

PureIMS has global rights to Colistin Cyclops™, a colistin pre-filled dry powder inhaler for the treatment of pulmonary *Pseudomonas aeruginosa* infections in cystic fibrosis. PureIMS is a clinical-stage pharmaceutical and medication systems company focused on developing and commercializing innovative inhaled therapies for the treatment of systemic and respiratory diseases with significant unmet medical needs.



Colistin

Colistimethate sodium (colistin) and tobramycin are effective antibiotics against *Pseudomonas aeruginosa* (Psa) and are, therefore, used to treat pulmonary Psa infections in cystic fibrosis and bronchiectasis. Pulmonary Psa infection is associated with increased sputum production, more extensive bronchiectasis, more hospitalizations and reduced quality of life.

Colistin can be administered by inhalation or infusion, but the available inhalers are very burdensome to the patient, as is parenteral administration. This reduces patient adherence to therapy and ultimately therapeutic efficacy. Colistin Cyclops™ provides an answer to the problems associated with other colistin administration routes and devices.

In addition to Colistin Cyclops™ PureIMS also develops Tobramycin Cyclops™. This enables continuous alternating inhaled therapy between colistin and tobramycin from very similar easy-to-use inhalers for maximum patient friendliness.

Colistin Cyclops™

Cyclops™:

Cyclops™ is an easy-to-use, pre-filled, disposable dry-powder inhaler (DPI) that PureIMS develops for high-dose drugs and emergency applications.



This patent-protected DPI is cost-effective to produce because of its simple yet sophisticated design. Upon inhalation it uses the patient's breath to disperse the dry powder into small particles appropriately sized for deep lung deposition and, if required, rapid absorption of the drug into the circulation. Cyclops™ has several advantages over standard-of-care products across key therapeutic areas. The above-mentioned attributes enable its hygienic and effective use on a worldwide scale.

Colistin Cyclops™:

Colistin Cyclops™ carries a formulation with a high drug load and has excellent *in vitro* and *in vivo* performance. Colistin Cyclops™ has clear advantages compared to other treatments. It offers patients easier, faster and more convenient handling. Cleaning of the disposable Cyclops™ is not necessary.

Colistin Cyclops™ causes less side-effects (like coughing) compared to other inhalers, because of the much lower, more efficient dose and higher resistance to air flow of Cyclops™. In addition, Colistin Cyclops™ is pre-filled and therefore does not require the sometimes complex handling of capsules.

Named patient program:

PureIMS produces Colistin Cyclops™ for a named patient program in the Netherlands. To date (January 2021) almost 40,000 doses of Colistin Cyclops™ have been prescribed to patients. The product is reimbursed by payers.

Regulatory:

Discussions with the EMA are ongoing to establish the clinical program for Colistin Cyclops™. EMA endorses the necessity for new inhaled antibiotics.

Manufacturing and IP Protection

PureIMS has a GMP manufacturing facility licensed for the production of Cyclops™ IMPs. Cyclops™ is IP-protected until at least 2035.

Contact

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