



This form, when completed, will be classified as 'For official use only'.

For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

## Special Access Scheme – Category C

### Important information

**Email completed form to [SAS@health.gov.au](mailto:SAS@health.gov.au) (preferred) or fax to 02 6232 8112.**

The therapeutic goods, indications and health practitioners that are authorised to supply these goods for the particular indication through the SAS Category C pathway are on the **back of this form**.

### Privacy information

For general privacy information, go to <https://www.tga.gov.au/privacy>.

The TGA is collecting personal information in this form in order to:

- verify the supply of the therapeutic goods occurred in accordance with the applicable Instrument
- The personal information of the health practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or health practitioner registration.

**Do not provide the name of the patient. Only provide the patient's initials and other information as requested on this form. Please complete the form clearly and in full. Forms cannot be processed if incomplete or illegible. PLEASE PRINT IN BLOCK LETTERS.**

### Patient details (do not provide the patient's name)

<b>Patient initials</b>	<b>Gender</b> Male <input type="checkbox"/> Female <input type="checkbox"/> Intersex/Indeterminate/Unspecified <input type="checkbox"/>	<b>DOB</b>	<b>MRN (if applicable)</b>
<b>Diagnosis(es)</b>			<b>Previous SAS No. (if applicable)</b>

### Product details

**SAS Category C code** (see back of form)

Note: for a valid notification to be accepted a code **MUST** be entered e.g. tick M, B or D and insert the code number

Medicine  Biological  Device  Code Number:

Trade name (for medicines only)

Expected duration of treatment

### Prescribing health practitioner details

<b>First name</b>	<b>Surname</b>
<b>AHPRA ID</b>	<b>Health practitioner type</b>
<b>Email</b>	<b>Speciality</b>
<b>Fax</b>	<b>Phone</b>
<b>Principal practice address</b>	

### Submitter details (if different)

<b>Business or practice name</b> (e.g. Pharmacy name)	
<b>First name</b>	<b>Surname</b>
<b>Health practitioner type</b>	<b>Fax</b>
<b>Email</b>	<b>Phone</b>
<b>Preferred Contact:</b> <input type="checkbox"/> Prescribing health practitioner <input type="checkbox"/> Submitter	<b>Preferred contact method:</b> Email <input type="checkbox"/> Fax <input type="checkbox"/> Phone <input type="checkbox"/>

Please note that the giving of false or misleading information is an offence under the *Criminal Code Act 1995* and that penalties may be imposed.

<b>Submitter's signature</b>	<b>Date of supply</b>
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Please only send the first page of this form to the TGA.

## SAS Category C codes

### Medicines

Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)	Code
Allergens – multiple, various (including control solutions), Drops, Skin prick	Confirmation of suspected allergic reactions	Medical Practitioner	M19
Allergens – multiple, various (including control solutions), Drops, Intradermal	Confirmation of suspected allergic reactions	Medical Practitioner	M28
Amifampridine (3,4-diaminopyridine), Tablet, Oral	Treatment of Lambert-Eaton Myasthenic Syndrome	Medical Practitioner	M91
Betaxolol 0.25% (preservative free), Eye drops, Ophthalmic	Treatment of elevated intraocular pressure where other treatments are inappropriate	Medical Practitioner	M92
Bifidobacterium bifidum & Lactobacillus acidophilus, Capsule, Oral	Prevention of necrotising enterocolitis	Medical Practitioner	M93
Bismuth subcitrate, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M7
Buspirone, Tablet, Oral	Treatment of generalised anxiety disorders	Medical Practitioner	M17
Calcitriol, Liquid, Oral	Prevention of hypophosphatemic rickets in children	Medical Practitioner	M29
Calcitriol, Liquid, Oral	Treatment of hypoparathyroidism (with severe hypocalcaemia)	Medical Practitioner	M30
Cholecalciferol, Capsule, Oral	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner	M26
Cholecalciferol, Injection, Intramuscular	Treatment of severe vitamin D deficiency and prevention of osteoporosis	Medical Practitioner	M27
Cinnarizine, Tablet, Oral	Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease)	Medical Practitioner	M13
Clobetasol propionate 0.05%, Cream, Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner	M94
Clobetasol propionate 0.05%, Lotion, Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner	M95
Clobetasol propionate 0.05%, Ointment, Topical	Treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed	Medical Practitioner	M96
Clofazimine, Capsule, Oral	Treatment of Leprosy	Medical Practitioner	M31
Clofazimine, Capsule, Oral	Treatment of granulomatous cheilitis	Medical Practitioner	M32
Clofazimine, Capsule, Oral	Treatment of Melkersson Rosenthal Syndrome	Medical Practitioner	M33
Clofazimine, Capsule, Oral	Treatment of confirmed mycobacterium avium paratuberculosis in immunocompromised patients recommended by an infectious disease specialist	Medical Practitioner	M34
Clofazimine, Capsule, Oral	Treatment of erythema nodosum leprosum	Medical Practitioner	M35
Cyclopentolate, 0.2%, & phenylephrine, 1%, Eye drops, Ophthalmic	Production of mydriasis.	Medical Practitioner	M20
Cyclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic	Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca.	Medical Practitioner	M12
Deflazacort, Tablet, Oral	Treatment of Duchenne muscular dystrophy	Medical Practitioner	M116
Dehydrated ethanol (alcohol) 96% - 100%, Ampoule, Topical	Treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure)	Medical Practitioner	M36
Diazoxide, Capsule, Oral	Treatment of hypoglycaemia	Medical Practitioner	M40
Diazoxide, Capsule, Oral	Treatment of hyperinsulinaemia	Medical Practitioner	M41
Diazoxide, Capsule, Oral	Treatment of Beckwith-Weiderman Syndrome	Medical Practitioner	M42
Diazoxide, Capsule, Oral	Treatment of insulinoma	Medical Practitioner	M43
Diazoxide, Suspension, Oral	Treatment of hypoglycaemia	Medical Practitioner	M44
Diazoxide, Suspension, Oral	Treatment of hyperinsulinaemia	Medical Practitioner	M45

Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)	Code
Diazoxide, Suspension, Oral	Treatment of Beckwith-Weiderman Syndrome	Medical Practitioner	M46
Diazoxide, Suspension, Oral	Treatment of insulinoma	Medical Practitioner	M47
Diazoxide, Tablet, Oral	Treatment of hypoglycaemia	Medical Practitioner	M48
Diazoxide, Tablet, Oral	Treatment of hyperinsulinaemia	Medical Practitioner	M49
Diazoxide, Tablet, Oral	Treatment of Beckwith-Weiderman Syndrome	Medical Practitioner	M50
Diazoxide, Tablet, Oral	Treatment of insulinoma	Medical Practitioner	M51
Diflunisal, Tablet, Oral	Treatment of amyloidosis	Medical Practitioner	M97
Dimethyl sulfoxide (DMSO), Solution, Intravesical	Symptomatic relief of interstitial cystitis	Medical Practitioner	M52
Flunarizine, Capsule, Oral	Treatment of vestibular disorders	Medical Practitioner	M53
Flunarizine, Tablet, Oral	Treatment of vestibular disorders	Medical Practitioner	M11
Furazolidone, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M23
Glycopyrronium bromide, Tablet, Oral	Treatment of excessive salivation in patients with neurological conditions	Medical Practitioner	M25
Hyoscine hydrobromide, Patch, Transdermal	Treatment of excessive salivation	Medical Practitioner	M56
Hypertonic sodium chloride, 5% Eye ointment, Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner	M15
Hypertonic sodium chloride, 5%, Eye drops, Ophthalmic	Temporary relief of corneal oedema (hypertonicity)	Medical Practitioner	M14
Indigo Carmine, Injection, Intravenous	For intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures	Medical Practitioner	M57
Indocyanine green dye, Injection, Intravenous	For intra-operative diagnostic use	Medical Practitioner	M58
Insulin Neutral-concentrated (Humulin R U-500), Solution for injection, Subcutaneous	Treatment of diabetes	Medical Practitioner	M98
Ketotifen, Tablet, Oral	Treatment of allergic conditions	Medical Practitioner	M59
Levofloxacin, Tablet, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M99
Levomepromazine, Tablet, Oral	Treatment of nausea and vomiting	Medical Practitioner	M100
Levomepromazine, Tablet, Oral	Treatment of agitation	Medical Practitioner	M101
Levomepromazine, Injection, Subcutaneous	Treatment of nausea and vomiting	Medical Practitioner	M102
Levomepromazine, Injection, Subcutaneous	Treatment of agitation	Medical Practitioner	M103
Lorazepam, Injection, Parenteral	Treatment of acute severe behavioural episodes in the hospital setting	Medical Practitioner	M104
Melatonin, Capsule, Oral	Treatment of sleep disorders	Medical Practitioner	M6
Melatonin, Immediate Release Tablet, Oral	Treatment of sleep disorders	Medical Practitioner	M5
Melatonin, Lozenge, Oral	Treatment of sleep disorders	Medical Practitioner	M62
Melatonin, Modified release tablet, Oral	Treatment of sleep disorders	Medical Practitioner	M4
Melatonin, Syrup, Oral	Treatment of sleep disorders	Medical Practitioner	M3
Mexiletine, Tablet, Oral	Treatment of ventricular arrhythmia	Medical Practitioner	M105
Mexiletine, Tablet, Oral	Treatment of myotonic disorders	Medical Practitioner	M106
Mexiletine, Capsule, Oral	Treatment of ventricular arrhythmia	Medical Practitioner	M107
Mexiletine, Capsule, Oral	Treatment of myotonic disorders	Medical Practitioner	M108
Midodrine, Tablet, Oral	Treatment of severe orthostatic hypotension	Medical Practitioner	M63
Moxifloxacin 0.5%, Eye drops, Ophthalmic	Treatment of refractory bacterial conjunctivitis	Medical Practitioner	M109
Nadolol, Tablet, Oral	Treatment of ventricular tachycardia	Medical Practitioner	M110
Nadolol, Tablet, Oral	Treatment of long QT syndrome	Medical Practitioner	M111

Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)	Code
Natamycin 5%, Eye drops, Ophthalmic	Treatment of refractory fungal blepharitis, conjunctivitis or keratitis	Medical Practitioner	M112
Nitazoxanide, Suspension, Oral	Treatment of giardiasis	Medical Practitioner	M64
Nitazoxanide, Suspension, Oral	Treatment of cryptosporidiosis	Medical Practitioner	M65
Nitazoxanide, Suspension, Oral	Treatment of blastocystis	Medical Practitioner	M66
Nitazoxanide, Tablet, Oral	Treatment of giardiasis	Medical Practitioner	M67
Nitazoxanide, Tablet, Oral	Treatment of cryptosporidiosis	Medical Practitioner	M68
Nitazoxanide, Tablet, Oral	Treatment of blastocystis	Medical Practitioner	M69
Paromomycin, Capsule, Oral	Antiprotozoal treatment of blastocystis hominis	Medical Practitioner	M70
Paromomycin, Capsule, Oral	Antiprotozoal treatment of dientamoeba fragilis	Medical Practitioner	M71
Paromomycin, Capsule, Oral	Antiprotozoal treatment of entamoeba histolytica	Medical Practitioner	M72
Paromomycin, Capsule, Oral	Antiprotozoal treatment of parasite infection	Medical Practitioner	M73
Pimozide, Tablet, Oral	Treatment of schizophrenia	Medical Practitioner	M74
Pimozide, Tablet, Oral	Treatment of chronic psychosis	Medical Practitioner	M75
Pimozide, Tablet, Oral	Treatment of Tourette syndrome	Medical Practitioner	M76
Pristinamycin, Tablet, Oral	Treatment of confirmed Methicillin-resistant Staphylococcus aureus and Vancomycin-resistant enterococci infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis.	Medical Practitioner	M77
Pristinamycin, Tablet, Oral	Treatment of refractory or resistant mycoplasma genitalium infections	Medical Practitioner	M78
Pristinamycin, Tablet, Oral	Treatment of other infections as prescribed by an infectious disease specialist	Medical Practitioner	M79
Pyrazinamide, Tablet, Oral	Treatment of tuberculosis	Medical Practitioner	M22
Riboflavin, 0.1% in 20% dextran, Eye Drops, Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus.	Medical Practitioner	M9
Riboflavin, 0.1% in sodium chloride , Eye Drops, Ophthalmic	Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus.	Medical Practitioner	M10
Ripasudil 0.4%, Eye drops, Ophthalmic	Treatment of refractory corneal oedema or Refractory glaucoma	Medical Practitioner	M117
Ripasudil 0.4%, Eye drops, Ophthalmic	Treatment of refractory glaucoma	Medical Practitioner	M118
Rufinamide, Tablet, Oral	Adjunct treatment of seizures associated with Lennox-Gastaut syndrome in patients over 4 years of age	Medical Practitioner	M80
Sodium benzoate, Tablet, Oral	Treatment of urea cycle disorders	Medical Practitioner	M113
Stiripentol, Capsule, Oral	Treatment of intractable epilepsy	Medical Practitioner	M81
Stiripentol, Capsule, Oral	Treatment of Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	Medical Practitioner	M82
Stiripentol, Sachet, Oral	Treatment of intractable epilepsy	Medical Practitioner	M83
Stiripentol, Sachet, Oral	Treatment of Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	Medical Practitioner	M84
Stiripentol, Tablet, Oral	Treatment of intractable epilepsy	Medical Practitioner	M85
Stiripentol, Tablet, Oral	Treatment of Dravet syndrome (severe myoclonic epilepsy of infancy (SMEI))	Medical Practitioner	M86
Tacrolimus 0.03%, Ointment, Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children	Medical Practitioner	M119
Tacrolimus 0.1%, Ointment, Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults	Medical Practitioner	M87

Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)	Code
Tetracycline, Capsule, Oral	Treatment of resistant Helicobacter Pylori infection	Medical Practitioner	M8
Tetracycline, Tablet, Oral	Treatment of resistant Helicobacter pylori infection	Medical Practitioner	M88
Tizanidine, Capsule, Oral	Treatment of spasticity where other treatments have failed	Medical Practitioner	M114
Tizanidine, Tablet, Oral	Treatment of spasticity where other treatments have failed	Medical Practitioner	M115
Tick-borne Encephalitis Vaccine, Injection, Intramuscular	Prevention of tick-borne encephalitis	Medical Practitioner	M89
Triamcinolone acetonide, Suspension for Injection, Ophthalmic	Treatment of inflammatory ocular conditions	Medical Practitioner	M1
Triamcinolone acetonide, Suspension for Injection, Ophthalmic	Visualisation during vitrectomy	Medical Practitioner	M2
Verteporfin Powder for injection, intravenous infusion	Photosensitisation for photodynamic therapy	Medical Practitioner	M21
Yttrium-90 (Y-90) Citrate, Injection, Intraarticular	Radiosynovectomy treatment	Medical Practitioner	M90

### Biologicals

Product Name, Active ingredient(s), Route of administration	Indication	Authorised Health Practitioner(s)	Code
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Graft protection and containment	Dental Practitioner	B10
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Flap extender to achieve primary closure	Dental Practitioner	B11
AlloDerm GBR RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B52
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Root coverage	Dental Practitioner	B12
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Gingival augmentation	Dental Practitioner	B13
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue ridge augmentation	Dental Practitioner	B14
AlloDerm RTM (human skin tissue matrix), Intra-oral graft	Soft tissue augmentation around implants	Dental Practitioner	B15
Amniotic Membrane, Ophthalmic	Ocular conditions	Medical practitioner	B30
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Extraction socket grafting	Dental Practitioner	B16
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental Practitioner	B17
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Bone augmentation around implants	Dental Practitioner	B18
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Bony defects	Dental Practitioner	B19
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Composite grafting	Dental Practitioner	B20
Grafton DBM Matrix (demineralised human bone tissue), Intra-oral graft	Filling of periodontal defects	Dental Practitioner	B21
MinerOss Cancellous (human bone allograft), Intra-oral graft	Ridge and sinus augmentation	Dental practitioner	B37
MinerOss Cancellous (human bone allograft), Intra-oral graft	Extraction socket grafting	Dental practitioner	B38
MinerOss Cancellous (human bone allograft), Intra-oral graft	Bony defects	Dental practitioner	B39
MinerOss Cortical (human bone allograft), Intra-oral graft	Ridge and sinus augmentation	Dental practitioner	B40
MinerOss Cortical (human bone allograft), Intra-oral graft	Extraction socket grafting	Dental practitioner	B41

Product Name, Active ingredient(s), Route of administration	Indication	Authorised Health Practitioner(s)	Code
MinerOss Cortical (human bone allograft), Intra-oral graft	Bony defects	Dental practitioner	B42
Puros Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental practitioner	B46
Puros Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Extraction socket grafting	Dental practitioner	B47
Puros Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Bony defects	Dental practitioner	B48
Puros Cortical Particulate Allograft (human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental practitioner	B49
Puros Cortical Particulate Allograft (human bone tissue), Intra-oral graft	Extraction socket grafting	Dental practitioner	B50
Puros Cortical Particulate Allograft (human bone tissue), Intra-oral graft	Bony defects	Dental practitioner	B51
Tutoplast Pericardium (sterilised human tissue allograft), Topical	Soft tissue graft	Medical Practitioner	B29

### Medical Devices

Product name, Manufacturer Name, Description (including manufacturer's intended purpose and any variant details)	Indication	Authorised Health Practitioner(s)	Code
Biodesign Enterocutaneous Fistula Plug	For repair of enterocutaneous fistulae	Medical practitioner	D6
BlastGen (Product No: 1205)	Culture of embryos from the 4-8 cell stage through to the blastocyst stage	Medical practitioner	D2
BlastGen (Product No: 1205)	Embryo transfer	Medical practitioner	D10
CollaCote Dressing	For haemostasis	Dental practitioner	D7
CollaCote Dressing	To protect the wound surface during dental procedures	Dental practitioner	D24
CollaPlug Absorbable Collagen Wound Dressing	For haemostasis	Dental practitioner	D8
CollaPlug Absorbable Collagen Wound Dressing	To protect the wound surface during dental procedures	Dental practitioner	D25
CollaTape Absorbable Collagen	For haemostasis	Dental practitioner	D9
CollaTape Absorbable Collagen	To protect the wound surface during dental procedures	Dental practitioner	D26
EmbryoGen V2 (Product No: 1204)	Culture of human embryos until the 2-8 cell stage	Medical practitioner	D3
EmbryoGen V2 (Product No: 1204)	Embryo transfer at day 2 or 3	Medical practitioner	D11
EmbryoGen & BlastGen (Product No: 1206)	Culture of embryos until the 2-8 cell stage (Embryogen) and culture of embryos from the 4-8 cell stage through to the blastocyst stage	Medical practitioner	D4
EmbryoGen & BlastGen (Product No: 1206)	Embryo transfer	Medical practitioner	D12
EmbryoGen (Product No: 1203)	Fertilisation and culture until the 2-8 cell stage	Medical Practitioner	D5
EmbryoGen (Product No: 1203)	Embryo transfer at day 2 or 3	Medical Practitioner	D13
Endotine Forehead	For use in subperiosteal browplasty surgery	Medical practitioner	D14
Endotine Midface	For use in subperiosteal midface suspension surgery	Medical Practitioner	D15
GM508 CultActive	For investigation of fertilization failure after previous ICSI-cycles	Medical Practitioner	D16
Ilex Skin Protectant	For use on a variety of dermal wounds and stomal irritations as a topical skin barrier	Medical Practitioner; Nurse Practitioner	D17

Product name, Manufacturer Name, Description (including manufacturer's intended purpose and any variant details)	Indication	Authorised Health Practitioner(s)	Code
Jupiter Sternal Protection Device	For use following median sternotomy incisions to add a protective layer over the entire cut surfaces of the sternal bone	Medical Practitioner	D18
Matriderm® Acellular Dermal Substitute	For the treatment of all deep dermal defects in combination with a split-thickness skin graft	Medical Practitioner	D19
Pro Osteon® Bone Graft Substitute 200R	For use as a bone graft substitute only for bony voids or gaps that are not intrinsic to the stability of the bony structure	Medical Practitioner; Dental Practitioner	D20
Pro Osteon® Bone Graft Substitute 500R	For use as a bone graft substitute only for voids or gaps that are not intrinsic to the stability of the bony structure	Medical Practitioner	D21
Quintip Individual Skin Test System	For allergy skin testing using puncture to apply the test extract	Medical practitioner	D22
Vicryl tape V152G	For the approximation of parenchymal tissue	Medical practitioner	D23
Vicryl tape V152G	For reconstruction of the collateral ligaments of the knee	Medical practitioner	D27

\* These will only be included if clinically relevant, for example where multiple dosage forms and/or routes of administration are known to exist and are used for substantially different indications these will be specified.