Epinephrine Cyclops® for first-aid treatment of allergies

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Epinephrine

To date, epinephrine (EPI) remains the most effective therapy available to treat **allergic reactions and anaphylaxis**. (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 autoinjector devices**, 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**; asier-to-use devices are therefore required.

Epinephrine Cyclops®

Cyclops® is a **credit card-size, easy-to-use, pre-filled, single-use dry powder inhaler (DPI),** ideal for emergency applications. 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® carries a **stable, dry powder formulation**, has excellent *in vitro* performance; and is **preservative- and antioxidant-free**, desirable in the target population to prevent triggering additional allergic reactions.

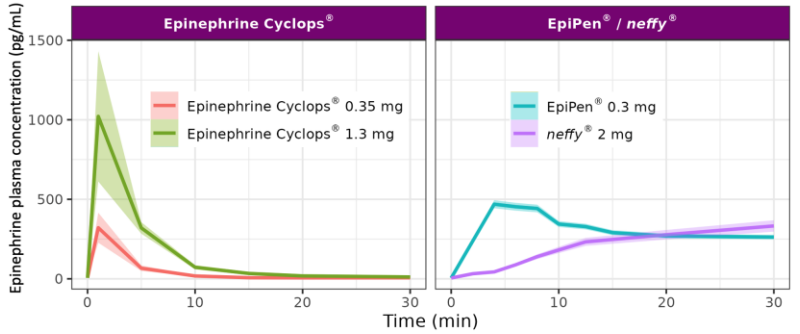
Inhalation has a **low barrier to use**: it is **non-invasive, easy and convenient to handle**, has a **fast onset of action** and a **short and high exposure,** which creates time for the body to recover (sufficiently suppress anaphylaxis), still allowing for **repeated treatment without dose stacking** 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 the reaction tends to progress more slowly and patients often have **asthma as comorbidity (>50%)**. 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**, **no adverse reactions** occurred, and **no cough** was observed.

Inhaled doses result in a much **shorter time to C_{max}** than intra-muscular and intranasal EPI, due to the very large surface area that the lungs provide compared to the nasal cavity.



This results 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.