Epinephrine Cyclops® for first-aid treatment of allergies with impending anaphylaxis

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Epinephrine

For over a century epinephrine (EPI) has been used to treat **allergic reactions and anaphylaxis**, and to date it remains the most effective therapy available.

(Severe) allergic reactions require **emergency treatment** to quickly counteract and stall progression of allergic symptoms to improve their recovery and minimise the risk of anaphylactic shock and even death.

Major unmet medical needs in people at risk of (severe) Type I allergic reactions and impending anaphylaxis:

- **People are reluctant to use an autoinjector device**, which puts them at risk of untimely treatment potentially leading to anaphylaxis.
- **Less than 50% of people at risk can use their autoinjector device correctly**. An easier-to-use device for EPI administration is therefore required.

Epinephrine Cyclops®

Cyclops®:

Cyclops® is a **credit card-size, easy-to-use, pre-filled, single-use dry powder inhaler (DPI)** that is ideally suited for emergency applications like allergic reactions.

Upon inhalation Cyclops® uses the patient's breath to disperse the dry powder into small particles appropriately sized for deep lung deposition and **rapid absorption** of epinephrine into the circulation.

Epinephrine Cyclops®:

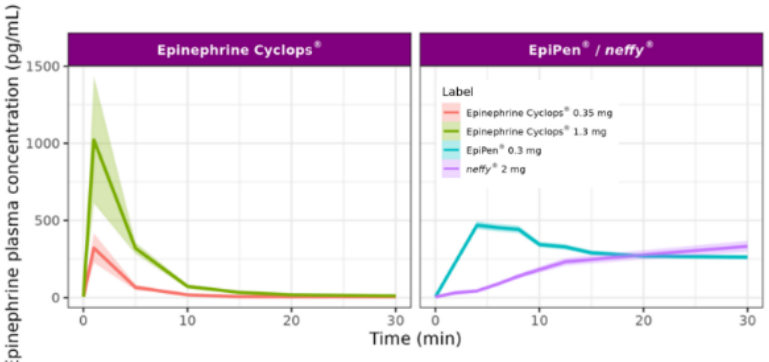
Epinephrine Cyclops® has excellent *in vitro* performance and carries a **stable, preservative- and antioxidant-free dry powder formulation**, which is desirable in a population prone to allergies as they may trigger additional allergic reactions.

It offers people suffering from mild to severe allergic reactions a **low barrier to use** because it is **non-invasive, easy and convenient to handle**, has a **fast onset of action** and a **short exposure**. The relatively short but high exposure is expected to create time for the body to recover (sufficiently suppress anaphylaxis), still allowing for **repeated treatment without dose stacking** when needed.

Epinephrine Cyclops® also acts as a **bronchodilator** and **bronchoconstriction** often occurs during (severe) allergic reactions. Especially **food allergies** are an ideal target population, because patients often have **asthma as comorbidity (>50%)** and the reaction tends to progress more slowly. Another advantage is that asthma patients are experienced inhaler users.

Clinical studies:

A Phase 1 clinical trial with Epinephrine Cyclops® has been conducted. Single doses of 0.35 up to 1.3 mg were **well tolerated** and **no adverse reactions** occurred and **no cough** was observed.



Inhaled doses result in a much **shorter time to maximum plasma concentration** than intramuscular and intranasal EPI, due to the very large surface area that the lungs provide compared to the nasal cavity. This will result in **fast and more predictable response** and limited to **no effect of comorbidity**, while this is the case for nasal EPI, where studies showed a strong effect of **nasal congestion** on its pharmacokinetics.

The exposure time is also shorter and less variable at all inhaled doses, which results in a plasma profile that approaches intravenous EPI.

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