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<tbody>
<tr>
<td>Type of therapy</td>
<td>Immunotherapy</td>
<td>Immunotherapy</td>
<td>Cytostatic agent</td>
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<tr>
<td>Field of application (bold print = recommended)</td>
<td>Ta, T1G1, T1G2, carcinoma in situ (CIS), at failure or contraindication of BCG</td>
<td>Ta (TaG3), T1G1, T1G2, T1G3, CIS</td>
<td>Ta, T1G1, T1G2, CIS</td>
</tr>
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| 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 disease 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) |
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