<table>
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<tbody>
<tr>
<td><strong>Type of therapy</strong></td>
<td>Immunotherapy</td>
<td>Immunotherapy</td>
<td>Cytostatic agent</td>
</tr>
<tr>
<td><strong>Field of application</strong></td>
<td>Ta-T1 (G1-G3), carcinoma in situ (CIS), at failure or contraindication of BCG</td>
<td>Ta (TaG3), T1G1, T1G2, T1G3, CIS</td>
<td>Recurrence prevention in adult patients with superficial urinary bladder carcinoma after transurethral resection not recommended for high-risk tumors</td>
</tr>
</tbody>
</table>
| **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) |
**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](http://www.biosyncorp.com), [www.biosynpharma.com](http://www.biosynpharma.com), [www.biosyn.de](http://www.biosyn.de)

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**Literature**


