

Intravesical instillation of **abnobaVISCUM[®]** Fraxini 20 mg

In superficial bladder Cancer Ta G1/G2 and T1G1/G2

Induction Therapy:

The medication will be instilled into the urinary bladder **once weekly for 6 weeks**.

The induction therapy may start anytime. If possible start the therapy 2 weeks after TRUB ¹⁾ and a single 'early instillation' ²⁾ of Mitomycin, or Doxorubicin.

Maintenance Therapy:

Maintenance instillations should be added during the first year: **one instillation every 6 weeks**.

Instillation:

The medication for intravesical instillation (abnobaVISCUM Fraxini 20 mg) has to be prepared short before usage. Each ampoule of abnobaVISCUM Fraxini 20 mg contains 1 ml. **The quantity for one instillation is 45 ml = 900 mg** = 45 ampoules of abnobaVISCUM Fraxini 20 mg ³⁾.

After complete emptying of the bladder the instillation of 45 ml of abnobaVISCUM Fraxini 20 mg (respectively 900 mg) will be performed with a disposable catheter. AbnobaVISCUM should **retain for two hours** in the bladder. After min. 2 hours the bladder can be emptied by regular micturition

Side effects: Up to now the database is too weak to determinate any side effects.

It may be that: mild inflammation of the bladder and micro hematuria are connected to the procedure of cystoscopy. There is a strong hint that a temporary pyrexia is related to abnobaVISCUM.

CAVE: The dosage above might not be safe for patients already pretreated with mistletoe extracts (any application)! In case of significant intolerance a dose reduction to half of the dosage (22,5 ml) is recommended.

Instillation of abnobaVISCUM Fraxini 20 mg in the urinary bladder is an **off-label use** and in the sole responsibility of the treating physician!

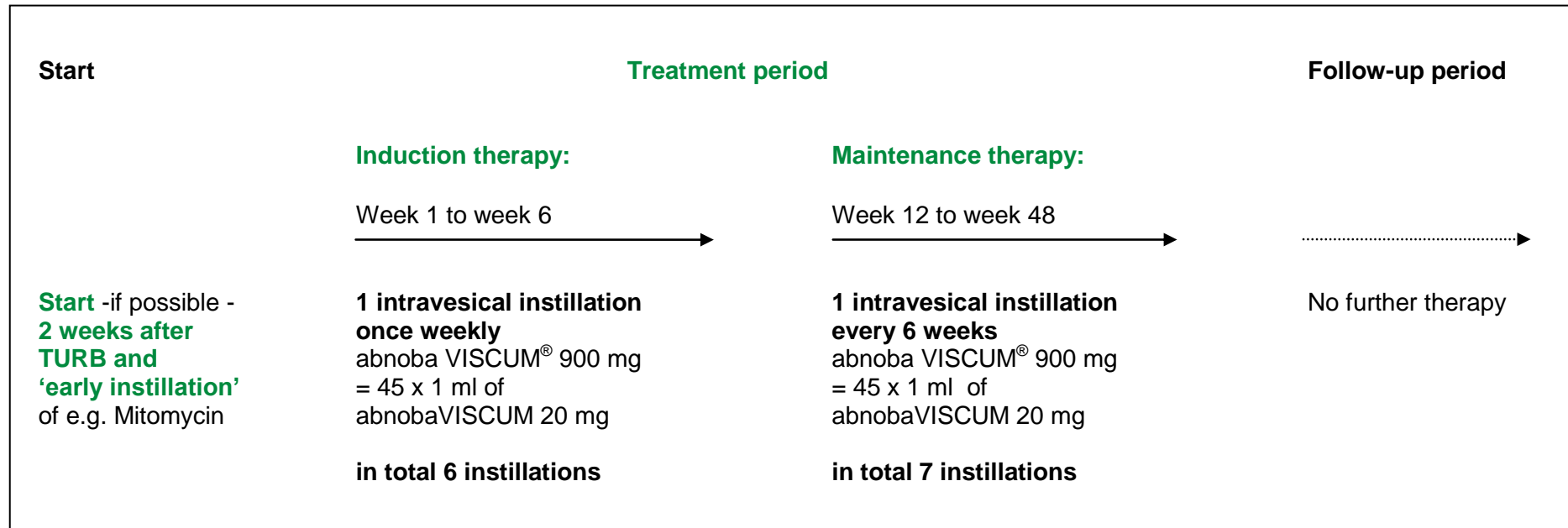
¹⁾ TURB: Transurethral resection of bladder cancer

²⁾ 'Early Instillation': one immediate intravesical instillation of chemotherapy after TURB significantly reduced the recurrence compared with TURB alone (Sylvester et al, 2004 and 2005)

³⁾ In a dose-escalation-phase-I/II-study a tolerable number of 45 ampoules (45 ml) for each instillation has been preliminarily determined in patients with superficial bladder cancer.

Schematic design of:

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Please don't hesitate to ask for further information.

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