



## RECOMBINANT ENDOSPORES OF *BACILLUS SUBTILIS* AS AN EDIBLE VACCINE AGAINST *CLOSTRIDIUM DIFFICILE* INFECTIONS

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### Product description

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*Clostridium difficile* as a dangerous etiological agent causing recurrent diarrhoea and pseudomembranous colitis is a great challenge for contemporary medicine. The presented vaccine contains endospores of non-pathogenic Gram-positive bacteria of *Bacillus subtilis* type. Bacterial endospores on their surface contain fusion proteins presenting TcdA and TcdB antigens, which are fragments of toxins, being responsible for immunisation of the vaccine. The vaccine applied orally enables immunisation directly in colons, thus the target place of *C. difficile* bacteria activity, which at the same time increases its effectiveness. Therapeutic efficiency of the vaccine, as well as its working have been determined during conduction of trials on experimental animals.

### Key words

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oral vaccine, recombinant endospores, *Bacillus subtilis*, *Clostridium difficile*

### Legal status of the product

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- Polish Patent Office:

Submitted patent application (21.12.2012, 8.04.2013, 26.11.2013) - entity solely entitled to the invention - Medical University of Gdańsk

### The aim of the offer

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The proposed product is oral vaccine against colon infections caused by microbes from *Clostridium difficile* species consisting of recombinant *Bacillus subtilis* endospores.

### Foregoing funding of studies on the product

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The project financed by funds of LIDER II (NCBR) programme.

### Analysis of competition on the market

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*C. difficile* infection is one of the main causes of nosocomial diarrhoea, which affect both adults and children, including infants and newborn babies.



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Recombinant *B. subtilis* endospores as an edible vaccine against *C. difficile* infections are a very desirable protective therapeutic type of product. Potential receivers of the product can include pharmaceutical companies, which offer vaccines and/or are interested in expanding their product range. Currently, there is no commercially available vaccine against infections caused by this pathogen on the pharmaceutical market, however, many pharmaceutical companies conduct developmental works on this topic very intensively.

### *Advantages of the product*

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*C. difficile* bacteria have the ability to permeate to blood stream and produce enterotoxins causing secretory diarrhoea, which can lead to necrosis of intestinal epithelium. The widely used treatment method of infections caused by *C. difficile* is antibiotic therapy, which can result in gastrointestinal tract sterilisation of colonic microflora, and consequently to increasing of number of resistant strains in gastrointestinal tract.

The oral vaccine against colon infections caused by *C. difficile* microbes, consisting of recombinant *B. subtilis* endospores contributes to the lesser frequency of becoming ill, and to effective fighting the disease. An innovative aspect of the product is usage of bacterial spores as the vaccine's carriers. Additionally, the fact that the vaccine is provided orally, enables immunisation directly in colons, so the target place of *C. difficile* bacteria activity, which at the same time increases its effectiveness.

The form of the vaccine's administration, which is friendly even for children, makes it able to obtain mucosal and systemic immunity, prolongs half-life of antigen implemented to digestive system, strengthens cell-mediated immune response, and is not destroyed in stomach.