Patient's data

Surname

First name

Phone

Emergency contact details

Surname

First name

Phone

Physician's contact details

Surname of physician

Phone

Address

Patient alert card for

BCG-medac

(BCG - Bacillus Calmette-Guérin)

:medac

IMPORTANT INFORMATION FOR HEALTHCARE PROVIDERS

This patient is/was being treated with BCG-medac for bladder cancer. BCG-medac can cause systemic infections which could be fatal if not treated adequately.

BCG contains a lyophilised suspension of live Bacillus Calmette-Guérin bacteria with low infectious potential derived from *Mycobacterium bovis*. This strain is not virulent. Therefore the patient does not need to be isolated.

Systemic BCG infections can occur even years after the last dose has been administered as an intravesical instillation. These infections may present as fever, night sweats, weight loss, pulmonary or hepatic granuloma, conjunctivitis or Reiter's syndrome, abscesses, infected aneurysms or an infection of an implant or graft also in the surrounding tissues. Early diagnosis and appropriate management are essential to minimise any consequences of the infection, which can be fatal.

Please note that a negative mycobacterial test result does not exclude a systemic BCG infection, regardless of the used specimen (blood, urine, serum). Several cases have been reported with negative blood/urine cultures even though the patient was suffering from a systemic BCG infection.

Treatment of a suspected BCG infection depends on the nature and severity of the clinical symptoms.

Please report suspected adverse reactions. Turn the card for national contact details.

For further information please consult the current summary of product characteristics (SmPC).

Consultation of a physician specialised in infectious diseases is recommended.

80161-VTK2_XX (PAC IE)
FAN-SC-00189

IMPORTANT INFORMATION FOR PATIENTS

This card contains important safety information that you need to be aware of, during and after treatment with BCG-medac. Keep this card in your wallet and show it to any healthcare professional treating you, not just your prescribing urologist.

Side effects of BCG-medac may occur at any time during treatment, even years after your treatment has ended. When diagnosed, they are treatable.

Also tell your doctor if you experience any other suspect symptoms not listed on this card that worry you.

Do not try to treat your symptoms with other medicines on your own.

Keep this card close to hand also after treatment with BCG-medac has been stopped.

Treatment with BCG-medac could result in the side effect of a systemic infection. This infection might develop at any time – even years after the last instillation. However, when diagnosed, it is treatable.

Signs and symptoms of a so called „delayed BCG infection“ are sometimes difficult to recognize, because they might resemble other diseases.

These signs and symptoms of an infection with BCG outside the bladder may be

- Fever above 39.5 °C during at least 12 hours or fever above 38 °C lasting for weeks; night sweats
- Weight loss of unknown origin
- Feeling increasingly poorly
- Signs of inflammation may differ and present as
  - breathing difficulties or a cough that does not feel like a normal cold,
  - liver problems: a feeling of pressure in right upper abdomen or, liver function test abnormalities (especially an enzyme called alkaline phosphatase), or
  - pain and redness of the eye, vision problems or blurry vision; “pink eye”
- A so-called granulomatous inflammation which has been shown in a biopsy.

If you experience two or more side effects as listed above, you must to go to a hospital, general practitioner or your urologist, even when your bladder cancer has been treated a long time ago:

- bring this card and a full list of your medications, including prescription and over-the-counter medicines, vitamins, and herbal supplements to the hospital,
- tell doctors and/or nurses that you are/were treated with BCG and show them this card, so they will know how to treat you.

For further information please read the patient information leaflet (PIL).

Reporting of side effects

If you get any side effects, it is crucial to talk to your doctor, pharmacist or nurse. You can additionally report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

Adverse drug reactions can also be reported directly to the marketing authorisation holder:
medac Gesellschaft für klinische Spezialpräparate mbH
Theaterstr. 6, 22880 Wedel, Germany
E-mail: Drugsafety@medac.de
Tel.: +49 4103 8006-0, Fax: +49 4103 8006-100

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