4.7. Effects on ability to drive and use machines
Uro-Vaxom is presumed to be safe and unlikely to produce a sedative effect.

4.8. Undesirable effects
The overall incidence of undesirable effects in clinical trials lies around 4%.
Gastrointestinal troubles (diarrhea, nausea, abdominal pain), dermatologic reactions (pruritus, exanthema), as well as generalized problems (slight fever) are the most frequent complaints reported.
In case of cutaneous reactions or fever, the treatment should be interrupted as these may constitute allergic reactions.

4.9. Overdose
No case of overdose known up to now. Due to the nature of Uro-Vaxom and the results of toxicity tests performed in animals, an overdosage seems impossible to reach.

5. Pharmacological properties
ATC code: G04BX

5.1. Pharmacodynamic properties
Immunostimulating agent.
In animals, a protective effect against experimental infections, a stimulation of macrophages, B-lymphocytes and immunocompetent cells in the Peyer’s patches, as well as an increase in IgA level in intestinal secretions have been reported.
In humans, Uro-Vaxom stimulates T-lymphocytes, induces production of endogenous interferon and increases slgA level in urine.

5.2. Pharmacokinetic properties
No experimental model available up to now.

5.3. Preclinical safety data
Extensive toxicity studies have not revealed any toxic effect.
6. Pharmaceutical particulars

6.1. List of excipients
1 capsule contains:
Pregelatinized maize starch, magnesium stearate, propyl gallate (E 310), sodium glutamate, mannitol, gelatine, ferric oxides, titanium dioxide.

6.2. Incompatibilities
No known up to now.

6.3. Shelf life
The medication should not be used after the expiration date printed on the package together with the mention “EXP”.

6.4. Special precautions for storage
The medication should be stored protected from heat (below 30ºC).
Store in the original package.

6.5. Nature and contents of container
Boxes containing 3 or 9 blisters (aluminium/ PVDC - PVC/PVDC foils) of 10 capsules.

6.6. Instructions for use/handling
No special instructions.

7. Marketing authorization holder
OM PHARMA, 22, rue du Bois-du-Lan, P.O. Box 84, 1217 Meyrin 2/Geneva (Switzerland)