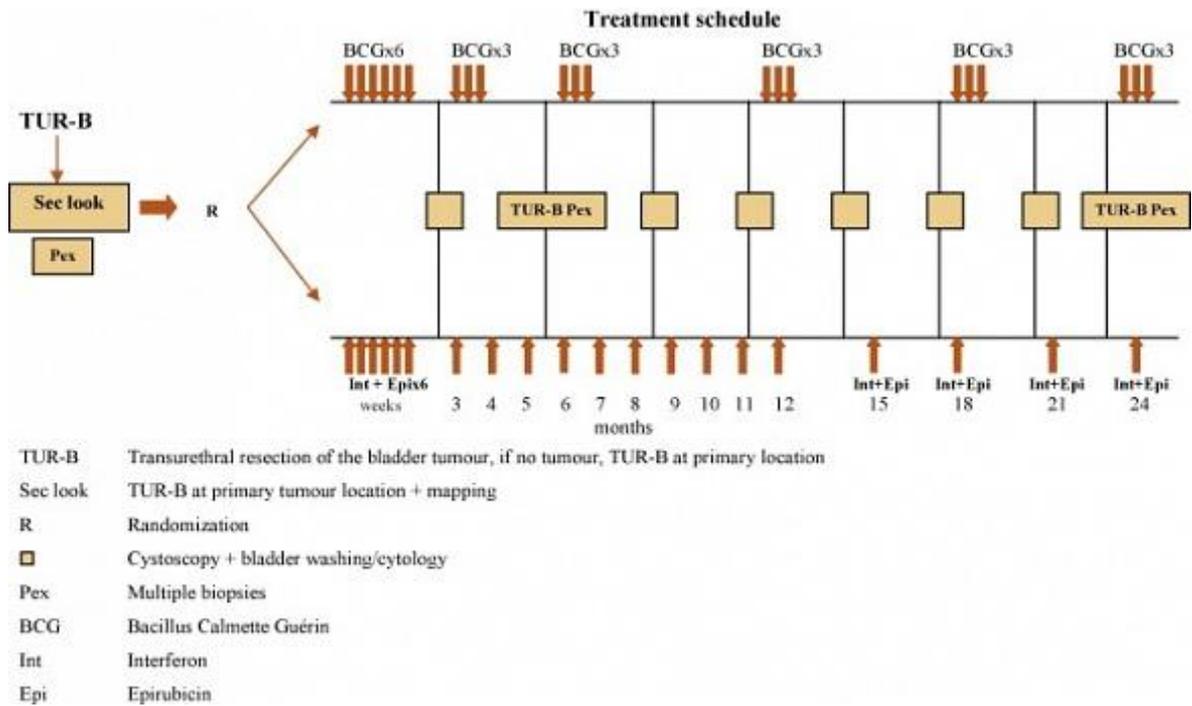




الشركة العامة لتسويق الادوية  
 والمستلزمات الطبية  
 قسم العلاقات العامة  
 لجنة التعليم الطبي المستمر  
 الشعبة العلمية / ٢٠١٥

## BCG (Bacillus calmette- Guerin) Bladder instillation



(كانون الاول / ٢٠١٥)

### **Qualitative and quantitative composition :**

BCG 12.5mg per vial containing  $2-8 \times 10^8$  CFU Tice BCG.

After reconstitution in 50 ml saline the suspension contains  $0.4-1.6 \times 10^7$  CFU/ml.

BCG is a freeze-dried preparation containing attenuated bacilli of *Mycobacterium bovis*, prepared from a culture of *Bacillus Calmette-Guérin* (BCG). For excipients

### **Pharmaceutical form :**

Powder for instillation fluid for intravesical use.

**Action And Clinical Pharmacology:** The precise mechanism of BCG, [*Bacillus Calmette-Guérin* (BCG), strain TICE], antitumor action is unknown; however, it appears to exert a variety of actions. BCG induces a granulomatous reaction at the local site of administration. Activated histiocytes responding to the BCG are able to kill tumor cells. BCG acts as both a specific and a nonspecific immunopotentiating agent and is able to stimulate, either directly or indirectly, a whole range of immune responses.

### **Therapeutic indications:**

BCG is indicated for 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.

BCG is only recommended for stage Ta grade 1 papillary tumours, when there is judged to be a high risk of tumour recurrence

### **Dosage:**

#### **Adults and the elderly /**

The contents of one vial of BCG, reconstituted and diluted as indicated, are instilled into the urinary bladder.

Induction treatment

Weekly instillation with BCG during the first 6 weeks.

When used as an adjuvant therapy after TUR of a superficial urothelial cell carcinoma of the bladder (see "Therapeutic indications"), treatment with BCG should be started between 10 and 15 days after performing the TUR. Treatment should not be started until mucosal lesions after TUR have healed. Treatment should also be delayed in cases of gross haematuria or major bladder irritability.

#### **Maintenance treatment :**

Maintenance treatment consists of weekly instillation with BCG during 3 consecutive weeks at months 3, 6, and 12 after initiation of the treatment. The need for maintenance treatment every 6 months beyond the first year of treatment should be evaluated on the basis of tumour classification and clinical response.

#### **Children /**

Not recommended.

### ***Intravesical instillation /***

Insert a catheter via the urethra into the bladder and drain the bladder completely. Connect the 50ml syringe containing the prepared BCG suspension to the catheter, and instil the suspension into the bladder. After instillation, remove the catheter. The instilled BCG suspension must remain in the bladder for a period of 2 hours. During this period care should be taken that the instilled BCG suspension has sufficient contact with the whole mucosal surface of the bladder. Therefore the patient should not be immobilised or, in case of a bed-ridden patient, should be turned over from back to

abdomen and vice versa every 15 minutes. After two hours, have the patient void the instilled suspension in a sitting position.

Urine should be voided in a sitting position for 6 hours after treatment and two cups of household bleach should be added to the toilet before flushing. The bleach and urine should be left to stand in the toilet for 15 minutes before flushing.

NOTE: The patient must not ingest any fluid for a period starting 4 hours prior to instillation, until bladder evacuation is permitted (i.e. 2 hours after instillation).

### **Pregnancy and lactation:**

BCG instillation for carcinoma of the bladder is contraindicated during pregnancy and lactation

### **Side effects:**

#### **Very common :**

Renal and urinary disorders	Cystitis, dysuria, pollakiuria, haematuria
General disorders and administration site conditions	Influenza-like illness, pyrexia, malaise, fatigue

#### **Common :**

Infections and infestations	Urinary tract infection
Blood and lymphatic system disorders	Anaemia
Respiratory, thoracic and mediastinal disorders	Pneumonitis
Gastrointestinal disorders	Abdominal pain, nausea, vomiting, diarrhoea
Musculoskeletal and connective tissue disorders	Arthralgia, arthritis, myalgia
Renal and urinary disorders	Urinary incontinence, micturition urgency, urine analysis abnormal
General disorders and administration site conditions	Rigors

#### **Uncommon:**

Infections and infestations	Tuberculous infections <sup>1</sup>
Blood and lymphatic system disorders	Pancytopenia, thrombocytopenia
Hepatobiliary disorders	Hepatitis
Skin and subcutaneous tissue disorders	Rashes, eruptions and exanthems NEC <sup>1</sup>
Renal and urinary disorders	Bladder constriction, pyuria, urinary retention, ureteric obstruction

#### **Rare :**

Respiratory, thoracic and mediastinal disorders	Cough
Reproductive system and breast disorders	Epididymitis

## Questions for (CME):

- 1- BCG is Freeze-dried preparation containing \_\_\_\_\_.
- 2- BCG induces agranulomatous reaction at the local sit of administration (T or F).
- 3- BCG acts as nonspecific immunopotentiating agent and is able to stimulate indirectly a whole range of immune responses (T or F).
- 4- Treatment of BCG should be delayed in cases of \_\_\_\_\_.
- 5- Maintenance treatment of BCG consists of \_\_\_\_\_.
- 6- BCG is recommended for Children (T or F).
- 7- a Very common Side effects of BCG are A \_\_\_\_\_ wich is \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_  
B \_\_\_\_\_ wich is \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_