
NEW PBS LISTING FOR CYSTIC FIBROSIS¹
BROADER PATIENT ACCESS FOR AUSTRALIAN DRUG DISCOVERY
BRONCHITOL[®] (MANNITOL)

Australians living with cystic fibrosis (CF) will benefit from expanded access to a portable treatment to help clear their lungs following a decision by the federal government.

Pharmaceutical research company Pharmaxis (ASX: PXS) today announced it has successfully achieved extended reimbursement of its drug Bronchitol (mannitol) on the Pharmaceutical Benefits Scheme (PBS)¹.

Effective from 1st January 2018, eligible people with cystic fibrosis who are taking Pulmozyme[®] (dornase alfa), another CF medication, will be able to add reimbursed Bronchitol to their treatment regime.

Cystic fibrosis is a genetic condition affecting one in every 2500 Australian babies². People with CF develop an abnormal amount of excessively thick and sticky mucus within the lungs, airways and the digestive system². The number and variety of therapies used by people with cystic fibrosis every day to fight infection and manage their disease is extensive, placing a huge burden on patients and their families².

Bronchitol is a portable therapy delivered using a small handheld inhaler, and may be a useful additional treatment for some people living with CF³. Bronchitol has been studied in more than 1000 clinical trial patients⁴ and is indicated for appropriate CF patients over 6 years of age³.

Dr Peter Cooper, Respiratory Physician, Westmead Children's Hospital said, "This new listing will allow clinicians treating cystic fibrosis to use two agents that work differently, and are proven to work together in the CF lung, to improve mucus clearance.

PBS reimbursement of this combined treatment approach will also significantly reduce paperwork for CF treating teams and improve access for patients."

An expanded PBS listing for Bronchitol was supported by the CF community, healthcare professionals and Cystic Fibrosis Australia in submissions to the government committee advising on medicine reimbursement.

Cystic Fibrosis Australia CEO Nettie Burke said “The plight of many people with cystic fibrosis is being further complicated by unnecessary restrictions on the combined use of certain drug treatments. Some people with CF will benefit from taking both Bronchitol and Pulmozyme in combination.

Cystic Fibrosis Australia believes it is important that people with CF are offered a variety of therapies tailored to the unique aspects of their disease and situation, and that equitable access to the best available treatments is paramount.”

Pharmaxis CEO Gary Phillips said, “We are delighted that more Australians with cystic fibrosis will now have access to treatment with Bronchitol under this expanded listing. We are proud that a locally developed and manufactured product is helping people living with this incurable disease.”

This product is listed on the PBS for the treatment of cystic fibrosis. Public Hospital Authority Required (STREAMLINED). Private Hospital Authority (Section 100). Please refer to PBS schedule for full PBS Authority Required Information.

Please review approved Product Information before prescribing. Product Information is available upon request from Pharmaxis Pty Ltd by calling 1800 274 365 or via the TGA website <https://www.ebs.tga.gov.au>

INDICATIONS: Treatment of cystic fibrosis (CF) in both paediatric and adult populations six years and above, as either an add-on therapy to dornase alfa, or in patients intolerant to, or inadequately responsive to, dornase alfa.

DOSAGE AND METHOD OF USE: Inhale contents of ten 40 mg capsules via the inhaler device, twice a day.

CONTRAINDICATIONS: Hypersensitivity to mannitol or to any of the capsule ingredients. Bronchial hyperresponsiveness to inhaled mannitol. PRECAUTIONS: Haemoptysis: Patients with a previous history of significant episodes of haemoptysis (>60 mL) should be carefully monitored. Bronchitol has not been studied in patients with a history of significant episodes of haemoptysis in the previous 3 months. Bronchitol should be withheld in the event of massive haemoptysis. Asthma: Patients with asthma must be carefully monitored for worsening signs and symptoms after the initiation dose of Bronchitol. Patients must be advised to report worsening signs and symptoms of asthma to their physician. Hyperresponsiveness to mannitol: Patients must be monitored for bronchial hyperresponsiveness before commencing the therapeutic dose regimen of Bronchitol. Bronchospasm: Bronchitol may cause bronchoconstriction requiring treatment, even in patients who were not hyperresponsive to the initiation dose of inhaled mannitol. Impaired Lung Function: Safety and efficacy have not yet been demonstrated in patients with a FEV₁ <30% of predicted. Impaired Hepatic / Renal Function: Bronchitol has not formally been studied in patients with impaired renal or hepatic function. ADVERSE REACTIONS: Very Common: Cough. Common: Upper respiratory tract infection*, bacterial disease carrier, decreased appetite, headache, haemoptysis, bronchospasm, wheezing, asthma*, condition aggravated, pharyngolaryngeal pain, productive cough, chest discomfort, throat irritation, bacteria sputum identified*, vomiting, post-tussive vomiting. * Note: Frequency of adverse reaction lower than noted in the control group. DATE OF PREPARATION: 8 October 2015

References: 1. www.pbs.gov.au 2. www.cysticfibrosis.org.au 3. Bronchitol Approved Product Information October 2015. 4. Data on file (Pharmaxis Ltd).

SOURCE: Pharmaxis Ltd, Sydney, Australia

CONTACT: Felicity Moffatt, phone +61 418 677 701 or email felicity.moffatt@pharmaxis.com.au

If you would like to be advised directly by email each time Pharmaxis issues a media release, please register on our website at <http://www.pharmaxis.com.au/investor-centre/subscribe/>.

About Pharmaxis

Pharmaxis (ACN 082 811 630) is an Australian pharmaceutical research company focused on inflammation and fibrosis with a portfolio of products at various stages of development and approval. Its product Bronchitol® for cystic fibrosis is marketed in Europe, Russia and Australia. Its product Aridol® for the assessment of asthma is sold in Europe, Australia and Asia. The company's development pipeline is centred on its expertise in amine oxidase chemistry and includes a series of Lysyl Oxidase Inhibitors that will enter clinical development in 2017 targeting fibrotic diseases of the heart, kidney, liver and lung. In May 2015, Boehringer Ingelheim acquired the Pharmaxis investigational drug PXS-4728A, a potent inhibitor of Semicarbazide-Sensitive Amine Oxidase (SSAO), to develop it for the treatment of the liver-related condition Non-alcoholic Steatohepatitis (NASH) and other inflammatory diseases. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office, manufacturing and research facilities are located in Sydney, Australia. For more information about Pharmaxis, please see www.pharmaxis.com.au

Forward-Looking Statements

Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential of products and drug candidates. All forward-looking statements included in this media release are based upon information available to us as of the date hereof. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forward-looking statements. These forward-looking statements are not guarantees or predictions of future results, levels of performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this document. Except as required by law we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.