

# WHAT TO EXPECT DURING YOUR BCG-MEDAC TREATMENT



INTENDED FOR PATIENTS

medac  
PHARMA

## DEAR PATIENT,

You will soon be receiving BCG-medac (Bacillus Calmette-Guérin) treatment for your non-muscle invasive bladder cancer (NMIBC), which you will have already discussed with your Urologist/Nurse Specialist.

To ensure that you are as prepared as possible, we have put together this leaflet providing you with a summary of the most important points about your first appointment for BCG-medac treatment. This will hopefully mean that you can start your therapy feeling more reassured.

## WHY DO I NEED TO HAVE BCG-MEDAC?

You have now completed the first step in your bladder cancer therapy, the surgical removal of the tumour.

Now it's time for the adjuvant (additional) treatment, which you will receive to help reduce the risk of the tumour coming back (recurrence).

BCG-medac is a type of immunotherapy medicine. Treatment with BCG-medac causes a localised inflammation in the bladder. This is intentional and is important because it activates your body's own defence mechanisms – similar to a vaccine. The BCG-medac induced inflammation makes your immune system able to recognise and specifically fight cancer cells. Consequently, the risk of recurrence and progression (worsening) of the bladder cancer can be reduced.

## WHAT YOU NEED TO KNOW BEFORE TREATMENT

It is important that you inform your urology team about any medications you are taking. Some medicines, in particular antibiotics, may affect the effectiveness of BCG-medac. If relevant, please also mention any past or current tuberculosis infections to your Urology team.

Do not drink any liquid for 4 hours before treatment. This is to ensure that you can keep the BCG-medac in your bladder for approximately 2 hours and that it will not be diluted during treatment.

## WHAT YOU NEED TO KNOW AFTER TREATMENT

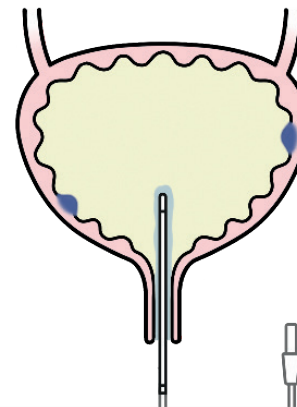
The BCG-medac solution remains in the bladder for approximately 2 hours. After 2 hours, you will be asked to pass urine to empty your bladder. So that no BCG-medac gets onto the toilet seat, it is important that you do this sitting down. Additionally, your nurse may ask for you to disinfect the toilet with bleach for the first 6-48 hours after treatment. Please clean your genital area and hands immediately afterwards to remove traces of BCG-medac.

It is important to drink plenty of fluids for 48 hours after treatment. This helps to reduce the risk of side effects.

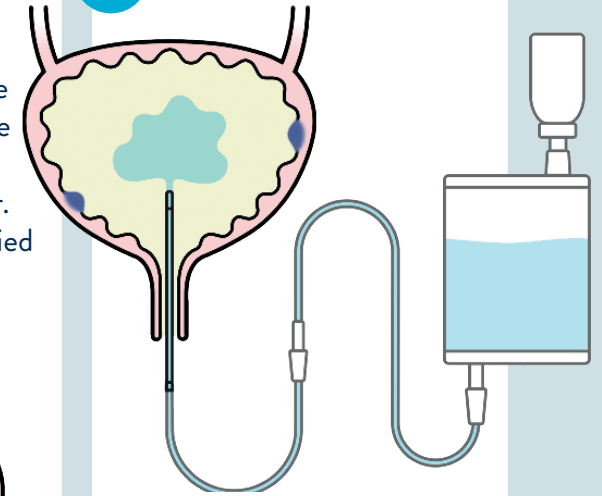
## THE BCG-MEDAC TREATMENT PROCEDURE

1

Your genital area will be cleaned and, while you are lying down, a small flexible tube (catheter) will be inserted into your bladder. Your bladder will be emptied at this point, prior to instillation.



2

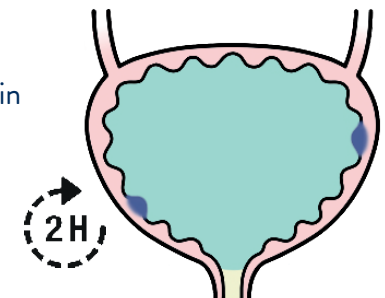


BCG-medac (approximately 50ml) is then run slowly into your bladder through the catheter.

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3

The catheter is removed. The BCG-medac should remain in your bladder for 2 hours. Afterwards you will be asked to go to the toilet to empty your bladder.



## MOST COMMON SIDE EFFECTS

Some of the most common side effects include 'cystitis-like' side effects, which include pain when urinating, greater frequency of urination and higher urgency to urinate. Other common side effects you may experience are 'flu-like' symptoms, such as tiredness, fever <math>< 38.5^{\circ}\text{C}</math>, general malaise or mild joint pain.

These side effects may occur after any treatment cycle of BCG-medac. They are generally mild and can last for up to 48 hours. If longer than 48 hours, please contact your CNS/Urologist.



**Talk to your Urologist/Nurse Specialist if you find the side effects worrying. They will be able to help you.**

## WHAT YOU SHOULD DO IF YOU NOTICE SIDE EFFECTS

In addition to the intended inflammatory reaction of the bladder, side effects relating to other areas of the body (systemic infection) may occur in more rare cases. Any of the following side effects should be reported immediately. **Signs and symptoms may include:**

- **Fever above  $39.5^{\circ}\text{C}$  lasting over 12 hours**
- **Fever above  $38.5^{\circ}\text{C}$  lasting over 48 hours**
- **Difficulty breathing or cough**
- **Pain in the right upper abdomen**
- **Visual impairment, blurred vision or pain or reddening in the eye similar to conjunctivitis**
- **Severe joint pains**
- **Feeling increasingly unwell (e.g. tired, weak or exhausted)**

**Please consult your Urologist/Nurse Specialist immediately if signs of such side effects occur or if you notice unexpected symptoms.**

# HOW TO OBTAIN FURTHER INFORMATION

You can obtain detailed information on bladder cancer and your BCG-medac therapy – just ask your Urology team within your hospital and they will be able to help you.

The opportunity to speak or interact with other bladder cancer patients during or after your treatment may offer you additional support and can be beneficial.

Patient organisations such as Action Bladder Cancer and Fight Bladder Cancer provide a great opportunity to do this. Please talk to your Urology team about this, to learn more about how you can get in touch.

Please read the Patient Information Leaflet and Patient Alert Card, contained within the BCG-medac carton, for further details.

It is important to carry the Alert Card with you at all times.

If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in the Patient Information Leaflet.

You can also report side effects directly via the Yellow Card Scheme at [yellowcard.mhra.gov.uk](http://yellowcard.mhra.gov.uk).

By reporting side effects, you can help provide more information on the safety of this medicine.