Manufactured Products
World Class Products. World Class Care.

BACK
Printer Friendly

Anticancer

SII®OncoBCG®

BACILLUS CALMETTE-GUERIN (BCG) VACCINE (LYOPHILISED)

SII®OncoBCG®

DESCRIPTION
SII-ONCO-BCG (Bacillus Calmette-Guerin (BCG) Vaccine) for intravesical instillation is a live lyophilized preparation derived from attenuated strain of Mycobacterium bovis (Bacillus Calmette Guerin).

COMPOSITION
Each vial contains :

Bacillus Calmette-Guerin strain	40mg/ml
Between 1-8 x10^8 Colony Forming Units (CFU)	
Stabilizer	Sodium Glutamate 5%

Reconstitute each vial with 50 ml of sodium chloride injection.

INDICATIONS
Carcinoma in situ of Urinary bladder (CIS):
Induction treatment:
The treatment schedule includes weekly repeated instillation with SII-ONCO-BCG during the first 6 weeks.
Maintenance treatment:
Followed by induction treatment, periodic repeated instillations for a period of at least 12 months.
Adjunctive therapy after TUR (Trans-urethral resection) of superficial carcinoma of Urinary bladder:
Treatment should be started 10-15 days after performing TUR. The treatment schedule is- a weekly repeated instillation with the drug during first 6 weeks, followed by an instillation in the 8th week and 12th week and then monthly instillations for 4 months.
The duration of maintenance treatment should be evaluated on the basis of tumour classification and clinical diagnosis.

THERAPEUTIC INDICATIONS
For the treatment of flat urothelial cell carcinoma in situ of urinary bladder and as adjunctive therapy following transurethral resection of primary or relapsing superficial noninvasive papillary tumors that are limited to the bladder mucosa (stage Ta/T1- Grade 1,2 or3).

DOSAGE AND METHOD OF ADMINISTRATION
FOR INTRAVESICAL INSTILLATION.
The following procedures are recommended under aseptic precautions prior to use:

RECONSTITUTION
Add 1 ml of a sterile isotonic preservative free saline (0.9 % NaCl) by means of a sterile syringe to the contents of 1 vial of SII-ONCO-BCG and allow stand for a few minutes. Then gently swirl the vial until a homogenous suspension is obtained (caution: avoid forceful agitation). The above procedure may be repeated to reconstitute each subsequent vial/s used.

PREPARATION OF SOLUTION FOR INSTILLATION
Transfer the reconstituted suspension from the vial/s into a 50 ml syringe. Rinse the empty vial/s with 1 ml each of sterile isotonic saline. Add the rinse fluid to the reconstituted suspension in the 50 ml syringe. Finally dilute the contents of the 50 ml syringe (by adding sterile physiological saline solution) up to a total volume of 50 ml. Mix the suspension carefully. The suspension is now ready for use.

ADMINISTRATION
Insert a catheter by aseptic technique through urethra into bladder and drain completely. Attach the syringe containing the prepared solution to the catheter and instill in to the bladder. On completion of instillation, remove the catheter. The prepared SII-ONCO-BCG suspension should be retained in the bladder for 2 hours. Care should be taken that instilled suspension is in contact with the whole mucosal surface of the bladder. Once retained in the bladder for 2 hours, the patient should be made to void the instilled contents in a sitting position. The patient should not ingest any fluid 4 hours before and 2 hours after instillation. Ensure proper cleansing of genital area and hands.

DOSAGE
Per instillation, the content of SII-ONCO-BCG (80-120 mg) i.e. 2-3 vials reconstituted and diluted as indicated above for instillation into the urinary bladder.

ADVERSE EFFECTS
Adverse effects are generally mild and transient. They appear to be directly related to cumulated CFU count of BCG administered in various instillations. Common side effects are:

- Frequency, urgency of micturition and dysuria- these symptoms usually occur from 2nd or 3rd instillation onwards.
- Cystitis and typical granulomatous inflammatory reactions which occur in the mucosa of Urinary bladder may be an essential component of anti-tumour activity of the drug. The symptoms usually disappear within 2 days and do not require treatment. Cystitis may be more prolonged during maintenance treatment and if severe, Isoniazid 300 mg daily can be given with analgesics until symptoms disappear.
- Malaise and low-medium grade fever and/ or a flu like syndrome. These symptoms usually occur after 4 hours of instillation

and disappear within 24-48 hours.

RARE ADVERSE EFFECTS

- Fever more than 39°C. The fever resolves within 24-48 hours with antipyretics and fluids.
- Systemic BCG infections due to traumatic catheterization, perforation of bladder or early BCG instillation after extensive TUR which may be manifested by pneumonitis, hepatitis or cytopenia. Patients with such symptoms should be treated with tuberculostatic drugs as per treatment schedules used. Triple drug therapy with or without Cycloserine for some weeks should be used.
- Granulomatous Prostatitis.
- Arthritis, Arthralgia, Haematuria, Orchitis, Transient urethral obstruction, Epididymitis or bladder contraction may occur.

CONTRAINDICATIONS
Bacillus Calmette-Guerin (BCG) Vaccine for intravesical instillation carcinoma in situ of bladder should not be used in:
Impaired immune response irrespective of whether this impairment is congenital or caused by disease, drugs or other therapy.
Positive HIV serology.
Pregnancy and lactation.
Positive tuberculin reaction in conjunction with clinical evidence of existing active tuberculosis.
Urinary tract infections: treatment should be withheld till urine culture is negative and antibiotic therapy is stopped.
Trauma to urinary bladder.
A patient with fever needs careful evaluation before therapy is instituted.
Safety of the mode of therapy in pregnant women, nursing mothers and children has not been evaluated.
On going treatment with antitubercular treatment.

PRECAUTIONS

Bacillus Calmette-Guerin (BCG) Vaccine should not be administered intravenously, subcutaneously or intramuscularly.
The vaccine is not intended for immunisation.
The preparation contains live attenuated mycobacterium (BCG) and should be used with aseptic technique. All equipment, supplies and receptacles in contact with BCG should be handled and disposed off as biohazardous. Urine voided for 6 hours after instillation also needs to be properly disinfected.

SPECIAL PRECAUTIONS FOR USE

- Do not expose the vaccine to light before and after reconstitution. Use the vaccine immediately after reconstitution and discard unused portion.
- SII-ONCO-BCG should not be administered I.V., S.C., I.M.
- Reconstitution, preparation and administration should be performed under aseptic conditions.
- Before the first instillation Tuberculin test should be performed, in case positive, the drug is contraindicated only if there is an evidence of active tuberculosis infection.
- Delay treatment in-patients who experience traumatic catheterization till mucosal damage has healed.
- Adequate HIV assays are recommended in-patients who are at risk of HIV infection.
- It is recommended to refrain from intercourse for one week after instillation or use a condom.

INTERACTIONS
SII-ONCO-BCG is sensitive to most antibiotics specially to anti-tubercular drugs like Streptomycin, Isoniazid, Ethambutol, Rifampicin and PAS (Para-amino Salicylic Acid). It is not known whether interactions occur during intra-vesical instillation of SII-ONCO-BCG or whether the interactions result in clinically relevant reduction of multiplication activity of SII-ONCO-BCG. Hence, it is not clear whether activity of SII-ONCO-BCG is influenced by concomitant therapy with antibiotics. If a patient is receiving antibiotics treatment then intra-vesical instillation should be postponed till completion of antibiotics treatment (Also see the "Contraindications"). Studies on interaction with other drugs are not performed.

STORAGE
SII-ONCO-BCG should be stored in dark at 2° to 8°C. Do not expose the vaccine to light before and after reconstitution. Use immediately after reconstitution. Discard unused portion.

SHELF LIFE
SII-ONCO-BCG has a shelf life of 24 months provided it is stored in dark at 2° to 8°C and protected from light.

PRESENTATION
One carton containing 1 vial of SII-ONCO-BCG.

TOP