



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 (minimum of 3 (three) identifiers required)

<b>Gender</b> Male <input type="checkbox"/> Female <input type="checkbox"/> Intersex/Indeterminate/Unspecified <input type="checkbox"/>	<b>Patient initials</b>	<b>DOB</b>	<b>MRN (if applicable)</b>
<b>Diagnosis(es) or Medical Condition(s)</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

M  B  D  Code Number:

Trade name (for medicines only)

Expected quantity<sup>j</sup> required for treatment and/or duration

## Treating health practitioner details

<b>First name</b>	<b>Surname</b>
<b>AHPRA ID</b>	<b>Health practitioner<sup>ii</sup> 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"/> Treating 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
Bismuth subcitrate, Tablet, Oral	Treatment of resistant <i>Helicobacter Pylori</i> 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
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
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
Dexamethasone, 0.1%, Eye drops, Ophthalmic	Treatment of non-infected, steroid responsive, inflammatory conditions of the eye	Medical Practitioner	M16
Dexamethasone, Implant, Intravitreal	Treatment of macular oedema	Medical Practitioner	M37
Dexamethasone, Implant, Intravitreal	Treatment of retinal vein occlusion	Medical Practitioner	M38
Dexamethasone, Implant, Intravitreal	Treatment of non-infectious uveitis	Medical Practitioner	M39
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
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

Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)	Code
Diazoxide, Tablet, Oral	Treatment of insulinoma	Medical Practitioner	M51
Dimethyl sulfoxide (DMSO), Solution, Intravesical	Symptomatic relief of interstitial cystitis	Medical Practitioner	M52
Flunarizine, Capsule, Oral	Prophylactic treatment of migraine	Medical Practitioner	M53
Flunarizine, Tablet, Oral	Prophylactic treatment of migraine	Medical Practitioner	M11
Fosfomycin, Sachet, Oral	Treatment of uncomplicated urinary tract infections	Medical Practitioner	M54
Fosfomycin, Sachet, Oral	Treatment of pseudomonas aeruginosa infections in Cystic Fibrosis patients	Medical Practitioner	M55
Furazolidone, Tablet, Oral	Treatment of resistant <i>Helicobacter Pylori</i> 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
Ketotifen, Tablet, Oral	Treatment of allergic conditions	Medical Practitioner	M59
Mannitol, Capsule, Inhalation	Treatment of bronchiectasis	Medical Practitioner	M60
Mannitol, Capsule, Inhalation	Treatment of cystic fibrosis (adjunct to dornase alpha or for patients intolerant to dornase alpha)	Medical Practitioner	M61
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
Midodrine, Tablet, Oral	Treatment of severe orthostatic hypotension	Medical Practitioner	M63
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 <i>blastocystis hominis</i>	Medical Practitioner	M70
Paromomycin, Capsule, Oral	Antiprotozoal treatment of <i>dientamoeba fragilis</i>	Medical Practitioner	M71
Paromomycin, Capsule, Oral	Antiprotozoal treatment of <i>entamoeba histolytica</i>	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 <i>Staphylococcus aureus</i> and Vancomycin-resistant <i>enterococci</i> infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis.	Medical Practitioner	M77

Active ingredient(s), Dosage Form, Release mechanism*, Route of administration*	Indication(s)	Authorised Health Practitioner(s)	Code
Pristinamycin, Tablet, Oral	Treatment of refractory or resistant <i>mycoplasma genitalium</i> 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
Rufinamide, Tablet, Oral	Adjunct treatment of seizures associated with Lennox-Gastaut syndrome in patients over 4 years of age	Medical Practitioner	M80
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 0.1%, Ointment, Topical	Treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis in adults	Medical Practitioner	M87
Tetracycline, Capsule, Oral	Treatment of resistant <i>Helicobacter Pylori</i> infection	Medical Practitioner	M8
Tetracycline, Tablet, Oral	Treatment of resistant <i>Helicobacter pylori</i> infection	Medical Practitioner	M88
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

Product Name, Active ingredient(s), Route of administration	Indication	Authorised Health Practitioner(s)	Code
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 & Cancellous (human bone allograft), Intra-oral graft	Ridge and sinus augmentation	Dental practitioner	B34
MinerOss Cortical & Cancellous (human bone allograft), Intra-oral graft	Extraction socket grafting	Dental practitioner	B35
MinerOss Cortical & Cancellous (human bone allograft), Intra-oral graft	Bony defects	Dental practitioner	B36
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
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
Puros Cortico-Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Ridge and sinus augmentation	Dental practitioner	B43
Puros Cortico-Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Extraction socket grafting	Dental practitioner	B44
Puros Cortico-Cancellous Particulate Allograft (human bone tissue), Intra-oral graft	Bony defects	Dental practitioner	B45
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
BlastGen (Product No: 1205)	BlastGen is for the culture of embryos from the 4-8 cell stage through to the blastocyst stage embryo transfer.	Medical practitioner	D2
EmbryoGen V2 (Product No: 1204)	EmbryoGen is for culture of human embryos until the 2-8 cell stage embryo transfer at day 2 or 3. <i>NB: use of EmbryoGen (Product No: 1204) does not include fertilisation.</i>	Medical practitioner	D3
EmbryoGen & BlastGen (Product No: 1206)	Embryogen is suitable for the culture of embryos until the 2-8 cell stage culture of embryos from the 4-8 cell stage through to the blastocyst stage.	Medical practitioner	D4
EmbryoGen (Product No: 1203)	EmbryoGen is for fertilisation and culture until the 2-8 cell stage. EmbryoGen can also be used for embryo transfer at day 2 or 3. This product is for IVF treatment of women, whether the cause of infertility is male or female. Recommended for patients who have experienced: <ul style="list-style-type: none"> <li>• Recurrent clinical and biochemical pregnancy loss</li> <li>• Recurrent implantation failure</li> <li>• Unexplained infertility</li> </ul>	Medical Practitioner	D5

\* 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.

<sup>i</sup> For substances captured by the Customs (Prohibited Imports) Regulations 1956 the quantity must be provided.

<sup>ii</sup> The health practitioner type is any of the following: Medical practitioner; ATSI health practitioner; dentist; radiographer; nurse; midwife; occupational therapist; optometrist; pharmacist ; podiatrist; psychologist.