

PRESS RELEASE

ATTENTION: GENERAL CONSUMER MEDIA



TRELEGY® ELLIPTA® listed on PBS for severe asthma *Single inhaler triple therapy for severe asthma reimbursed by the PBS in Australia*

Friday 1st April 2022 (tbc) – Melbourne, Australia: GSK Australia has welcomed the announcement that TRELEGY® ELLIPTA® 200 (Fluticasone furoate, umeclidinium and vilanterol; 200/ 62.5/ 25mcg) will be reimbursed by the Pharmaceutical Benefits Scheme (PBS) for maintenance therapy of severe asthma* for Australian adults from the 1st of April 2022.

Trelegy Ellipta becomes the latest “*three in one*” therapy for severe asthma to be reimbursed by the PBS.

While 2.7 million Australians are affected by asthma¹, based on international studies it is estimated that 3-10% of these people have severe asthma². This represents between 52,800 and 176,000 people in Australia².

Research shows that up to 30% of people living with asthma report uncontrolled asthma symptoms despite regularly using preventer medicines containing inhaled corticosteroids.^{3,4}

Trelegy Ellipta contains three active ingredients – fluticasone furoate, umeclidinium and vilanterol – that are delivered via a single inhaler. Fluticasone furoate (steroid) reduces the swelling and irritation in the small air passages in the lungs and so eases breathing problems. Umeclidinium and vilanterol work together to help open the airways and make it easier for air to get in and out of the lungs.⁴

Australian respiratory specialist Professor Greg King, said that having access to a new option was important for Australians with severe asthma.

“We need to help patients with severe asthma to control their symptoms, such as breathing difficulties and improve their quality of life. That’s why new evidence-based options are very welcome among doctors. Trelegy Ellipta is an addition to our options for patients with severe asthma” said Professor King.

Michele Goldman, CEO at Asthma Australia, said it can be a difficult journey for someone with severe asthma to find the right treatment.

“Severe asthma can be a debilitating breathing condition that is difficult to treat and can lead to multiple hospital admissions. Asthma Australia welcomes new severe asthma treatment options and their listing on the PBS, as they offer hope of better health for these people” said Ms Goldman.

Dr Alan Paul, Country Medical Director at GSK Australia said the announcement was part of GSK’s ongoing commitment to improving the lung health of Australians.

“We are proud to be able to bring new options to Australians affected by severe asthma. GSK is committed to bringing our innovative medicines to the people that need them most and today’s announcement provides clear evidence of that,” said Dr Paul.

*Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

ENDS

For more information or interviews please contact:

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About TRELEGY ELLIPTA (FF/UMEC/VI)

TRELEGY ELLIPTA is indicated for the maintenance treatment of asthma in adult patients who are not adequately controlled with a combination of inhaled corticosteroid and a long acting beta2-agonist.

TRELEGY provides a combination of three molecules in a single inhaler that can be taken in a single inhalation, once a day. It contains fluticasone furoate, an inhaled corticosteroid, umeclidinium, a long-acting muscarinic antagonist; and vilanterol, a long-acting beta2-adrenergic agonist, delivered in Ellipta dry powder inhaler. Trelegy for asthma is a new addition to the GSK Ellipta portfolio.

See FULL AUS product information here: www.gsk.com.au/trelegy

Important Safety Information (ISI) for TRELEGY ELLIPTA⁴

Patient must have experienced at least one severe exacerbation, which has required use of systemic corticosteroids, in the previous 12 months while receiving optimized asthma therapy, despite formal assessment of an adherence to correct inhaler technique, which has been documented.

TRELEGY ELLIPTA should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack you must use a quick-acting inhaler (such as VENTOLIN).⁵

TRELEGY ELLIPTA should not be used in children or adolescents under the age of 18 years.

TRELEGY ELLIPTA should not be used if allergic (hypersensitive) to lactose or milk protein or allergic (hypersensitive) to fluticasone furoate, umeclidinium, vilanterol or any other ingredients of TRELEGY ELLIPTA.

Common side effects include common cold, headache, cough, hoarseness, painful and frequent urination (may be signs of a urinary tract infection), joint pain, back pain, constipation, itchy, runny or blocked nose, pain in the back of the mouth and throat, inflammation of the sinuses, inflammation of the lungs (bronchitis), flu (influenza), infection of the nose, sinuses or throat, infection of the upper airways, infection of the lungs.⁵

Consumer Medicine Information can be accessed at www.gsk.com.au/trelegy

Minimum Product Information. Trelegy Ellipta (Fluticasone furoate/Umeclidinium (as bromide)/Vilanterol (as trifenate))

Trelegy Ellipta (Fluticasone furoate/Umeclidinium (as bromide)/Vilanterol (as trifenate) 100/62.5/25 mcg and 200/62.5/25 mcg

PBS Information: Severe asthma (200/62.5/25 mcg presentation): Authority Required (Streamlined). Criteria apply. Refer to PBS for full information.

PLEASE REVIEW PRODUCT INFORMATION BEFORE PRESCRIBING
Product Information can be accessed at www.gsk.com.au/trelegy

Minimum Product Information

Indications: Maintenance treatment of asthma in adult patients who are not adequately controlled with an ICS+LABA. **Contraindications:** Severe milk-protein allergy or hypersensitivity to any of the ingredients. **Precautions:** An increased incidence of pneumonia cannot be excluded with higher ICS dose. Not for treatment of acute asthma symptoms. Paradoxical bronchospasm, unstable cardiac disease, hepatic impairment, active or quiescent TB, systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. Narrow angle glaucoma, urinary retention. **Pregnancy:** Category B3. **Interactions:** Beta-blockers, strong CYP3A4 inhibitors, sympathomimetics, monoamine oxidase inhibitors, tricyclic antidepressants and other LAMAs and LABAs. **Adverse Effects:** Nasopharyngitis, headache, cough, oropharyngeal pain, pneumonia, upper respiratory tract infection, viral respiratory tract infection, influenza, pharyngitis, dysphonia, rhinitis, arthralgia, back pain, constipation, sinusitis, bronchitis, urinary tract infection, candidiasis of mouth and throat. **Dosage:** One inhalation once daily. After inhalation, rinse mouth with water without swallowing.
Trelegy Min PI Asthma v1. For further details, please refer to the full PI

For information on GSK products or to report an adverse event involving a GSK product, please contact GSK Medical Information on 1800 033 109.

About GSK

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If you are an Australian healthcare professional, please visit www.health.gsk.com for more information on GSK vaccines.

You can follow GSK on Twitter for more Australian updates [@GSK AU](https://twitter.com/GSK_AU).

Additional information:

In relation to this GSK media announcement, no honorarium was provided to Professor King . He has been briefed by GSK on the approved use of the product.

GlaxoSmithKline Australia Pty Ltd. Melbourne, VIC. ABN 47 100 162 481. TRELEGY ELLIPTA is a registered trademark of the GSK group of companies.

NP-AU-FVU-PRSR-220001. Approved March 2022

References

1. 2017–18 Australian Bureau of Statistics (ABS) National Health Survey (NHS) (ABS 2018).” Asthma - Australian Institute of Health and Welfare (aihw.gov.au)
2. See <https://www.severeasthma.org.au/> and Asthma Australia <https://asthma.org.au/about-asthma/severe-asthma/>
3. Bateman ED, et al. *Am J Respir Crit Care Med.* 2004;170:836–44
4. Reddel HK, Sawyer SM, Everett PW, Flood PV, Peters MJ. Asthma control in Australia: a cross-sectional web-based survey in a nationally representative population. *Med J Aust.* 2015 May 18;202(9):492-7. doi: 10.5694/mja14.01564. PMID: 25971575.
5. Consumer Medicine Information, Trelegy Ellipta 100/62.5/25 and 200/62.5/25, <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-CMI-01155-1&d=20220206172310101>

This media release has been issued by Palin Communications on behalf of GSK.