OncoTICE® powder for instillation fluid for intravesical use containing 2-8 x 10^8 CFU Tice BCG

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION

OncoTICE® BCG 12.5mg equivalent to 2-8 x 10^8 CFU. Powder for intravesical instillation. Reconstitute before use.

USES

Treatment of primary or concurrent carcinoma-in-situ of the urinary bladder and for the prevention of recurrence of high grade and/or relapsing superficial papillary transitional cell carcinoma of the urinary bladder Stage Ta (grade 2 or 3) or T1 (grade 1,2 or 3) after transurethral resection (TUR). OncoTICE is only recommended for stage Ta grade 1 papillary tumours, when there is judged to be a high risk of tumour recurrence.

DOSAGE AND ADMINISTRATION

Adults and the elderly: Instill the contents of one reconstituted and diluted vial into the urinary bladder.
Induction treatment: Weekly instillation during the first 6 weeks. Begin treatment 10 to 15 days after TUR. Do not start treatment until mucosal lesions after TUR have healed. Delay treatment in cases of gross haematuria or major bladder irritability.
Maintenance treatment: Weekly instillation during 3 consecutive weeks at months 3, 6 and 12 after initiation of treatment. Evaluate the need for maintenance treatment every 6 months beyond the first year of treatment on the basis of tumour classification and clinical response.
Paediatric population: No data available.

CONTRAINDICATIONS

Gross haematuria (in these cases therapy should be stopped or postponed until the haematuria has been successfully treated or resolved); impaired immune response (irrespective of whether this impairment is congenital or caused by disease, drugs or other therapy); in patients with a positive Tuberculin test, instillations are contra-indicated if there is supplementary medical evidence for an active tuberculous infection. OncoTICE is contraindicated during treatment with anti-tuberculosis drugs like streptomycin, para-amino-salicylic acid (PAS), isoniazid (INH), rifampicin and ethambutol.
Urinary tract infections; interrupt therapy until the bacterial culture from urine becomes negative and therapy with antibiotics and/or urinary antiseptics is stopped.
Positive HIV serology.
Pregnancy and lactation.

PRECAUTIONS

A Tuberculin test (PPD) should be performed before the first instillation. Do not administer intravenously, subcutaneously or intramuscularly. Reconstitution and preparation of the suspension for instillation and administration should be performed under aseptic conditions. Any spillage should be treated with tuberculocidal disinfectant and waste must be handled as biohazard material. If self-inoculation is suspected, PPD testing is advised at the time of the accident and six weeks later.
Traumatic catheterisation or other injuries to the urethra or bladder mucosa can promote systemic BCG infection. Delay administration in such patients until mucosal damage has healed.
Screen patients with known HIV risk factors prior to therapy. Patients should be monitored for the presence of systemic BCG infection and signs of toxicity during treatment. To protect the partner intercourse is not recommended for one week after treatment (or a condom should be used). The use of OncoTICE may sensitise patients to tuberculin resulting in a positive reaction to PPD.

Drug interactions:
Tice BCG is sensitive to most antibiotics, particularly anti-tuberculosis drugs streptomycin, para-amino salicylic acid (PAS), isoniazid (INH), rifampicin and ethambutol. Postpone therapy until the end of antibiotic treatment. Immunosuppressants and/or bone marrow depressants and/or radiation should not be used in combination with OncoTICE.

SIDE EFFECTS – Refer to SmPC for complete information on side effects.
Very common side effects: Cystitis or bladder irritation such as dysuria, pollakiuria and haematuria. The cystitis and inflammatory reactions (granulomas) may be an essential part of the antitumour activity. In most cases the symptoms disappear within two days and the cystitis does not require treatment. If symptoms are severe isoniazid (300 mg daily) and analgesics can be given until the symptoms resolve. Malaise, a low to medium grade fever and/or flu-like symptoms which may accompany the localised irritative toxicities that often reflect hypersensitivity reactions have been commonly observed. Treat symptomatically. Symptoms usually appear within 4 hours of administration and last for 24 - 48 hours. Fever above 39°C that does not resolve within 12 hours despite antipyretic therapy must be considered as systemic BCG-infection. This may be manifested by pneumonitis, hepatitis, cytopenia, vasculitis, infective aneurysm and/or sepsis after fever and malaise during which symptoms progressively increase. Patients should be treated with anti-tuberculosis drugs. Further treatment with Tice BCG is contraindicated.
Common side effects: arthralgia, arthritis, myalgia, nausea, vomiting, abdominal pain, diarrhoea, pneumonitis, anaemia, urinary incontinence, micturition urgency, urinary tract infection, abnormal urine analysis, rigors.
Uncommon side effects: Skin rash, hepatitis, increase in hepatic enzymes, pancytopenia, thrombocytopenia, pyuria, bladder constriction, uretic obstruction and urinary retention. **Rare and very rare side effects:** Reiter's syndrome, lymphadenopathy, anorexia, hypotension, bronchitis, dyspnoea, acute renal failure, chest pain, peripheral oedema and increase in prostatic specific antigen (PSA).

OVERDOSE
Patients should be closely monitored for signs of systemic BCG infection and if necessary treated with anti-tuberculosis drugs.

PACKAGE QUANTITIES AND BASIC NHS COST
1 x 2ml glass vial £71.61

Marketing Authorisation Number
PL 53095/0003

Marketing Authorisation Holder
Merck Sharp & Dohme (UK) Limited
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