|  |  |  |  |
| --- | --- | --- | --- |
| Therapeutic Goods Administration |  | | |
|  | TGA use only |  |
|  |  |  |

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 medical 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)

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient initials** | **Gender**  Male  Female  Intersex/Indeterminate/Unspecified | **DOB** | **MRN (if applicable)** |
| **Diagnosis(es) or Medical Condition(s)** | | | **Previous SAS No.** (if applicable) |

## Product details

### Medicine/biological/medical device

|  |  |
| --- | --- |
| **SAS Category C code** (see back of form) | **Trade name** (for medicines only) |
| **Expected quantity**[[1]](#endnote-1) **required for treatment and/or duration** | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Treating health practitioner details  |  |  | | --- | --- | | **First name** | **Surname** | | **AHPRA ID** | **Health practitioner**[[2]](#endnote-2) **type** | | **Email** | **Speciality** | | **Fax** | **Phone** | | **Principle practice address** | | | Submitter details (if different)  |  |  | | --- | --- | | **Business or practice name** (e.g. Pharmacy name) | | | **First name** | **Surname** | | **Health practitioner type** | **Fax** | | **Email** | **Phone** | | **Preferred Contact:**  Treating health practitioner  Submitter | **Preferred contact method:**  Email  Fax  Phone | |

|  |  |
| --- | --- |
| **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.** | |
| **Submitter’s signature** | **Date** |

**Please only send the first page of this form to the TGA.**

## SAS Category C codes

## Medicines <<https://www.legislation.gov.au/Details/F2017L00859>>

|  |  |  |  |
| --- | --- | --- | --- |
| Code | Active ingredient(s), Dosage Form, Release mechanism\*, Route of administration\* | Indication(s) | Authorised Health Practitioner(s) |
| M1 | Triamcinolone acetonide, Suspension for Injection, ophthalmic | Treatment of inflammatory ocular conditions | Medical Practitioner |
| M2 | Triamcinolone acetonide, Suspension for Injection, ophthalmic | Visualization during vitrectomy. | Medical Practitioner |
| M3 | Melatonin, Syrup, Oral | Treatment of sleep disorders | Medical Practitioner |
| M4 | Melatonin, Modified release tablet, oral | Treatment of sleep disorders | Medical Practitioner |
| M5 | Melatonin, Tablet, Oral | Treatment of sleep disorders | Medical Practitioner |
| M6 | Melatonin, Capsule, Oral | Treatment of sleep disorders | Medical Practitioner |
| M7 | Bismuth subcitrate, Tablet, Oral | Treatment of resistant *Helicobacter Pylori* infection | Medical Practitioner |
| M8 | Tetracycline, Capsule, Oral | Treatment of resistant *Helicobacter Pylori* infection | Medical Practitioner |
| M9 | 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 |
| M10 | Riboflavin, 0.1% (in other diluents), Eye Drops, Ophthalmic | Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment for progressive keratoconus. | Medical Practitioner |
| M11 | Flunarizine, Tablet, Oral | Prophylactic treatment of migraine | Medical Practitioner |
| M12 | Cyclosporin, 0.05%, Eye drops, Emulsion, Ophthalmic | Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca. | Medical Practitioner |
| M13 | Cinnarizine, Tablet, Oral | Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease). | Medical Practitioner |
| M14 | Hypertonic sodium chloride, 5%, Eye drops, Ophthalmic | Temporary relief of corneal oedema (hypertonicity) | Medical Practitioner |
| M15 | Hypertonic sodium chloride, Eye drops, Ophthalmic | Temporary relief of corneal oedema (hypertonicity) | Medical Practitioner |
| M16 | Dexamethasone, 0.1%, Eye drops, Ophthalmic | Treatment of non-infected, steroid responsive, inflammatory conditions of the eye | Medical Practitioner |
| M17 | Buspirone hydrochloride, Tablet, Oral | Treatment of generalised anxiety disorders | Medical Practitioner |
| M18 | Paromomycin, Capsule, Oral | Antiprotozoal treatment of the following amoebic infections:- *blastocystis hominis, dientomoeba fragilis, entamoeba histolytica* and parasite infection | Medical Practitioner |
| M19 | Allergens – multiple, various | Confirmation of suspected allergic reactions | Medical Practitioner |
| M20 | Cyclopentolate, 0.2%, & phenylephrine, 1%, Eye drops, Ophthalmic | Production of mydriasis. | Medical Practitioner |
| M21 | Verteporfin Powder for injection, intravenous infusion | Photosensitisation for photodynamic therapy | Medical Practitioner |
| M22 | Pyrazinamide, Tablet, Oral | Treatment of resistant tuberculosis | Medical Practitioner |
| M23 | Furazolidone, Tablet, Oral | Treatment of resistant *Helicobacter Pylori* infection | Medical Practitioner |
| M24 | Pristinamycin, Tablet, Oral | Treatment of confirmed Methicillin-resistant *Staphylococcus* aureus and Vancomycin-resistant enterococcus infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis. Treatment of other infections as prescribed by an infectious disease specialist | Medical Practitioner |
| M25 | Glycopyrronium bromide, Tablet, Oral | Treatment of excessive salivation in patients with neurological conditions | Medical Practitioner |
| M26 | Cholecalciferol, Capsule, Oral | Treatment of severe vitamin D deficiency and prevention of osteoporosis | Medical Practitioner |
| M27 | Cholecalciferol, Intramuscular Injection | Treatment of severe vitamin D deficiency and prevention of osteoporosis | Medical Practitioner |

## Biologicals <<https://www.legislation.gov.au/Details/F2017L00868>>

|  |  |  |  |
| --- | --- | --- | --- |
| Code | Product Name, Active ingredient(s), Route of administration | Indication | Authorised Health Practitioner(s) |
| B1 | MinerOss Cortical & Cancellous Chips (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B2 | MinerOss Block Allograft (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B3 | MinerOss Cancellous (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B4 | MinerOss Cortical (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B5 | MinerOss X Cancellous (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B6 | MinerOss X Cortical (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B7 | MinerOss X Syringe (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B8 | MinerOss X Collagen (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B9 | MinerOss XP Cancellous (anorganic bovine bone), Oral-maxillofacial | Calcium source for particulate bone grafts | Dental Practitioner |
| B10 | AlloDerm GBR RTM (human skin tissue matrix), Oral-maxillofacial | Graft protection and containment | Medical Practitioner  Dental Practitioner |
| B11 | AlloDerm GBR RTM (human skin tissue matrix), Oral-maxillofacial | Flap extender to achieve primary closure | Medical Practitioner  Dental Practitioner |
| B12 | AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial | Root coverage | Dental Practitioner |
| B13 | AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial | Gingival augmentation | Dental Practitioner |
| B14 | AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial | Soft tissue ridge augmentation | Dental Practitioner |
| B15 | AlloDerm RTM (human skin tissue matrix), Oral-maxillofacial | Soft tissue augmentation around implants | Dental Practitioner |
| B16 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Extraction socket grafting | Dental Practitioner |
| B17 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Ridge and sinus augmentation | Dental Practitioner |
| B18 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Bone augmentation around implants | Dental Practitioner |
| B19 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Bony defects | Dental Practitioner |
| B20 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Composite grafting with appropriate MinerOss® products only | Dental Practitioner |
| B21 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Filling of periodontal defects | Dental Practitioner |
| B22 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Extraction socket grafting | Dental Practitioner |
| B23 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Ridge and sinus augmentation | Dental Practitioner |
| B24 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Bone augmentation around implants | Dental Practitioner |
| B25 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Bony defects | Dental Practitioner |
| B26 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Composite grafting with MinerOss® | Dental Practitioner |
| B27 | Grafton DBM Matrix (demineralized human bone tissue), Oral-maxillofacial | Filling of periodontal defects | Dental Practitioner |
| B28 | Tutoplast (sterilized human tissue allograft), Ocular | Ocular conditions | Medical Practitioner |
| B29 | Tutoplast (sterilized human tissue allograft), Topical | Soft tissue graft | Medical Practitioner |
| B30 | Amniotic Membrane, Ophthalmic | Ophthalmic use | Medical practitioner |
| B31 | Puros Cortico-Cancellous Particulate Allograft (human bone tissue),  Oral-maxillofacial | For hard and soft tissue augmentation procedures | Medical Practitioner  Dental Practitioner |
| B32 | Puros Cancellous Particulate Allograft (human bone tissue), Oral-maxillofacial | For hard and soft tissue augmentation procedures | Medical Practitioner  Dental Practitioner |
| B33 | Puros Cortical Particulate Allograft (human bone tissue), Oral-maxillofacial | For hard and soft tissue augmentation procedures | Medical Practitioner  Dental Practitioner |

## Medical Devices <<https://www.legislation.gov.au/Details/F2017L00867>>

|  |  |  |  |
| --- | --- | --- | --- |
| Code | Product name, Manufacturer Name, Description (including manufacturer’s intended purpose and any variant details) | Indication | Authorised Health Practitioner(s) |
| D1 | Synovasure lateral flow test IFU | An adjunct for the detection of periprosthetic joint infection (PJI) in the synovial fluid of patients experiencing pain, inflammation, or both, in a replacement joint | Medical practitioner |

\* 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.

1. For substances captured by the Customs (Prohibited Imports) Regulations 1956 the quantity must be provided. [↑](#endnote-ref-1)
2. The health practitioner type is any of the following: Medical practitioner; ATSI health practitioner; dentist; radiographer; nurse; midwife; occupational therapist; optometrist; pharmacist ; podiatrist; psychologist. [↑](#endnote-ref-2)