NEW FIXED-DOSE COMBINATION

Indacaterol + glycopyrronium + mometasone (ENERZAIR BREEZHALER°) in asthma

NOTHING NEW

According to two comparative trials, adding *glycopyrronium* to *indacaterol + mometasone* dual therapy produces a modest reduction in the risk of exacerbations, but offers no advantages over triple therapy containing *tiotropium*. Like *tiotropium*, *glycopyrronium* mainly has antimuscarinic and cardiac adverse effects.

ENERZAIR BREEZHALER° - *indacaterol + glycopyrronium + mometasone* powder for inhalation in capsules

- **114 microg** of *indacaterol* + **46 microg** of *glycopyrronium* + **136 microg** of *mometasone furoate* per dose emitted from the mouthpiece (30 capsules + 1 Breezhaler° inhaler per box, with or without an electronic sensor)

Novartis Pharma

■ **Long-acting beta-2 agonist + long-acting muscarinic antagonist + corticosteroid**

■ **Indication**: "*maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta-2 agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year*". [EU centralised procedure]

■ **Dosage**: "*one capsule to be inhaled once daily*".

A sensor with no proven value. The Enerzair Breezhaler° is available with or without an electronic sensor (Propeller°) inside the box. This sensor is designed to be attached to the base of the inhaler. It records each administration of the drug, and transmits various details to an application (Propeller°), installed on a smartphone or tablet. The app can be configured to send a reminder if a dose is missed. The inhaler can be used with or without the sensor. According to the European Medicines Agency's public assessment report, the sensor's value to patients remains to be demonstrated (see "Collected data", opposite) (2).

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Literature search up to 10 February 2022

In response to our request for information, Novartis Pharma provided us with published documents and packaging items.

1- Prescrire Rédaction "Bronchodilatateurs atropiniques" Interactions Médicamenteuses Prescrire 2022.

2- EMA - CHMP "Public assessment report for Enerzair Breezhaler. EMEA/H/C/005061/0000" 30 April 2020: 142 pages.

3- EMA "SPC-Enerzair Breezhaler" 12 November 2021: 24 pages.

EDITORS' OPINION

Collected data

Enerzair Breezhaler°, a product authorised for use in asthma, is marketed with or without an electronic sensor (see left). When attached to the inhaler, this sensor records various details about the doses of the drug which the patient takes. The data can then be transmitted to an application installed on a smartphone or tablet, to be monitored by the patient, healthcare professional or carer. The patient is invited to enter other personal data into the application.

All this is entirely free of charge in France: the application is free to use, and the Enerzair Breezhaler° is sold for the same price with the sensor as without it. Could this be due to the generosity of the state, a benevolent initiative from the national health insurance system, or a dynamic group of selfless patients? No. The website of the company that developed the application shows that it is owned by a company listed on the New York Stock Exchange.

A few questions come to mind when faced with a "connected" drug, for example: who are we working for when we collect data? Are these data shared with third parties known to the patient, or perhaps even unknown? How is data security achieved during transmission and storage on various electronic devices (computers, smartphones)? Are they collected for commercial purposes? Are European regulations on the protection of personal data being observed?

Personal data has great financial value, and health data is no exception. Certain connected health products may help improve health care. But take care when the objectives are not clearly stated, and when a gadget is primarily designed to collect personal data and serves commercial interests more than the interests of patients.

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