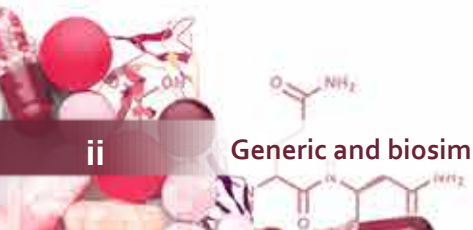
Australian Government
Department of Health
Therapeutic Goods Administration

Generic and biosimilar prescription medicines:

TGA annual summary 2016

Contents





Generic prescription medicines

A generic medicine is an additional brand of an existing medicine. It contains the same active ingredient (the chemical that makes the medicine work) as the existing medicine and can be manufactured and sold by other companies once the patent for the existing brand has expired.

Generic prescription medicines meet the same standards of quality, safety and efficacy as the existing medicine and the TGA continually monitors the safety of registered medicines once they become available on the market.

Apart from containing the same active ingredient, generic medicines must also be 'bioequivalent'. That is, if you take the same dose of a generic medicine as an existing medicine, the same amount of active ingredient is absorbed by your body over the same period of time.

114 submissions resulted in the registration of new generic medicines in the Australian Register of Therapeutic Goods (ARTG).

These submissions involved 73 discrete active ingredients across a range of therapeutic areas.

First generic medicines

Of the generic prescription medicines registered in 2016, 20 submissions resulted in the registration of the 'first generic' version that contains a particular active ingredient.

The listing of the first generic brand of a medicine by the Department of Health triggers a statutory price reduction of 16 per cent under the Pharmaceutical Benefits Scheme (PBS).

The first generic version registered by the TGA may not necessarily be the first that is PBS listed. The PBS website should be consulted for further information. TGA registration does not imply PBS listing.

www.pbs.gov.au/

The sponsor name reflects the information in the ARTG at the time of registration.

As product sponsors may change over time, please see the ARTG for up-to-date details https://www.tga.gov.au/australian-register-therapeutic-goods.

This publication does not include information relating to the available or marketed trade names or strengths. Please refer to the ARTG for more details.

2016 registration highlights for chemical entities

For full information in relation to these products, please refer to the Australian Register of Therapeutic Goods (ARTG): https://www.tga.gov.au/australian-register-therapeutic-goods. The ARTG will include information relating to the registered strengths, dosage form, packaging, brand names and approved indication.

Antidotes and agents treating gastrointestinal disorders

domperidone (as maleate)

Domperidone tablets are indicated for the short-term treatment in adults of:

- Symptoms associated with idiopathic or diabetic gastroparesis (once control of diabetes has been established by diet and/or insulin, an attempt should be made to discontinue domperidone)
- Intractable nausea and vomiting from any cause.

Medreich Australia Pty Ltd	*30 May 2016*	*Tablet*

naloxone hydrochloride

Naloxone injections are indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by opioids including natural and synthetic opioids, propoxyphene, methadone and the narcotic-antagonist analgesics: nalbuphine, pentazocine and butorphanol. Naloxone injections are also indicated for the diagnosis of suspected acute opioid overdosage.

Juno Pharmaceuticals Pty Ltd	*10 March 2016*	*Injection*

Anti-infective agents

abacavir (as sulfate) / lamivudine

The tablets contain a combination of two nucleoside analogues, abacavir and lamivudine and are indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age.

Apotex Pty Ltd	*03 August 2016*	*Tablet*

atovaquone / proguanil hydrochloride

Atovaquone and proguanil tablets are indicated for prophylaxis of plasmodium falciparum malaria in adults and the treatment of plasmodium falciparum malaria in adults.

Sanofi-Aventis Australia Pty Ltd	*27 June 2016*	*Tablet*

itraconazole

Itraconazole capsules are indicated for use in adults for the treatment of:

- Superficial dermatomycoses not responding to topical treatment
- Fungal keratitis which has failed to respond to topical treatment or where the disease is either progressing rapidly or is immediately sight threatening
- Pityriasis versicolor not responding to any other treatment
- Vulvovaginal candidiasis not responding to topical treatment
- Oral candidiasis in immunocompromised patients
- Onychomycosis caused by dermatophytes

Systemic mycoses:

- Systemic aspergillosis, histoplasmosis, sporotrichosis
- Treatment and maintenance therapy in AIDS patients with disseminated or chronic pulmonary histoplasmosis infection
- Treatment of oropharyngeal and/or oesophageal candidiasis when first line systemic antifungal therapy is inappropriate or has proven ineffective
- Treatment of non-invasive candidiasis in non-neutropenic patients when first-line systemic antifungal therapy is inappropriate or has proven ineffective. This may be due to underlying pathology, insensitivity of the pathogen or drug toxicity.

Generic Partners Pty Ltd	*9 August 2016*	*Capsule*

moxifloxacin (as hydrochloride monohydrate)

Moxifloxacin tablets are indicated for the treatment of adults with infections caused by susceptible organisms in the conditions:

- Acute bacterial sinusitis
- Community acquired pneumonia
- Acute exacerbations of chronic bronchitis

Apotex Pty Ltd	*15 March 2016*	*Tablet*
Fresenius Kabi Australia Pty Ltd	*9 May 2016*	*Solution for intravenous infusion*
Claris Lifesciences Australia Pty Ltd	*30 August 2016*	*Solution for intravenous infusion*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

tenofovir

Tenofovir tablets in combination with other antiretroviral agents are indicated for the treatment of:

- HIV-infected adults and paediatric patients 12 years of age and older
- chronic hepatitis B in adults
- chronic hepatitis B in paediatric patients 12 years of age and older with compensated liver disease and with evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels or evidence of active inflammation

tenofovir disoproxil fumarate

Apotex Pty Ltd	*29 April 2016*	*Tablet*

tenofovir disoproxil maleate

Alphapharm Pty Ltd	*15 December 2016*	*Tablet*

tenofovir disoproxil maleate / emtricitabine

Treatment of HIV-1 infection

Tenofovir disoproxil maleate and emtricitabine combination tablets are indicated for the treatment of:

- HIV infected adults over the age of 18 years, in combination with other antiretroviral agents and
- In combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples

Alphapharm Pty Ltd	*15 December 2016*	*Tablet*

tobramycin

Micro-organism infections

Tobramycin injections are indicated for the treatment of the following serious infections caused by susceptible micro-organisms:

- central nervous system infections, including meningitis
- septicaemia and neonatal sepsis
- gastro-intestinal infections, including peritonitis
- complicated and recurrent urinary tract infections such as pyelonephritis and cystitis
- lower respiratory tract infections, including pneumonia, bronchopneumonia and acute bronchitis
- bone, skin and skin structure infections, including burns

Cystic fibrosis

Tobramycin inhalation solutions are indicated for the management of cystic fibrosis patients with *P. aeruginosa* infections. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 ≤ 25% or ≥ 80% predicted at screening, or patients colonized with *Burkholderia cepacia* (see Product Information).

Alphapharm Pty Ltd	*25 February 2016*	*Injection*
Amneal Pharma Australia Pty Ltd	*13 April 2016*	*Inhalation solution*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

Cardiovascular and endocrine agents

bosentan (as monohydrate)

Bosentan tablets are indicated for the treatment of:

- idiopathic pulmonary arterial hypertension
- familial pulmonary arterial hypertension
- pulmonary arterial hypertension associated with scleroderma, or
- pulmonary arterial hypertension associated with congenital systemic to pulmonary shunts including Eisenmenger's physiology in patients with WHO functional Class II, III or IV symptoms

Apotex Pty Ltd	*25 February 2016*	*Tablet*
Accord Healthcare Pty Ltd	*22 March 2016*	*Tablet*
Ranbaxy Pty Ltd	*11 July 2016*	*Tablet*
Tolmar Australia Pty Ltd	*16 November 2016*	*Tablet*
Sandoz Pty Ltd	*22 November 2016*	*Tablet*
Alphapharm Pty Ltd	*19 December 2016*	*Tablet*
Dr Reddy's Laboratories Australia Pty Ltd	*21 December 2016*	*Tablet*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

ezetimibe

Adults (≥ 18 years)

Primary Hypercholesterolaemia

Ezetimibe administered alone, or with an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia.

Homozygous Familial Hypercholesterolaemia (HoFH)

Ezetimibe, administered with a statin, is indicated for patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis).

Children and Adolescents 10-17 years (Pubertal status: boys Tanner Stage II and above and girls who are at least one year post-menarche).

Heterozygous Familial Hypercholesterolaemia (HeFH)

Ezetimibe, co-administered with simvastatin (doses up to 40 mg) is indicated as an adjunctive therapy to diet in adolescent patients (10-17 years old) with heterozygous familial hypercholesterolaemia where use of a combination product is appropriate:

- patients not appropriately controlled with a statin or ezetimibe alone
- patients already treated with a statin and ezetimibe

Homozygous Familial Hypercholesterolaemia (HoFH)

Ezetimibe, co-administered with simvastatin (doses up to 40 mg) is indicated in adolescent patients (10-17 years old) with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis).

Apotex Pty Ltd	*30 June 2016*	*Tablet*
Lupin Australia Pty Limited	*4 July 2016*	*Tablet*
Accord Healthcare Pty Ltd	*5 October 2016*	*Tablet*
Sandoz Pty Ltd	*24 November 2016*	*Tablet*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

solifenacin succinate

Solifenacin succinate tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency or increased urinary frequency.

Apotex Pty Ltd	*12 January 2016*	*Tablet*
Generic Partners Pty Ltd	*19 May 2016*	*Tablet*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

warfarin sodium (as clathrate)

Warfarin tablets are indicated for the treatment of:

- prophylaxis and/or venous thrombosis and its extension and pulmonary embolism
- prophylaxis and/or thromboembolic complications associated with atrial fibrillation

Warfarin is not indicated in patients with lone atrial fibrillation who are less than 60 years of age with no risk factors (e.g. previous thromboembolism (TIA, ischaemic stroke), diabetes mellitus, hypertension) and an otherwise normal heart.

Warfarin is indicated for use as an adjunct in the treatment of coronary occlusion.

Apotex Pty Ltd	*5 May 2016*	*Tablet*

Antiemetic and antineoplastic agents

mitomycin

Mitomycin powder for injection is indicated in the palliative treatment of carcinoma of the stomach, pancreas, colon, lung (non-small cell), breast, cervix, head and neck, liver and bladder.

Omegapharm Pty Ltd	*8 March 2016*	*Powder for injection*

palonosetron (as hydrochloride)

Palonosetron injections are indicated for prevention of nausea and vomiting induced by cytotoxic chemotherapy.

Apotex Pty Ltd	*13 May 2016*	*Solution for injection*
Dr Reddy's Laboratories Australia Pty Ltd	*13 July 2016*	*Solution for injection*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

Agents for respiratory and endocrine disorders

budesonide

Budesonide nasal spray is indicated for the treatment of short term (3-6 months) prophylaxis or treatment of seasonal allergic rhinitis in adults and children aged 12 years and over and for perennial allergic rhinitis in adults 18 years and over.

Apotex Pty Ltd	*19 September 2016*	*Nasal spray*

budesonide / formoterol

Asthma

The combination of budesonide and formoterol in a powder for inhalation is indicated for the treatment of asthma where use of a combination (inhaled corticosteroid and long acting beta 2-agonist) is appropriate. This includes:

- Patients who are symptomatic on inhaled corticosteroid therapy
- Patients who are established on regular long acting beta-agonist and inhaled corticosteroid therapy

There are two alternative treatment regimens:

- Maintenance and reliever therapy
- Maintenance therapy

Budesonide / formoterol 400/12 strength should not be used for the maintenance and reliever therapy regimen. Budesonide / formoterol is not indicated in children and adolescents under the age of 18 years as the 100/6 dose is not available.

Chronic obstructive pulmonary disease (COPD)

Budesonide and formoterol powder for inhalation is indicated for the symptomatic treatment of moderate to severe COPD (FEV1 less than or equal to 50% predicted normal) in adults with frequent symptoms despite long-acting bronchodilator use, and/or a history of recurrent exacerbations.

Budesonide and formoterol powder for inhalation is not indicated for the initiation of bronchodilator therapy in COPD.

Teva Pharma Australia Pty Ltd	*19 December 2016*	*Powder for inhalation*

calcipotriol / betamethasone (as dipropionate)

Ointment containing calcipotriol and betamethasone is indicated for the once daily topical treatment of plaque-type psoriasis vulgaris amenable to topical therapy.

Sandoz Pty Ltd	*26 August 2016*	*Ointment*

cinacalcet (as hydrochloride)

Cinacalcet tablets are indicated for the treatment of:

- biochemical manifestations of secondary hyperparathyroidism in patients with end stage renal disease, receiving dialysis
- hypercalcaemia in patients with parathyroid carcinoma
- biochemical manifestations of primary hyperparathyroidism in patients for whom parathyroidectomy is not a treatment option.

Cinacalcet should be used as adjunctive therapy.

Apotex Pty Ltd	*30 May 2016*	*Tablet*

fluticasone propionate / salmeterol (as xinafoate)

For the regular treatment of asthma where the use of a combination product is appropriate.

This may include:

- Patients on effective maintenance doses of long-acting beta2-agonists and high-dose inhaled corticosteroids
- Patients who are symptomatic on current inhaled high-dose corticosteroid therapy

For the symptomatic treatment of patients with severe COPD (FEV1 < 50% predicted normal) and a history of repeated exacerbations who have significant symptoms despite regular beta-2 agonist bronchodilator therapy in COPD.

Not indicated for the initiation of bronchodilator therapy in COPD.

Sandoz Pty Ltd	*28 October 2016*	*Powder for inhalation*
Cipla Australia Pty Ltd	*15 December 2016*	*Pressurised aerosol*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

Additional 2016 registrations of new generic prescription medicines

When more than one submission resulted in registration, the number of submissions is provided in square brackets [#].

Antipsychotics, antidepressants and analgesics

Amisulpride

Aripiprazole

Atomoxetine (as hydrochloride)

Levodopa / carbidopa / entacapone

Cisatracurium besylate [2]

Donepezil (as hydrochloride)

Gabapentin

Levetiracetam

Metoclopramide (as hydrochloride)

Olanzapine

Pregabalin [2]

Quetiapine (as fumarate) [2]

Remifentanil (as hydrochloride)

Rivastigmine

Rizatriptan (as benzoate)

Ursodeoxycholic acid

Agents for respiratory and endocrine disorders

Alendronate acid (as sodium) / colecalciferol / calcium carbonate

Bimatoprost

Dorzolamide (as hydrochloride) / timolol (as maleate)

Fluorouracil

Glimepiride

Latanoprost / timolol (as maleate)

Mometasone furoate (as monohydrate) [2]

Montelukast (as sodium)

Olopatadine (as hydrochloride)

Anti-infectives and vaccines

Adrenaline [2]

Amoxicillin (as trihydrate) / clavulanic acid (as potassium)

Azithromycin (as dehydrate)

Caspofungin (as acetate) [3]

Entecavir (as monohydrate) [6]

Linezolid [6]

Nevirapine

Valganciclovir (as hydrochloride) [3]

Voriconazole [4]

Antineoplastic and haematological agents

Azacitidine

Imatinib (as mesylate) [3]

Irinotecan (as hydrochloride) / trihydrate

Letrozole

Oxaliplatin

Pemetrexed (as disodium) [2]

Tropisetron (as hydrochloride)

Cardiovascular agents

Amiodarone (as hydrochloride)

Bivalirudin (as trifluoroacetate) [2]

Clonidine (as hydrochloride)

Ezetimibe [3]

Fenofibrate

Flumazenil [2]

Olmesartan medoxomil

Olmesartan medoxomil / amlodipine (as besylate)

Perindopril arginine / amlodipine (as besylate)

Rosuvastatin (as calcium)

Valsartan / hydrochlorothiazide

Biosimilar prescription medicines

A biosimilar medicine is a version of an already registered biological prescription medicine, which is referred to as the reference medicine. These medicines are referred to elsewhere as similar biological medicinal products (in Europe), similar biotherapeutic products (by the WHO) and subsequent entry products (in Canada). Both the biosimilar and its reference medicine will have core similar characteristics such as physicochemical, biological, immunological, efficacy and safety (demonstrated using comprehensive comparability studies). Most biosimilar medicines are likely to contain biotechnology-derived proteins as the active substance.

etanercept (rch)

Etanercept injections are indicated for the treatment of the following conditions:

Adults (≥ 18 years)

Rheumatoid Arthritis

Active, adult rheumatoid arthritis in patients who have had inadequate response to one or more disease-modifying antirheumatic drugs. Can be used in combination with methotrexate.

Severe, active rheumatoid arthritis in adults to slow progression of disease-associated structural damage in patients at high risk of erosive disease.

Psoriatic Arthritis

The signs and symptoms of active and progressive psoriatic arthritis in adults, when the response to previous disease-modifying anti-rheumatic therapy has been inadequate. Etanercept has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

Plaque Psoriasis

Adult patients with moderate to severe chronic plaque psoriasis, who are candidates for phototherapy or systemic therapy.

Ankylosing Spondylitis

The signs and symptoms of active ankylosing spondylitis in adults.

Non-radiographic Axial Spondyloarthritis

Treatment of adults with active* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or MRI change who have had an inadequate response to NSAIDs.

*Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥ 4.

Samsung Bioepis AU Pty Ltd	*22 July 2016*	*Solution for injection autoinjector*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.

infliximab

Infliximab injections are indicated for the treatment of the following conditions:

Rheumatoid Arthritis in adults

In combination with methotrexate, indicated for the reduction of signs and symptoms and prevention of structural joint damage (erosions and joint space narrowing) in:

- patients with active disease despite treatment with methotrexate
- patients with active disease who have not previously received methotrexate

Should be given in combination with methotrexate. Efficacy and safety in rheumatoid arthritis have been demonstrated only in combination with methotrexate.

Ankylosing Spondylitis

Indicated for the reduction of signs and symptoms and improvement in physical function in patients with active disease.

Psoriatic arthritis

Indicated for the treatment of the signs and symptoms, as well as for the improvement in physical function in adult patients with active and progressive psoriatic arthritis who have responded inadequately to disease-modifying anti-rheumatic drug therapy. May be administered in combination with methotrexate.

Psoriasis

Indicated for the treatment of adult patients with moderate to severe plaque psoriasis for whom phototherapy or conventional systemic treatments have been inadequate or are inappropriate. Safety and efficacy beyond 12 months have not been established.

Crohn's Disease in Adults and in Children and adolescents (6 to 17 years)

Indicated for the treatment of moderate to severe Crohn's disease, to reduce the signs and symptoms and to induce and maintain clinical remission in patients who have an inadequate response to conventional therapies.

Refractory Fistulising Crohn's Disease

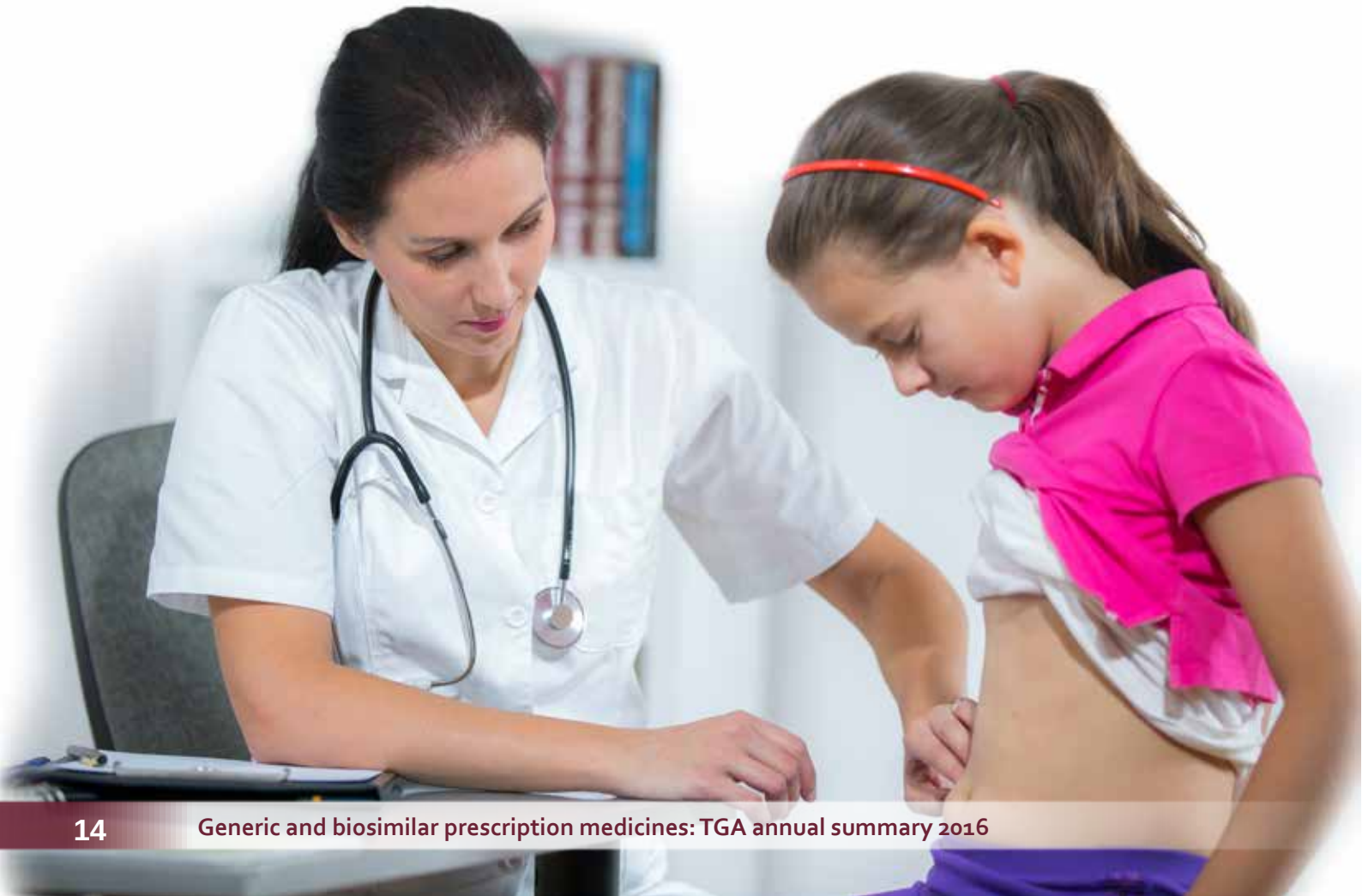
Indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients.

Ulcerative colitis in Adults and in Children and adolescents (6 to 17 years)

Indicated for the treatment of moderately severe to severe active ulcerative colitis in patients who have had an inadequate response to conventional therapy.

Samsung Bioepis AU Pty Ltd	*28 November 2016*	*Powder for injection*

For the full approved indications see: https://www.tga.gov.au/australian-register-therapeutic-goods.



ISSN: 2204-9843 (print)
ISSN: 2207-6840 (online)

Copyright

© Commonwealth of Australia 2017

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the Copyright Act 1968 or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to tga.copyright@tga.gov.au.

Department of Health
Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au • Phone: 1800 020 653 • Fax: 02 6232 8605

https://www.tga.gov.au