# Onko BCG 50, Onko BCG 100, powder and solvent for suspension for intravesical use, (BCG - Bacillus Calmette-Guérin): Introduction of the Patient Alert Card

Dear Consultants,

Synthaverse S.A., in agreement with the Malta Medicines Authority, would like to provide you with the following information:

**Summary**

**- There is a possible risk of exacerbation of latent BCG infection with potentially fatal consequences.**

**- Appropriate therapy for exacerbation of latent BCG infection is of utmost importance.**

**- The introduction of the Alert Card is intended to ensure that patients and healthcare professionals are aware of the risk of BCG infection, even many years after treatment with the product. The Alert Card attached to this communication should be read and given to patients. Contact details for ordering additional Alert Cards are given below.**

**- The Alert Card should be given to the patient and any questions regarding this warning answered.**

**Additional safety information**

Onko BCG 100 are indicated for the treatment of superficial, epithelial, non-invasive bladder tumours (carcinoma urotheliale Ta, Tis, T1).

A possible side effect after administration of Onko BCG 100 is disseminated BCG infection, which may occur many years after therapy. This may lead to a latent BCG infection which may persist for several years. This latent BCG infection may worsen many years after the initial infection, and in particular may develop from granulomatous pneumonia, abscesses, infection within an aneurysm, implant, graft or surrounding tissue, which may go undetected and persist long after BCG therapy has ended. Exacerbation of such infections poses a risk to patient safety with a potentially fatal outcome.

Consultation with an infectious disease specialist is recommended in cases of disseminated infection, as the course of the disease is similar to that of M. tuberculosis infection. BCG mycobacteria (attenuated mycobacteria of M. bovis) are non-pathogenic to humans; therefore, patients do not need to be isolated after diagnosis of disseminated infection.

**Patient Alert Card**

A Patient Alert Card has been developed to minimise the risk of patients developing unrecognised severe systemic BCG infection with potentially fatal consequences.

Before the first intravesical infusion containing the product is given, the patient should be informed of the symptoms of severe systemic infection that may occur. The Patient Alert Card should be completed with details of the patient and the urologist performing the procedure. The patient should carry the card with them at all times and give it to each doctor they see (general practitioner, hospital doctor) so that appropriate treatment can be given in time in the event of a systemic BCG infection.

The Patient Alert Card also contains a brief description of the symptoms of a systemic infection and information on BCG mycobacteria and the risk of exacerbation of a latent BCG infection, so that general practitioners and hospital doctors who are not directly involved in treatment with Onko BCG 100 are aware of the possibility of such a complication. A case of systemic BCG infection or any other adverse reaction should be reported in accordance with the applicable adverse reaction reporting requirements.

**Reporting of adverse reactions**

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

The SmPC sections 4.4 - Special warnings and precautions for use and 4.8 - Adverse reactions have been updated. The patient information leaflet has been amended accordingly in Section 2 - Warnings and Precautions.

The current issue of SPC and PIL can be found at the link:

https://medicinesauthority.gov.mt/medicine-details?id=104651

Please refer to the Patient Warning Card included with this communication. Additional cards can be ordered from leki@synthaverse.com