IMMUCOTHEL® – for recurrence prevention of superficial urinary bladder carcinomas

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Comparison of therapies for superficial urinary bladder carcinomas

	IMMUCOTHEL®[1]	BCG[2, 3]	Mitomycin C[4]
Type of therapy	Immunotherapy	Immunotherapy	Cytostatic agent
Field of application (bold print = recommended)	Ta, T1G1, T1G2, carcinoma in situ (CIS), at failure or contraindication of BCG	Ta (**TaG3**), T1G1, **T1G2, T1G3, CIS**	**Ta, T1G1,** T1G2, CIS
Exclusion criteria	• Hypersensitivity to the active ingredient • Well-known general hypersensitivity to exogenous proteins	• TUR within the last 2 weeks • Traumatic catheter examination • Macroscopic hematuria • Urethral stenosis • Active tuberculosis • Prior BCG sepsis • Immunosuppression • Urinary tract infection	• Hypersensitivity to mitomycin C • In case of pancytopenia, leukopenia or thrombocytopenia • Hemorrhagic diathesis • Acute infections • Bladder wall perforation
Probability of recurrence	30 %	24 %	34 %
Five years free of disease	17 %	37 %	9 %
Rate of progression	10 %	10 %	14 %
Side effects (cystitis)	5 %	54 %	40 %
Allergic reaction	0 %	2 %	5 %
Therapy failure rate	1 %	20 %	17 %
Handling	• **No special personal protection required** • **Simple handling**	• Closed instillation system required • Re-suspension under aseptic conditions • Skin contact with BCG must be avoided • The use of gloves is recommended	• Closed instillation system required • Gloves, protective mask, protective clothing • Air exhaust if possible • Essential to avoid contact with skin and mucosa
Disposal	Residual waste	Infectious waste	Cytotoxic waste (transport of hazardous goods)

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A brief overview of the most important facts

- IMMUCOTHEL® is approved for the prevention of recurrent superficial bladder carcinoma (Tis, Ta-T1 (G1-G3)) after transurethral resection as immunotherapy for recurrence prevention.
- IMMUCOTHEL® is reimbursable as a second-line therapy after standard therapy (yellow Box/RE2).
- The standard therapy with a cytostatic agent or BCG cannot be used for all patients. Side effects, intolerances, or limited availability (BCG) often present limiting factors.
- IMMUCOTHEL® is available as a well-tolerated instillation therapy effective as an immunotherapy for recurrence prevention of superficial urinary bladder carcinomas. Patients appreciate the advantage of the comparable effectiveness over chemo- or immunotherapy of BCG with significantly fewer side effects
- In contrast to cytostatic agents and BCG, IMMUCOTHEL® can be prepared in ready-to-use form without special personal or product protection.
- The substance can be disposed of along with normal medical practice waste and does not fall under the cytostatic agent/CMR substance ordinance; this is a logistical advantage in daily medical practice routine.
- Additional information for KLH / IMMUCOTHEL®: www.biosyncorp.com

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 03/15 e
Marketing authorization holder: biosyn Arzneimittel GmbH, Schorndorfer Strasse 32, 70734 Fellbach, Germany, Tel. +49 711 575 32-00, Fax +49 711 575 32-99, E-Mail: info@biosyn.de, www.biosyn.de

Sources

[1] Fachinformation IMMUCOTHEL® 10 mg Trockensubstanz mit Lösungsmittel, biosyn Arzneimittel GmbH, April 2007

[2] Fachinformation BCG-medac Pulver und Lösungsmittel zur Herstellung einer Suspension zur intravesikalen Anwendung, medac GmbH, August 2014

[3] Babjuk M, Burger M, Zigeuner R, Shariat SF, van Rhijn BW, Compérat E, Sylvester RJ, Kaasinen E, Böhle A, Palou Redorta J, Rouprêt M; European Association of Urology. Eur Urol. 2013 Oct;64(4):639-53. doi: 10.1016/j.eururo.2013.06.003. EAU guidelines on non-muscle-invasive urothelial carcinoma of the bladder: update 2013.

[4] Fachinformation Mito-medac®, medac GmbH, Oktober 2009

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