

INNOVUS

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SYNSURF - Synthetic Lung Surfactant

Innovus Technology Transfer (PTY) Ltd is Stellenbosch University's wholly-owned technology transfer company. Contact Anita Nel, Innovus Chief Executive Officer, on (021) 808 3826 or send an email to ajnel@sun.ac.za for more information.



This invention is a synthetic surfactant formulation consisting of a combination of readily accessible phospholipids and synthetic peptides which may be administered as either a liquid or in a nebulised/aerosolised form.



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BRIEF DESCRIPTION

A Pulmonary surfactant is a surface-active lipoprotein complex having both hydrophilic and hydrophobic properties. The surfactant facilitates gaseous exchange by adsorbing to the air-water interface of lung alveoli thereby reducing its surface tension. Surfactants are therefore essential for the breathing process and the absorption of oxygen in alveoli. Respiratory diseases may be treated with surfactants in order to avoid a decline in respiratory function.

This invention is a synthetic surfactant formulation consisting of a combination of readily accessible phospholipids and synthetic peptides which may be administered as either a liquid or in a nebulised/aerosolised form. It offers several advantages over currently available surfactants.

TARGET MARKET

Respiratory diseases affect a significant part of the world's population. Disease complexes such as respiratory distress syndrome (RDS) have serious repercussions and can be life threatening. RDS typically affects mainly premature born infants (~ 50% of infants born before 32 weeks) whilst acute RDS (ARDS or "lung injury"), affects young infants, children and adults.

Our novel surfactant, "Synsurf", can potentially be used in the treatment of RDS, asthma, chronic obstructive pulmonary disease (COPD), adult respiratory syndrome, HIV/AIDS related lung diseases (PJP infection), tuberculosis, severe acute respiratory distress syndrome, near-drowning events and hydrocarbon poisoning. Furthermore, Synsurf can also play an important role in the administration of pulmonary drugs as a carrier for active pharmaceutical ingredients (API's) such as immuno suppressants, glucocorticosteroids, vasodilators, β -sympathomimetics, antibiotics, short interfering RNA's and monoclonal antibodies in pulmonary and other conditions.

VALUE PROPOSITION/BENEFITS

Synsurf is an entirely synthetic formulation that mimics the action of naturally occurring surfactant protein.

The advantages of this product are that it:

- shows superior efficacy as a surfactant compared to leading commercially-available surfactants, showing better oxygenation values in preclinical trials;
- is inexpensive to manufacture as the formulation contains readily available components;
- is less complicated to manufacture since it does not rely on protein purification and harvesting from animal sources;
- reduces the risk of the transmission of animal-derived pathogens;
- decreases the potential of allergenic responses because its components are not animal-derived
- can be administered by means of a nebuliser or aerosol device; and
- it is a potential drug carrier and/or permeation-enhancing agent for various API's.

UNIQUE CHARACTERISTICS

Synsurf's unique characteristics are that it:

- is completely synthetic and devoid of possibly animal protein contamination, therefore eliminating the possibility of transmitting animal-associated diseases;
- is supplemented with spreading agents and polypeptides, mimicking SP-B function;
- allows for scalable production;
- consists of simple commercially available polypeptides which form a peptide complex in vivo that mimics an essential surfactant protein for enhanced pulmonary function;
- has superior surface tension lowering ability; and
- has demonstrable drug carrier capacity.

TECHNICAL DESCRIPTION

Synsurf comprises a lipidaceous carrier and a peptide complex consisting of a mixture of poly-L-lysine and poly-L-aspartic acid or pharmaceutically acceptable salts of these peptides.

The poly-L-lysine is predominantly positively charged and the poly-L-glutamic acid is predominantly negatively charged. The poly-L-lysine is longer than the poly-L-glutamic acid by which means that, when permitted to complex with one another, they form a peptide complex comprising a substantially charge-neutralised region and a positively-charged region. The substantially charge-neutralised region of the peptide complex is therefore capable of interacting with the lipidaceous carrier, while the positively-charged region is available to interact with an aqueous and/or polar environment.

In addition, the formulation comprises pharmaceutical excipients suitable for pulmonary administration in liquid form or by nebulisation. The composition is administered into the lungs to temporarily substitute for natural pulmonary surfactant. The surfactant reduces surface tension at alveolar interfacial surfaces, thereby facilitating expansion of the alveolar spaces.

INNOVATION STATUS

The efficacy of Synsurf has been demonstrated in both *in vitro* and *in vivo* studies.

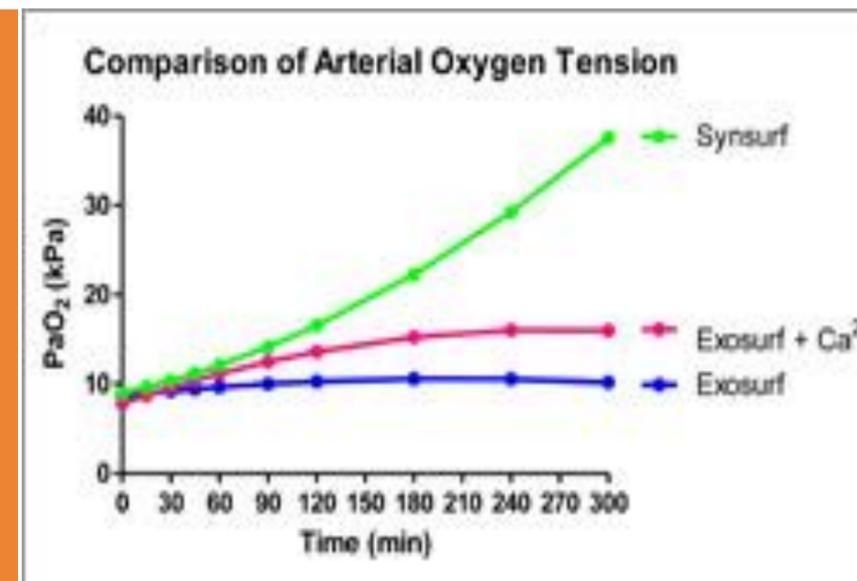
Regulatory acceptable toxicity studies have not been conducted and such studies need to be conducted in order to bring the product closer to commercialisation.

The components of the surfactant are all readily available and have had some sort of FDA or equivalent approval in other products.

An EU patent has been granted for this invention – patent no. 2538960, as well as national patents in China (Patent no. 201180013887.2) South Africa (Patent no. 2012/06987), India (Patent Nr 303197) and USA (Patent Nr US 10,124,015)

An improvement patent was filed in South Africa, granted as no. 2016/06808) and is pending in the USA.

Synsurf is an entirely synthetic formulation that mimics the action of naturally occurring surfactant protein.



PRINCIPLE RESEARCHERS

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