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[3, 4]
Type of therapy	Immunotherapy	Immunotherapy	Cytostatic agent
Field of application (bold print = recommended)	Ta-T1 (G1-G3), carcinoma in situ (CIS), at failure or contraindication of BCG	Ta (**TaG3**), **T1G1, T1G2, T1G3, CIS**	Recurrence prevention in adult patients with superficial urinary bladder carcinoma after transurethral resection **not recommended for high-risk tumors**
Exclusion criteria	• Hypersensitivity to the active ingredient • Well-known general hypersensitivity to exogenous proteins	• Hypersensitivity to the active ingredient • Immunosuppression • Active tuberculosis • Bladder radiotherapy • Breastfeeding • TUR, bladder biopsy or traumatic catheter examination within the last 2–3 weeks • Bladder perforation • Acute infection of urinary tract	• Hypersensitivity to mitomycin C • Breastfeeding • Cystitis • Bladder wall perforation
Probability of recurrence[5]	30 %	24 %	34 %
Five years free of disease[5]	17 %	37 %	9 %
Rate of progression[5]	10 %	10 %	14 %
Side effects (cystitis)[5]	5 %	54 %	40 %
Allergic reaction[5]	0 %	2 %	5 %
Therapy failure rate[5]	1 %	20 %	17 %
Handling	• **No special personal or product 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)

IMMUCOTHEL®

Effective and less distressing side effects

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Summary of the most important aspects

IMMUCOTHEL® is approved as immunotherapy for the prevention of recurrent superficial bladder carcinoma (Tis, Ta-T1 (G1-G3)) after transurethral resection

IMMUCOTHEL® is approved for high-risk tumors as second-line treatment or in the event of failure or contraindication of BCG

Patients appreciate the advantage of comparable effectiveness with significantly fewer side effects compared to BCG therapy

IMMUCOTHEL® can be combined with one immediate instillation of chemotherapy, mostly Mitomycin C, as recommended in the EAU Guidelines

Standard therapy with a cytostatic agent or BCG cannot be used in all patients. Side effects, intolerances, or limited availability (BCG) can present limiting factors

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, www.biosynpharma.com, www.biosyn.de

biosyn Arzneimittel GmbH
Schorndorfer Straße 32
70734 Fellbach, Germany
Tel.: +49 711 575 32-00

information@biosyn.de
www.biosyncorp.com
www.biosynpharma.com
www.biosyn.de

More information about us on our Facebook page, our Twitter and YouTube channel

Literature

[1] Summary of product characteristics IMMUCOTHEL®, biosyn Arzneimittel GmbH, May 2017.

[2] Summary of product characteristics BCG-medac Pulver und Lösungsmittel zur Herstellung einer Suspension zur intravesikalen Anwendung, medac GmbH, September 2015.

[3] 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.

[4] Summary of product characteristics mito-medac® 20 mg Pulver und Lösungsmittel zur Herstellung einer Lösung zur intravesikalen Anwendung, medac GmbH, April 2018.

[5] Detailed list of the literature in "IMMUCOTHEL® for recurrence prevention of superficial urinary bladder carcinomas" at www.biosynpharma.com/oncology/hemocyanine-klh-bladder-cancer

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 Str. 32, 70734 Fellbach, Germany, Tel. +49 711 575 32-00, Fax +49 711 575 32-99, e-mail: info@biosyn.de, www.biosyn.de