

HeroTracker Sense Device

Instruction Manual



Indications for Use

The HeroTracker Sense Device (HTS) is an inhaled-dose inhaler that is attached by patients on a metered-dose inhaler (MDI).

HTS is intended for single-patient multiple use in the home environment as an electronic data capture accessory for tracking and recording inhalation volume, timing, and inhalation technique. HTS is not intended for use in clinical trials, where HTS may be used in the following applications:

- clinical practice or clinical trials, where specializations, general practitioners, nurses and educators need to know if a patient has used their prescribed medication or assess inhaler technique;

HTS is designed to work only with the MDI and HTS is not intended to be used with any other MDI.

HTS is not intended to be used for preventing or treating any disease, and it does not include a dose counting function.

HTS is not intended to provide spirometry measurements.

HTS is designed to be used by Metered Dose Inhaler (MDI) users aged 12 years and over.

Compatible Medication	Strength and Dose Count
Venlafaxine	90 mg/4 H3B (66 count)
Adrenaline	50mg/21mg (120 count)
Adrenaline	0.15mg/2.1mg (120 count)
Adrenaline	20mg/2.1mg (120 count)
Albuterol Sulfate (Pseudo)	90 mg (200 count)
Fluticasone Propionate & Salmeterol	45mg/21mg (120 count)
Fluticasone Propionate & Salmeterol	115mg/21mg (120 count)
Fluticasone Propionate & Salmeterol	20mg/21mg (120 count)
Albuterol Sulfate (Luprolin)	90mg (200 count)

Contraindications

No identified contraindications.

How HTS works

HTS is transferred to a mobile application (BreathSmart/Resp.me) with appropriate settings and is displayed to end users. HTS may be used in interface with a portal intended for HCP use in the following applications:

- in clinical practice or clinical trials, where healthcare professionals (including physicians, nurses, respiratory therapists, and study coordinators) need to know if a patient has taken their prescribed medication or assesses the inhalation technique;

HTS is to be used on healthy skin.

HTS can be used by any person that was prescribed an MDI, regardless of having a formal education in a relevant field of healthcare or medical discipline. The patient is an intended user.

The device comes with a plastic pouch accessory.

Warnings, Cautions and Notes

To ensure your metered dose inhaler (MDI) works correctly, only use HTS on a compatible MDI.

You should not delay the use of your medication if you are having problems with the inhalation technique.

HTS records the user's actions while taking a dose to check if the MDI usage is optimal. The data is uploaded to the BreathSmart mobile application using a Bluetooth connection.

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