Produkt	Karta Ostrzegawcza_PL_EN
Wymiary	280x300
Kolory	C90_Y50_K20
Typy fontów	Arial **bold**/normal 8,5 pkt Arial Narrow 10 pkt Arial **bold** 14pkt

Patient's data

Name

Surname

Phone

Emergency contact details

Name

Surname

Phone

Physician's contact details

Surname

Phone

Address

Patient alert card for

Onko BCG 50 and Onko BCG 100

(BCG – Bacillus Calmette-Guérin)

SYNTHAVERSE

IMPORTANT INFORMATION FOR HEALTHCARE PROVIDERS

This patient is or was being treated with Onko BCG 50 or Onko BCG 100 for bladder cancer. These products can cause systemic infections which could be fatal if not treated adequately.

This medicinal product is a lyophilised suspension of live Bacillus Calmette-Guérin bacteria of low infectious potential, derived from *Mycobacterium bovis*. This strain is non-virulent and does not require patient isolation.

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).

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

Please report suspected adverse reactions. Contact details for reporting adverse drug reactions are presented below.

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

Consultation of a physician specialised in infectious diseases is recommended.

IMPORTANT INFORMATION FOR PATIENT

This card contains important safety information that you need to be aware of, during and after treatment with Onko BCG 50 or Onko BCG 100. Keep this card and show it to any healthcare professional treating you, not just your urologist prescribing BCG therapy.

Side effects after administration of Onko BCG 50 or Onko BCG 100 may occur at any time during treatment, even years after your treatment has ended. When adequatly diagnosed, they are treatable.

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

Do not try to treat your symptoms on your own.

Keep this card close to hand also after the end of treatment with Onko BCG 50 or Onko BCG 100.

Treatment with Onko BCG 50 or Onko BCG 100 could result in the side effect of a systemic infection. This infection might develop at any time – even years after the last instillation with the drug. However, when adequatly diagnosed, it is treatable.

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

These signs and symptoms of a systemic infection 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
- Worsening malaise
- 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 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,
- Tell doctors or nurses that you 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

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt
Adverse drug reactions may also be reported directly to the Marketing Authotisation Holder:

Synthaverse S.A.
10 Uniwersytecka Str.
20-029 Lublin
Email: leki@synthaverse.com
Tel.: +48 515 035 071
+48 515 035 040
Fax: +48 81 533 80 60