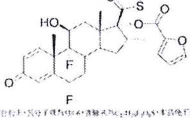
肺樂喜易利達92/55/22 mcg乾粉吸入劑
TRELEGY ELLIPTA 92/55/22 mcg Inhalation Powder

[illegible]



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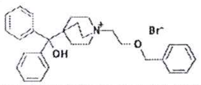

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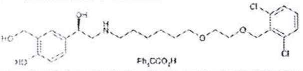

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表1 12歲(含)以上之氣喘受試者的嚴重氣喘相關事件綜合分析

	ICS/LABA (n = 17,537)ᵃ	ICS (n = 17,552)ᵃ	ICS/LABA vs. ICS 風險比率 (95% CI)ᵇ
嚴重氣喘相關事件ᶜ	115	105	1.10 (0.85, 1.44)
氣喘相關死亡	2	0	
氣喘相關插管(侵入性)	1	2	
氣喘相關住院(留院≥24小時)	115	105	

[illegible]

表2. 在Umeclidinium+Fluticasone Furoate/Vilanterol組中之發生率≥1%且高於安慰劑+Fluticasone Furoate/Vilanterol組的不良反應(COPD受試者) (試驗1與2)

不良反應	Umec + FF/VI (n=412) %	安慰劑+ FF/VI (n=412) %
神經系統疾患		
頭痛	4	3
味覺障礙	2	<1
肌肉骨骼與結締組織疾患		
背痛	4	2
呼吸道、胸腔與縱膈疾患		
咳嗽	1	<1
口咽疼痛	1	0
胃腸道疾患		
腹瀉	2	<1
感染與寄生蟲侵染		
胃腸炎	1	0

Umec=Umeclidinium，FF/VI=Fluticasone Furoate/Vilanterol。

試驗3－長期安全性資料

[illegible]

表3. 在氣喘受試者中，使用TRELEGY ELLIPTA治療時之發生率≥1%的不良反應(試驗5)

不良反應	FF/Umec/VI 200/62.5/25 mcg (n=408) %	TRELEGY ELLIPTA 100/62.5/25 mcg (n=406) %	FF/VI 200/25 mcg (n=406) %	FF/VI 100/25 mcg (n=407) %
感染與寄生蟲侵染				
鼻咽炎/咽炎	15	17	16	16
上呼吸道感染/病毒性上呼吸道感染	7	5	6	7
支氣管炎	5	4	5	3
呼吸道感染/病毒性呼吸道感染	3	4	2	4
鼻竇炎/急性鼻竇炎	3	2	2	3
泌尿道感染	2	<1	<1	1
鼻炎	1	2	2	1
流行性感冒	1	4	2	3
肺炎	<1	1	2	2
神經系統疾患				
頭痛	5	9	6	7
肌肉骨骼與結締組織疾患				
背痛	2	3	1	4
呼吸道、胸腔與縱膈疾患				
發音困難	1	1	2	1
口咽疼痛	1	1	<1	<1
咳嗽	1	<1	1	1

FF/VI=Fluticasone Furoate/Vilanterol。
FF/Umec/VI=Fluticasone Furoate/Umeclidinium/Vilanterol。

[illegible]

8.3 上市後經驗

[illegible]

圖1. 在COPD病人中，給予投予之後，內在因素對Fluticasone Furoate (FF)、Umeclidinium (UMEC)與Vilanterol (VI)之藥物動力學(PK)的影響

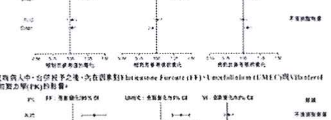

圖2. 在氣喘病人中，給予投予之後，內在因素對Fluticasone Furoate (FF)、Umeclidinium (UMEC)與Vilanterol (VI)之藥物動力學(PK)的影響

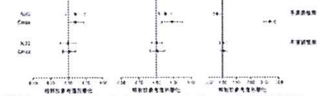

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圖3. 投予Fluticasone Furoate/Vilanterol複方或投予單獨之Vilanterol與Umeclidinium之後，內在因素、與併用藥物對Fluticasone Furoate (FF)及Vilanterol (VI)之藥物動力學(PK)的影響

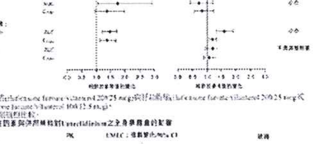

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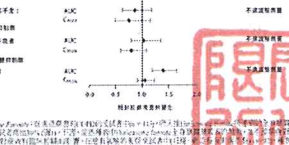
圖4. 內在因素與併用藥物對Umeclidinium之全身暴露量的影響



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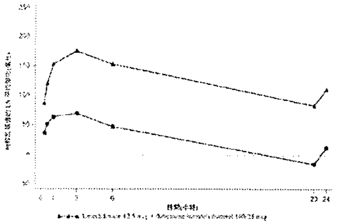

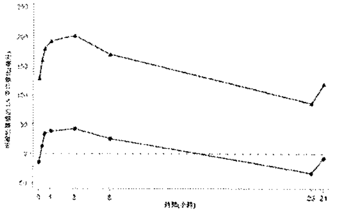

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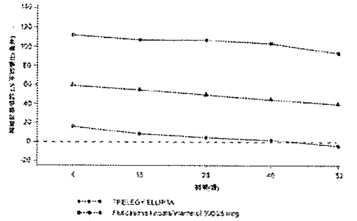

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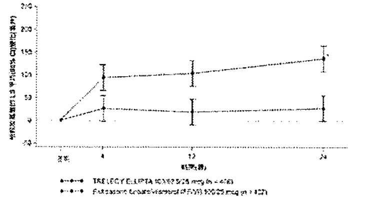

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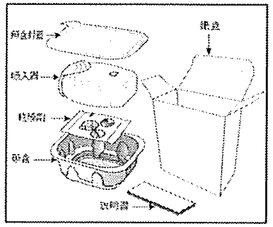

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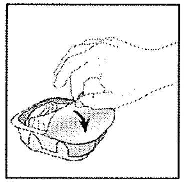

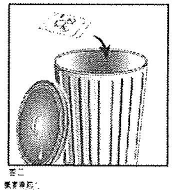

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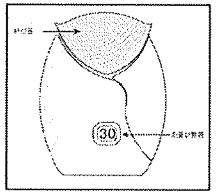
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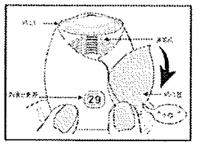
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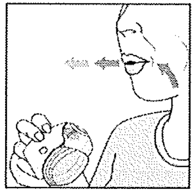

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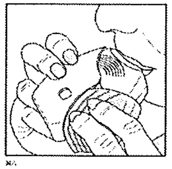

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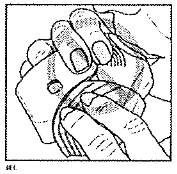

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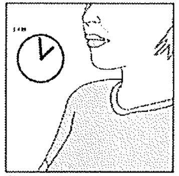

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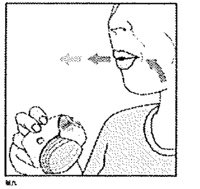

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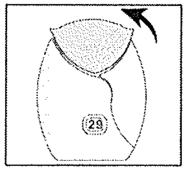
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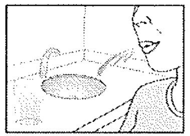

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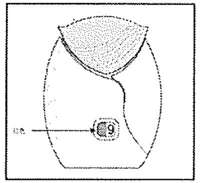
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