

Uro-Vaxom®

Composition

Active principle

1 capsule contains: 6 mg of lyophilized bacterial lysates of *Escherichia coli*.

Excipients

1 capsule contains: antiox. E310, glutamate, excipients for capsule.

Properties/Effects

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 secretory IgA level in urine.

Preclinical safety data

Extensive toxicity studies have not revealed any toxic effect.

Pharmacokinetics

No experimental model available up to now.

Indications/Possibilities of use

Immunotherapy. Prevention of recurrent lower urinary tract infections. Co-medication in the treatment of acute urinary tract infections.

Posology and method of administration

Preventive treatment and/or consolidation therapy: 1 capsule daily on an empty stomach, for 3 consecutive months.

Treatment during acute episodes: 1 capsule daily on an empty stomach as co-medication to conventional antimicrobial therapy, until disappearance of the symptoms but for at least 10 consecutive days.

Limitations for use

Contra-indications

Known hypersensitivity towards the constituents of Uro-Vaxom®.

Precautions

The efficacy and safety of Uro-Vaxom® have not been established in children below 4 years.

Effects on ability to drive and use machines

Uro-Vaxom® is presumed to be safe and unlikely to produce a sedative effect.

Pregnancy and lactation

Reproduction studies in animals have not demonstrated any risk to the fetus, but controlled studies in pregnant women are not available. As regards breast-feeding, no specific studies have been performed and no data have been reported up to now.

Undesirable effects

The global incidence of adverse effects observed in the clinical studies is approximately 4%. The adverse effects reported are classed below in accordance with their frequency (common: 1 to 10%, uncommon: 0.1 to 1%, rare: 0.01 to 0.1%, very rare: less than 0.01% and including isolated cases).

Nervous system disorders: headache (common).

Gastrointestinal disorders: nausea (common), abdominal pain (uncommon), diarrhoea (common), gastric intolerance (common) or dyspepsia (common).

General disorders: fever (uncommon).

Cutaneous disorders: allergic reaction (uncommon), rash (uncommon), pruritus (uncommon), mild exanthema (uncommon).

Other adverse effects, none severe, have been reported, principally several cases of alopecia. Isolated but serious cases have also been reported, such as oral oedema and peripheral oedema.

If skin reactions, fever or oedema occur, the treatment must be stopped since they may be signs of an allergic reaction.

Interactions

No drug interaction is known up to now.

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 overdose seems impossible to reach.

Particular remarks

Incompatibilities

No known up to now.

Shelf life

Stored in its original package, Uro-Vaxom® has a shelf life of 5 years.

Special precautions for storage

The medication should be stored protected from heat (below 30°C).

The medication should not be used after the expiration date printed on the package together with the mention "EXP".

Presentations

Capsules: 30 and 90.

This is a medicament

A medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.

Follow strictly the doctor's prescription, the method of use and instruction of the pharmacist who sold the medicament.

The doctor and the pharmacist are experts in medicine, its benefits and risks.

Do not by yourself interrupt the period of treatment prescribed for you.

Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Supplier/Manufacturer

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PHARMA

OM PHARMA
Meyrin-Geneva Switzerland

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