine
- a weak immune system or are taking drugs that weaken your immune system
- had an operation on your bladder within the past 7 to 14 days

**Do not receive ImmuCyst if you are allergic to it or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

**Do not give ImmuCyst to a child or adolescent.**

There is no experience with its use in children or adolescents under 18 years old.

**Do not receive it if you are pregnant or intend to become pregnant.**

It is not known whether ImmuCyst can affect your developing baby if you are given it during pregnancy.

**Do not receive it if you are breastfeeding or planning to breastfeed.**

It is not known if ImmuCyst passes into breast milk and there is a possibility your baby may be affected.

**Do not receive it after the expiry date (EXP) printed on the carton.**

If you receive it after the expiry date has passed, it may not work as well.

**Do not receive it if the packaging is damaged or shows signs of tampering.**

#### **Before you are given it**

**Tell your doctor if you have allergies to:**

- any of the ingredients listed at the end of this leaflet
- latex
- any other substances, such as foods, preservatives or dyes

**Tell your doctor if you are pregnant or intend to become pregnant.**

Like most medicines of this kind, ImmuCyst is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of being given it if you are pregnant.

**Tell your doctor if you are breastfeeding or planning to breastfeed.**

It is not known whether ImmuCyst passes into breast milk. Your doctor will discuss the risks and benefits of being given it if you are breastfeeding or planning to breastfeed.

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- tuberculosis or a cough
- an illness with a fever
- an operation to remove a bladder tumour within the past 7 days
- infection of your urinary tract or bladder
- a weak immune system

**Tell your doctor if you plan to have surgery.**

**If you have not told your doctor about any of the above, tell them before you are given ImmuCyst.**

### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.** Some medicines may interfere with the effect of ImmuCyst. These include:

- medicines that weaken your immune system
- medicines used to treat bacterial infections (antibiotics)
- medicines used to treat tuberculosis

These medicines may be affected by ImmuCyst, or may affect how well it works. ImmuCyst should not be mixed with other medicines.

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## **How it is given**

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ImmuCyst should only be administered by trained professionals, with appropriate handling, in a hospital or clinic environment.

### ***How much to be given***

**Your doctor will decide what dose of ImmuCyst you will receive.**

Ask your doctor if you want to know more about the dose of ImmuCyst you receive.

### ***How it is given***

When prepared following recommended instructions, one ImmuCyst treatment is a 53 mL liquid solution. To administer ImmuCyst, your doctor or nurse will insert a tube (a catheter) into your bladder and drain any urine. After the bladder is emptied, the ImmuCyst solution will be slowly run into your bladder via gravity.

You must then lie on your sides for 15 minutes each. You will be allowed up for the next hour. At the end of 2 hours, or sooner if you cannot hold the ImmuCyst in your bladder any longer, the ImmuCyst in your bladder can be passed like urine. You may pass the urine using the rubber catheter tube, or if you use the toilet, you must be in a seated position.

### ***How long it will be given***

ImmuCyst is usually given once a week for 6 weeks. Your doctor will discuss with you whether further doses will be necessary. Some people are given further ImmuCyst treatments over a 2 year period, to help prevent recurrence of disease.

### ***If you receive too much (overdose)***

**As ImmuCyst is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given ImmuCyst, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital.**

You may need urgent medical attention.

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## **While you are being given it**

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### ***Things you must do***

**Tell all the doctors, dentists and pharmacists who are treating you that you are being given ImmuCyst.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being given ImmuCyst.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.**

**If you become pregnant while you are being given this medicine, tell your doctor immediately.**

### ***Things you must not do***

**Do not receive this medicine to treat any other complaints.**

### ***Things to be careful of***

**It is important that for 6 hours following your ImmuCyst treatment, you go to the toilet in a seated position.**

This is because ImmuCyst is prepared from bacteria and is still able to cause infection in some people.

**Any urine you pass in these 6 hours must be disinfected with bleach (such as ‘White King’).**

This can be done by adding an equal amount of bleach to the urine and leaving it for 15 minutes in the toilet bowl before flushing.

**Be careful driving or operating machinery until you know how ImmuCyst affects you.**

There have been no studies on the effects of ImmuCyst on the ability to drive or operate machines.

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## **Side effects**

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All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Tell your doctor as soon as possible if you do not feel well while you are being given ImmuCyst.**

It helps most people with bladder cancer, but it may have unwanted side effects in a few people.

**Tell your doctor if you have any of the following for longer than 48 hours after treatment, or they increase in severity:**

- pain or burning when passing urine
- fever, chills or tiredness
- cough and flu-like symptoms

**Tell your doctor immediately if you notice any of the following:**

- blood in the urine or a need to urinate frequently
- joint pain
- pain, irritation or redness of the eyes
- cough
- skin rash
- feeling of nausea and vomiting
- diarrhoea or loss of appetite
- genital pain or swelling of the male sex organs

**If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- **swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.**
- **hives**
- **fainting**
- **yellowing of the skin and eyes (jaundice)**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to ImmuCyst. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Other side effects not listed above may occur in some consumers.

**Ask your doctor to answer any questions you may have.**

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## After being given it

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**If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor.**

### Storage

**ImmuCyst must be stored at 2°C - 8°C.**

The best place is in the bottom of your refrigerator. ImmuCyst will be damaged and will not work if it gets too warm, is put into your freezer or is exposed to light.

**ImmuCyst must stay sealed in its original pack until your doctor or nurse is ready to prepare it for use. It must not be opened in the sunlight.**

### Disposal

**If your doctor tells you to stop using ImmuCyst, or the medicine has passed its expiry date, return any unused medicine to your pharmacist.**

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## Product description

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### What it looks like

One ImmuCyst pack contains one vial.

### Ingredients

Active Ingredient:

Each dose (one vial) of ImmuCyst contains between 1.8 - 19.2 x 10<sup>8</sup> bacteria of the Connaught strain of Bacillus of Calmette and Guerin (BCG).

Inactive Ingredients:

ImmuCyst also contains monosodium glutamate (MSG).

### Manufacturer/Sponsor

ImmuCyst is supplied in Australia by:

sanofi-aventis australia Pty Ltd  
12-24 Talavera Road  
Macquarie Park NSW 2113

ImmuCyst is supplied in New Zealand by:

sanofi-aventis new zealand limited  
Level 8, James and Wells Tower  
56 Cawley Street  
Ellerslie  
Auckland

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