

רופא/ה, רוקח/ת נכבד/ה,

חברת קמהדע בע"מ מודיעה על עדכון עלון הרופא לתכשיר:

טרימבו 100/6/12.5 ; Trimbow 100/6/12.5**Pressurised solution for inhalation**

השינויים שבוצעו (טקסט שנמחק-קו חוצה, טקסט חדש- מסומן באדום):

4.2 Posology and method of administrationPosology*Adults*

The recommended dose is two inhalations twice daily.

The maximum dose is two inhalations twice daily.

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Asthma

When choosing the starting dose strength of Trimbow (100/6/12.5 micrograms or 200/6/12.5 micrograms), the patients' disease severity, their previous asthma therapy including the inhaled corticosteroid (ICS) dose as well as the patients' current control of asthma symptoms and risk of future exacerbation should be considered.

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Special populations

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Renal impairment

Trimbow 100/6/12.5 can be used at the recommended dose in patients with mild to moderate renal impairment and a glomerular filtration rate [GFR] of ≥ 30 to < 80 mL/min/1.73 m². Use in patients with severe (GFR < 30 mL/min/1.73 m²) renal impairment or end-stage renal (GFR < 15 mL/min/1.73 m²) disease requiring dialysis, especially if associated with significant body weight reduction, should be considered only if the expected benefit outweighs the potential risk (see sections 4.4 and 5.2).

Hepatic impairment

There are no relevant data on the use of Trimbow 100/6/12.5 in patients with severe hepatic impairment (classified as having Child-Pugh class C) and the medicinal product should be used with caution in these patients (see sections 4.4 and 5.2).

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Method of administration

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Tel: +972.8.9406472 | Fax: +972.8.9406473 | www.kamada.com**MANUFACTURING PLANT**Kibbutz Beit Kama, M.P. Negev, Israel, 8532500
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Use with a spacer

Single dose pharmacokinetic data (see section 5.2) have demonstrated that in comparison to routine use without a spacer device, the use of Trimbow 100/6/12.5 with the AeroChamber Plus spacer device increased the total systemic exposure (AUC_{0-t}) to glycopyrronium. However, available safety data from long-term clinical studies have not raised any significant safety concerns (see section 5.1).

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5.2 Pharmacokinetic properties

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Effect of a spacer

In patients with COPD, the use of Trimbow with the AeroChamber Plus spacer increased the lung delivery of beclometasone 17-monopropionate, formoterol and glycopyrronium (maximum plasma concentration increased by 15%, 58% and 60% respectively). The total systemic exposure (as measured by AUC_{0-t}) was slightly reduced for beclometasone 17-monopropionate (by 37%) and formoterol (by 24%), while it was increased for glycopyrronium (by 45%). See also section 4.2.

Effect of renal impairment

Systemic exposure (AUC_{0-t}) to beclometasone dipropionate, to its metabolite beclometasone 17-monopropionate and to formoterol was not affected by mild to severe renal impairment **glomerular filtration rate [GFR] of ≥ 30 to < 80 mL/min/1.73 m²**. For glycopyrronium, there was no impact in subjects with mild and moderate renal impairment **glomerular filtration rate [GFR] of ≥ 30 to < 80 mL/min/1.73 m²**. However, an increase in total systemic exposure of up to 2.5-fold was observed in subjects with severe renal impairment (glomerular filtration rate below 30 mL/min/1.73 m²), as a consequence of a significant reduction of the amount excreted in urine (approximately 90% reduction of glycopyrronium renal clearance). Simulations performed with a pharmacokinetic model showed that even when covariates had extreme values (body weight less than 40 kg and concomitant glomerular filtration rate below 27 mL/min/1.73 m²), exposure to Trimbow active substances remains in approximately a 2.5-fold range compared to the exposure in a typical patient with median covariate values.

העלון לרופא והעלון לצרכן מתפרסמים במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל הרישום, חברת קמהדע בע"מ (טל" 08-9406472).

להלן הקישור למאגר התרופות: <https://israel drugs.health.gov.il/#!/byDrug>



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