

3M Drug Delivery Systems

The Role of the Delivery Device in Effective Asthma and COPD Products

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Summary

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Critical to clinical success of asthma and COPD products is the Active Pharmaceutical Ingredient (API) and its physiological effectiveness. However, the API can only be effective if it is appropriately delivered to the patient via the drug delivery device. Device design must first insure correct use by the patient and avoid the numerous failure modes that can occur. Secondly, the device needs to deliver the appropriate respirable dose without delivering excess non-respirable dose that can contribute to safety and side effect concerns. And finally, a device needs to have an overall efficiency to minimize the total amount of API that must be loaded into a device.

3M's Taper Multi-Dose Dry Powder Inhaler (DPI) incorporates design elements specifically desired by patients (over 100 asthma patients in 3 countries were involved), caregivers, specialist respiratory nurses, physicians, and pharmaceutical companies. More specifically, extremely simple patient use procedures (open-inhale-close) are combined with audible and visual feedback which insures the patient and caregiver know the dose was delivered. Delivery efficiency of the 3M™ Taper DPI is significantly higher compared to several commercial products providing the opportunity for both reduced overall drug delivery to the patient, as well as overall drug requirements for the device, key attributes desired by physicians and pharma companies.

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3M™ Taper Dry Powder Inhaler

3M™ Taper Dry Powder Inhaler

The 3M™ Taper DPI uses a unique design that stores API on a microstructured carrier tape. Patient-friendly design helps ensure effective delivery and correct dosing.

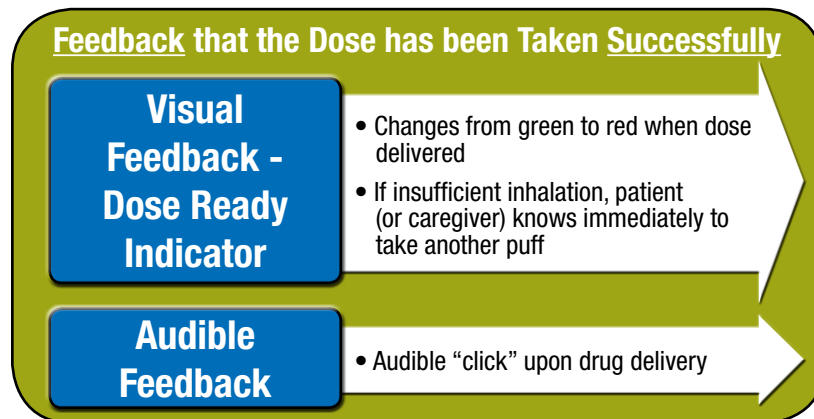
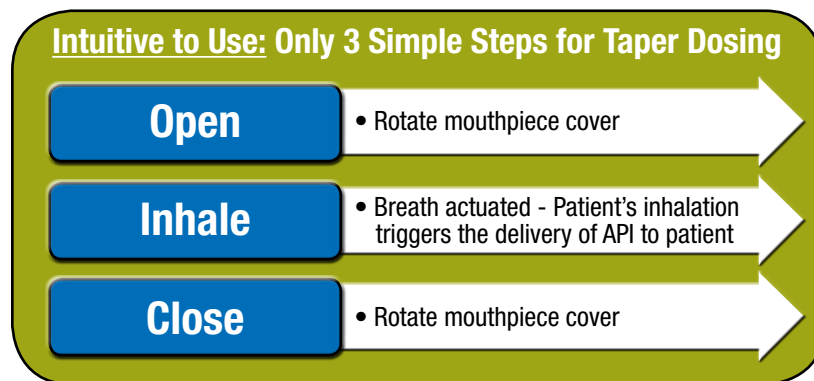
- Can be used with single or combination drugs
- Eliminates need for complex powder treatments or lactose in most formulations
- Holds up to 120 doses in pocket sized design
- Patented 3M breath actuated technology
- Utilizes active aerosolization without electronics



Patient and Caregiver Benefits of the 3M™ Taper DPI

Methods

Patient research was conducted in two stages; observing use and interviews. Top needs expressed by patients and caregivers included ease of use and feedback so the patient (or caregiver) knows the dose has been taken.



Physician and Pharmaceutical Company Benefits of the 3M™ Taper DPI

Company Benefits

An external market research company conducted interviews with 32 respondents from 10 countries. Top needs identified included: efficacy (e.g. fine particle fraction), consistent dosing and compatibility with a range of formulations. Ease of use (number of steps, clarity of numerals, etc.) and robustness were also important DPI device features.

Taper DPI Feature	Impact	Efficacy	Safety	Compliance	Cost
High Efficiency	<ul style="list-style-type: none"> • Equivalent lung dose achieved in-vitro with approximately 50% lower delivered dose than currently marketed DPIs • Less drug loaded in device • Less drug throat deposition 	✓	✓		✓
Flow Rate Independence	<ul style="list-style-type: none"> • Fine particle dose similar at low and high inspiration flow rates and for different simulated inhalation profiles 	✓	✓	✓	
Broad Dose Range	<ul style="list-style-type: none"> • Able to consistently deliver doses from approximately 4 to 2000 µg • Dose range suitable across therapeutic range of current asthma/COPD medicines 	✓	✓		
Lactose Not Required	<ul style="list-style-type: none"> • No concerns with severe milk protein allergy • Potentially lower formulation development cost 		✓		✓
3-Step Delivery	<ul style="list-style-type: none"> • Easy to use with few steps 			✓	
Ready Indicator and Dose Counter	<ul style="list-style-type: none"> • Feedback ensures successful delivery • Dose-by-Dose counter ensures patient knows when to refill prescription before medicine runs out 	✓		✓	

3M™ Taper Comparative Performance vs. Advair®

Performance vs. Advair®

• Representative *In Vitro* Performance Data:



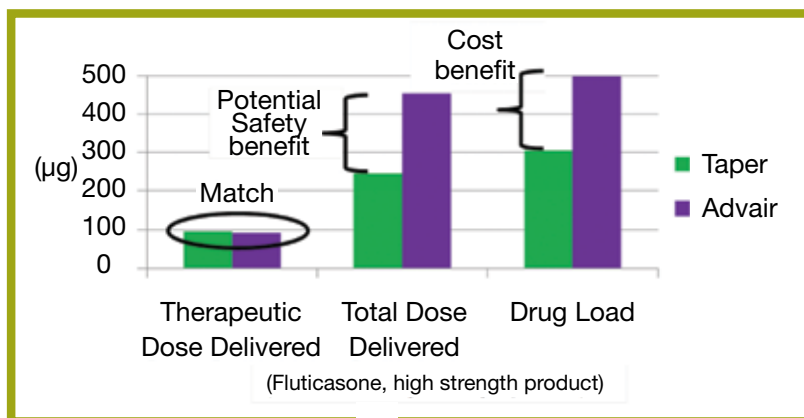
API		Taper	Advair*
Salmeterol	Drug Load	14 ug	50 ug
	Total Dose Delivered	11 ug	40 ug
	Therapeutic Dose Delivered	6 ug	6 ug
Fluticasone	Drug Load	48 ug	100 ug
	Total Dose Delivered	36 ug	92 ug
	Therapeutic Dose Delivered	15 ug	15 ug

Taper = High Efficiency Device

*Advair low strength 100/50

*Advair is a registered trademark of GlaxoSmithKline.

Similar Taper *in vitro* results vs medium and high strength Advair products.



3M Drug Delivery Systems Overview

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With a successful 50-year history that includes development of the first metered-dose inhaler (MDI) and first CFC-free propellant pressurized Metered-Dose Inhaler, 3M Drug Delivery Systems is a leader in inhalation product development and manufacturing.

3M DPIs are highly efficient and are designed to overcome the traditional challenges associated with DPI delivery.

3M Dry Powder Inhalers:

- Patient-friendly inhalers that are also efficient and value-driven
- Effective drug aerosolization technology without electronics
- Single and multi-dose DPIs expand range of possible applications
- Deliver efficacious dose to the lungs with low throat deposition
- Two types of DPIs – 3M™ Taper and 3M Conix™ – are available to meet a variety of formulation needs



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