



Effective and less
distressing side effects

IMMUCOTHEL® – effective and less distressing side effects

IMMUCOTHEL® is approved as immunotherapy for the prevention of superficial recurrence of bladder cancer [Tis, Ta-T1 (G1-G3)] after transurethral resection.

Alternative for BCG failure

IMMUCOTHEL® is particularly recommended in case of BCG failure or BCG intolerance. These include severe side effects due to BCG. IMMUCOTHEL® may provide an alternative to radical cystectomy in patients where the risk, morbidity and limitations on quality of life outweigh the benefits.^[1]

Questions on presensitization

Pre-sensitization should take place around the time of the TUR. If no positive skin reaction occurs, the presensitization should be repeated. According to a recent study, it is recommended to start instillation after 4 days, even if no reaction is present.^[2] A not insignificant percentage shows no reaction, whereas non-occurrence does not allow a prognosis regarding the response to IMMUCOTHEL®.^[2]

Additional information for KLH/IMMUCOTHEL®:
www.biosyncorp.com, www.biosynpharma.com, www.biosyn.de

Pre-sensitization with IMMUCOTHEL® 1 mg

TUR

Therapy can be started before or during TUR^[3]

Apply 1 mg s.c. or i.c. in the forearm (positive skin reaction/DTH desired, but not required)

Instillation therapy with IMMUCOTHEL® 10 mg

1st–2nd
month

Initial therapy

20 ml (2 × IMMUCOTHEL® 10 mg) weekly in week 1–6

3rd–12th
month

Maintenance therapy

20 ml (2 × IMMUCOTHEL® 10 mg) monthly

[1] Babjuk M et al. Eur Urol. 2017 Mar; 71(3): 447-61. [EAU Guidelines on Non-Muscle-invasive Urothelial Carcinoma of the Bladder: Update 2016](#).

[2] Lammers RJ et al. J Clin Oncol. 2012 Jun 20; 30(18): 2273-9. [Intracutaneous and intravesical immunotherapy with keyhole limpet hemocyanin compared with intravesical mitomycin in patients with non-muscle-invasive bladder cancer: results from a prospective randomized phase III trial](#).

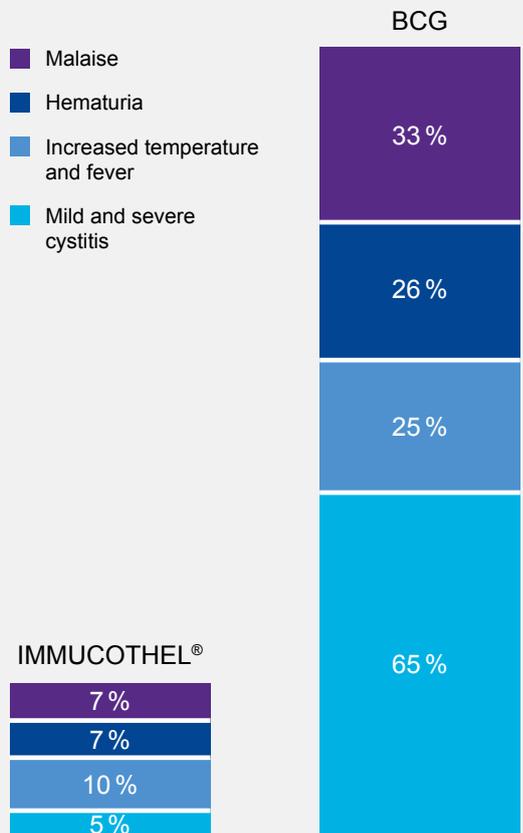
[3] [Summary of product characteristics IMMUCOTHEL®](#), biosyn Arzneimittel GmbH, May 2017.

IMMUCOTHEL® 1 mg, powder for solution for injection/IMMUCOTHEL® 10 mg, powder for solution for intravesical use

Active ingredient: Immunocyanin. **Indications:** Prevention of bladder carcinoma recurrence after transurethral resection and after failure of established therapies for this indication. **Composition:** IMMUCOTHEL® 1 mg: 1 vial with 54.63 mg powder for injections contains 1 mg biotechnically obtained, chromatographically uniform, molecularly standardized immunocyanin. Each vial is accompanied by 1 ampoule with 1 ml solvent. IMMUCOTHEL® 10 mg: 1 vial with 546.3 mg powder for intravesical instillations contains 10 mg of biotechnically obtained, chromatographically uniform, molecularly standardized immunocyanin. Each vial is accompanied by 1 ampoule with 10 ml solvent. **Excipients:** Powder: Glycine, sodium hydroxide, sodium chloride, sucrose. Solvent: Water for injections. **Contra-indications:** Immunosuppression. Known hypersensitivity to proteins foreign to the body. **Undesirable effects:** *Hepatobiliary disorders:* Rare (≥ 1/10,000 to < 1/1,000): increase of γ-glutamyl transferase and of glutamate pyruvate transaminase. *Renal and urinary disorders:* Rare (≥ 1/10,000 to < 1/1,000): Urgency, feeling of pressure or pain. Not known (cannot be estimated from the available data): Allergic reactions of the bladder manifesting as sterile leukocyturia. *General disorders and administration site conditions:* Uncommon (≥ 1/1,000 to < 1/100): Subfebrile temperatures are sometimes reported but are reversible after 3 days. **Interactions:** Specific interactions were not observed. The immunostimulating effect of IMMUCOTHEL® may be impaired by concurrent immunosuppressive radio- or chemotherapy or by simultaneous administration of corticosteroids. **Packages:** IMMUCOTHEL® 1 mg/10 mg: 1 vial of 1 mg/10 mg immunocyanin and 1 ampoule with 1 ml/10 ml solvent. Subject to prescription

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Minor side effect spectrum for IMMUCOTHEL® compared to BCG



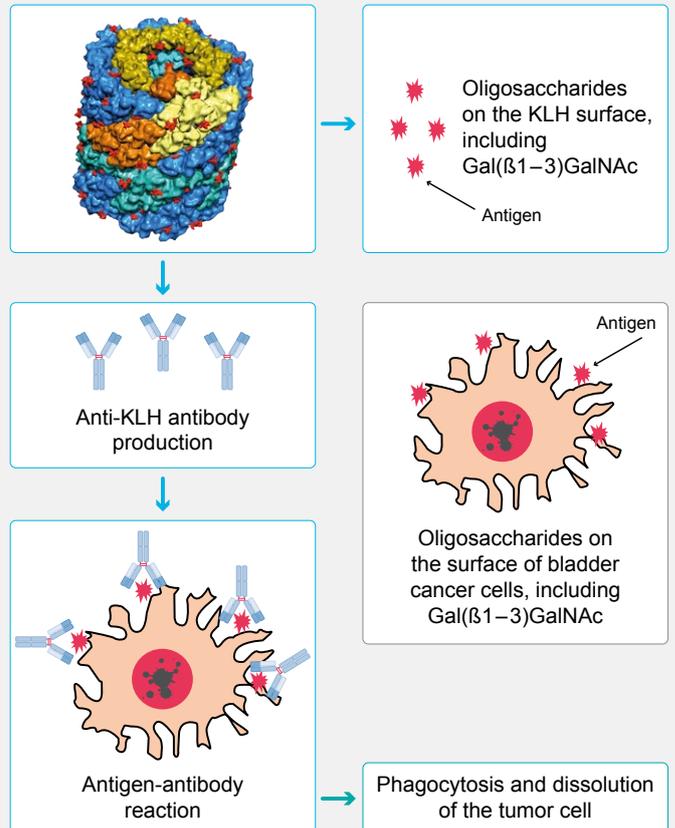
Modified according to:

Kälble T et al. Urologe A. 1991 Mar; 30(2): 118-21. [[Intravesical prevention of recurrence of superficial urinary bladder cancer with BCG and KLH. A prospective randomized study.](#)]

Jurincic-Winkler C et al. Anticancer Res. 1995 Nov-Dec; 15(6B): 2771-6. [[Effect of keyhole limpet hemocyanin \(KLH\) and bacillus Calmette-Guérin \(BCG\) instillation on carcinoma in situ of the urinary bladder.](#)]

Lamm DL. J Urol. Urognäkol 2003; 10(2): 18-21. [[Laboratory and clinical experience with keyhole limpet hemocyanin \(IMMUCOTHEL®\) in superficial bladder cancer.](#)]

KLH antibodies can recognize and destroy bladder carcinoma cells



Modified according to:

Wirguin I et al. Cancer Immunol Immunother. 1995 May; 40(5): 307-10. [[Keyhole limpet hemocyanin contains Gal\(beta 1-3\)-GalNAc determinants that are cross-reactive with the T antigen.](#)]

Yokoyama M et al. Hinyokika Kyo. 1988 Feb; 34(2): 255-8. [[Thomsen-Friedenreich antigen in bladder cancer tissues detected by monoclonal antibody.](#)]

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