

IMMUCOTHEL®

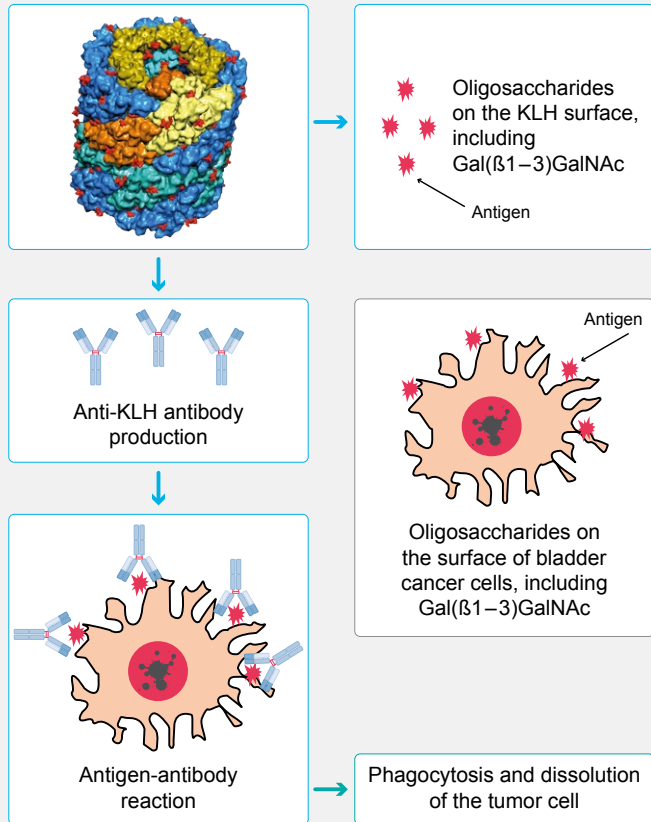
Effective and less distressing side effects

IMMUCOTHEL®

Therapy scheme for superficial urinary bladder carcinoma



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.](#)

Yokoyama M et al. [Hinyokika Kyo. 1988 Feb; 34\(2\): 255-8.](#)

we are
research



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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 ($\geq 1/10,000$ to $< 1/1,000$): increase of γ -glutamyl transferase and of glutamate pyruvate transaminase. **Renal and urinary disorders:** Rare ($\geq 1/10,000$ 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 ($\geq 1/1,000$ 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 03/15e

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IMMUCOTHEL®

Therapy scheme for superficial urinary bladder carcinoma



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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]

Pre-sensitization with IMMUCOTHEL® 1 mg

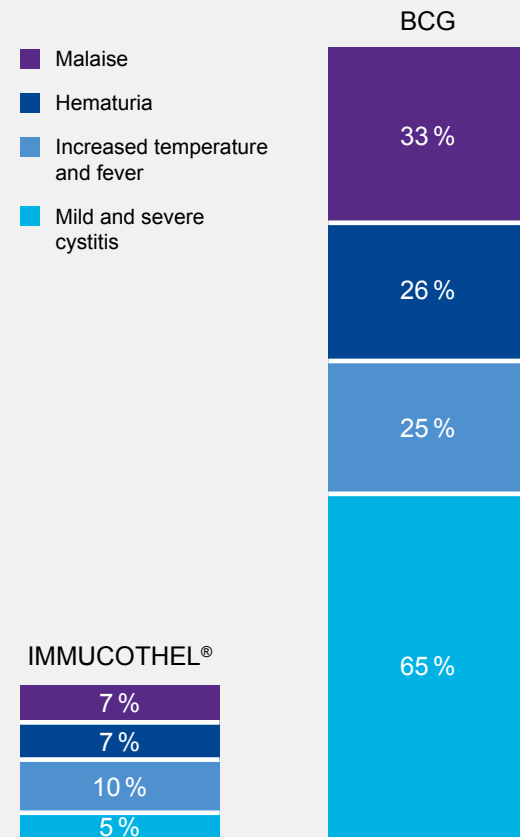
TUR	Therapy can be started before or during TUR ^[3]
	Apply 1 mg s.c. or i.c. in the forearm (positive skin reaction/ DTH desired, but not required)

Instillation therapy with IMMUCOTHEL® 10 mg

1 st – 2 nd month	Initial therapy
	20 ml (2 × IMMUCOTHEL® 10 mg) weekly in week 1–6
3 rd – 12 th month	Maintenance therapy
	20 ml (2 × IMMUCOTHEL® 10 mg) monthly

- [1] Babjuk M et al. *Eur Urol.* 2017 Mar; 71(3): 447-61.
[2] Lammers RJ et al. *J Clin Oncol.* 2012 Jun 20; 30(18): 2273-9.
[3] *Summary of product characteristics IMMUCOTHEL®*, biosyn Arzneimittel GmbH, May 2017.

Minor side effect spectrum for IMMUCOTHEL® compared to BCG



Modified according to:
Kälble T et al. *Urologe A.* 1991 Mar; 30(2): 118-21.
Jurincic-Winkler C et al. *Anticancer Res.* 1995 Nov-Dec; 15(6B): 2771-6.
Lamm DL. *J Urol. Urogyňn kol* 2003; 10(2): 18-21.