



Onko BCG[®]

Live, attenuated Bacillus Calmette-Guerin bacilli

100 mg, 50 mg
powder and solvent for intravesical suspension

**Treatment of superficial non-invasive
tumours of the urinary bladder**

SV SYNTHA
VERSE

INDICATIONS

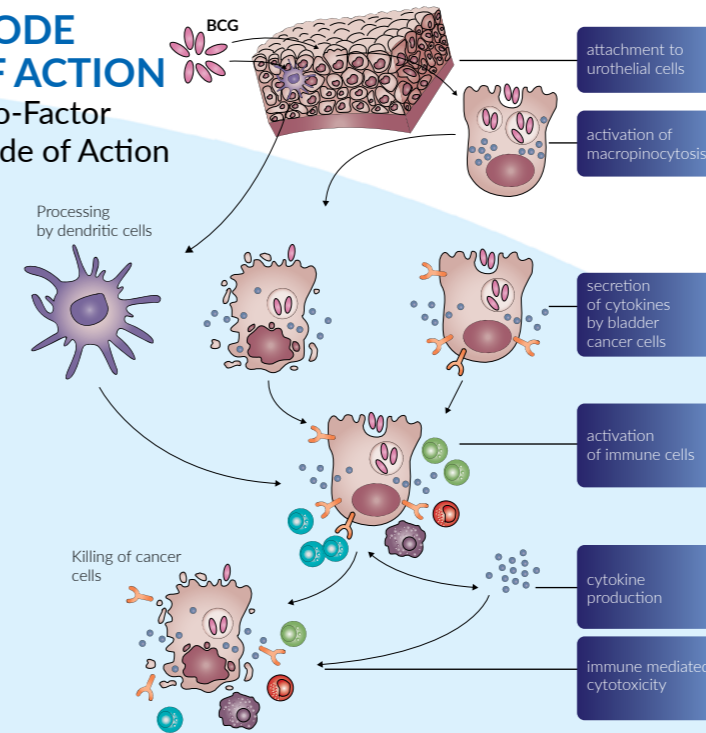
- Treatment of superficial epithelial non-invasive bladder tumours.
- The 50 mg dose may be used in the event of recurrent adverse reactions (dysuria, increased body temperature) or increased tuberculin reaction.

DISORDER PROFILE

1. About half a million new cases are recognised worldwide each year, of which 200,000 are fatal
2. The incidence is 15/100,000 among men and 3/100,000 among women¹
3. About 5% increase in bladder cancer incidence each year
4. BCG immunotherapy is a standard treatment in Ta, Tis, T1 bladder cancer, which is about 30% of all bladder neoplasms¹
5. Complete cure rate following BCG immunotherapy is 82%²

MODE OF ACTION

Two-Factor Mode of Action



Model of BCG mechanism of action in bladder cancer³

BENEFITS OF THERAPY

- Complete cure rate up to 82%¹
- Higher efficacy of BCG immunotherapy than intravesical chemotherapy in preventing recurrence
- Progression-free survival in patients undergoing BCG therapy is twice as long as in the untreated group¹

SAFETY PROFILE

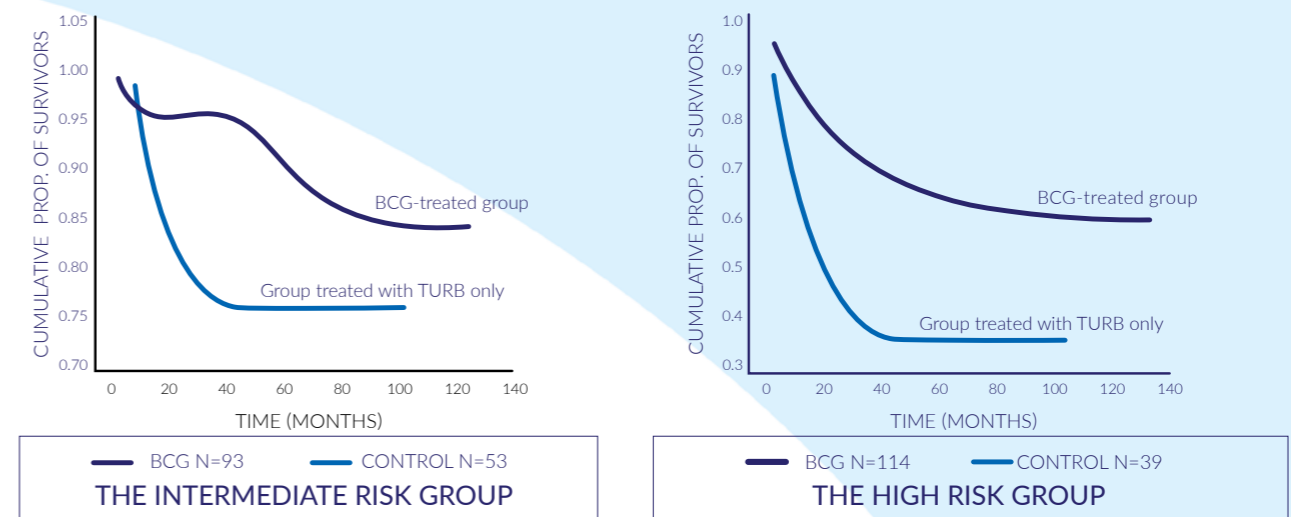
- Provision of the highest European Union standards concerning production of biotech drugs
- The Brazilian Moreau substrain, unique, very safe and efficient strain of live, attenuated BCG (Bacillus Calmette-Guerin)

PRODUCT PROFILE OVERVIEW

ACTIVE INGREDIENT	freeze-dried suspension of live attenuated BCG bacilli, the Brazilian Moreau substrain
PHARMACEUTICAL FORM	powder and solvent for intravesical suspension
DOSAGE/ADMINISTRATION	INITIAL DOSE: 1 INFUSION A WEEK FOR 6 WEEKS MAINTENANCE DOSE: AFTER 3, 6, 12, 18, 24 MONTHS OF THE INITIAL DOSE 1 INFUSION A WEEK FOR 3 WEEKS
PACKAGING	1 ampoule with powder and 1 ampoule with solvent
STORAGE CONDITIONS	at 2°C-8°C (in the refrigerator). Protect from light
SHELF LIFE	2 years 2-YEAR SHELF LIFE

CLINICAL EFFICACY

Efficacy of BCG immunotherapy in preventing bladder cancer progression



Kołodziej A. et al. - 299 subjects / mean follow-up 56 months¹

Much higher proportion of subjects free of cancer progression following BCG therapy.

¹New infections with 1 of 4 STIs: chlamydia, gonorrhoea, syphilis and trichomoniasis ²Herpes simplex virus

ADVANTAGES

- Safety and efficacy of BCG therapy
- Many years of experience in the treatment of superficial bladder cancers
- Cost of therapy is two times lower than that of chemotherapy
- Very safe and efficient strain of live, attenuated BCG bacilli - the **Brazilian Moreau substrain**

Onko BCG®

AUTHORISED PHARMACEUTICAL FORM

- **Onko BCG® 100**

**1 ampoule with powder 100 mg
and 1 ampoule with solvent 1 ml**

Live, attenuated Bacillus Calmette-Guerin, Brazilian BCG Moreau substrain - 100 mg. 1 ampoule or 1 vial of Onko BCG 100 contains not less than 300 million of live BCG.

- **Onko BCG® 50**

**1 ampoule with powder 50 mg
and 1 ampoule with solvent 1 ml**

Live, attenuated Bacillus Calmette-Guerin, Brazilian BCG Moreau substrain - 50 mg. 1 ampoule or 1 vial of Onko BCG 50 contains not less than 150 million of live BCG.

REFERENCES:

1. A.Kolodziej, 2007, „BCG immunotherapy of bladder cancer”.
2. Donald L. Lamm, Dale R. Riggs, Clinical Immunotherapeutics , 1994 pp 331-341, „Immunotherapy of Superficial Bladder Cancer”.
3. Gil Redelman-Sidi, Michael S Glickman, Bernard H. Bochner, Published 2014 in Nature Reviews Urology, DOI:10.1038/nrurol.2014.15

QR code of SPC Onko BCG is an integral part of the promotional material of BCG Onko 9/2023

