|  |  |
| --- | --- |
| 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>>.

**Authorised Prescriber Scheme** – **Application form**

|  |  |
| --- | --- |
| **Email completed form to:**Authorised.Prescribers@health.gov.au **(preferred)** or fax to +61 2 6203 1105HREC approval or specialist college endorsement is not required if the medicine, concentration (if any), dosage from, route of administration and indication match those listed on the **back of this form**. You will need to provide the relevant **item code** for the medicine you wish to apply for. | Privacy informationFor general privacy information, go to <<https://www.tga.gov.au/privacy>>.The TGA is collecting personal information in this form in order to:* Assess the application; and
* Contact you, as the medical practitioner applying to supply the ‘unapproved’ therapeutic goods, to discuss the application where necessary.

The personal information of the medical practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or health practitioner registration. |
| **PLEASE PRINT IN BLOCK LETTERS. Please complete the form clearly and in full. Forms cannot be processed if incomplete or illegible.**  |

## Product details

|  |
| --- |
| **Item code** (see back of form)Only the item code, prescriber details and signature are required to be completed for medicines that match an entry on the back of this form (HREC approval or specialist college endorsement not required). Code Number:       |
| **Trade name**       | **Sponsor / supplier’s name and address**      |
| **Active ingredient / device product description** (including variant)      |
| **Dosage form**      | **Route of administration**      |
| **Indication / reason for prescribing**      |

## Prescribing medical practitioner details

|  |  |
| --- | --- |
| **First name**       | **Surname**      |
| **AHPRA ID**      | **Specialty**      |
| **Email**      |
| **Phone**      | **Fax**      |
| **Principal practice address**      |

## Approving/endorsing body

|  |
| --- |
| **Name of approving ethics committee** (if applicable)      |
| **Name of endorsing specialist college** (if applicable)      |

**Please tick:**

|  |  |
| --- | --- |
| [ ]  | I have attached the most recent letter from the approving ethics committee or endorsing specialist college **AND** |
| [ ]  | I have attached a declaration from the ethics committee or specialist college that all necessary documentation has been reviewed and is appropriate **OR** |
| [ ]  | Human Research Ethics Committee (HREC) approval or specialist college endorsement is not required as the medical practitioner is applying to become an Authorised Prescriber of medicines that match an entryon the back of this form. |

I understand that:

* the product is not approved for marketing in Australia and that the Therapeutic Goods Administration (TGA) is unable to vouch for the quality, safety or efficacy of this unapproved product, and that its use is regarded as experimental;
* the giving of an authority under subsection 19(5) or sections 32CM or 41HC does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of the use of, therapeutic goods by that person or another person;
* that in order to be given such an authority, I must be either:
	+ a medical practitioner engaged in clinical practice in a hospital and have approval from the ethics committee of the hospital to supply and or use the unapproved product, or
	+ a medical practitioner treating patients outside a hospital setting and without access to an ethics committee that could approve the supply who has obtained endorsement from a specialist college that has an established expertise relevant to the use of the unapproved product, or
	+ the product is included in the list of medicines specified in Regulation 12B(1B) of the *Therapeutic Goods Regulations 1990*.

I agree to:

* the collection of my personal information for the purposes set out above;
* obtain from each patient (or guardian) informed consent in relation to the proposed use of the unapproved product, and in this context, inform the patient that the product is not approved in Australia; OR inform the requesting doctor that the in vitro diagnostic medical device used to perform the test is not approved in Australia;
* the product only being prescribed for patients in my immediate care;
* the product only to being used in accordance with the treatment directions (being the protocol or product information or instructions for use);
* continuing to have an appropriate approval or endorsement in order to supply and or use the product (if applicable);
* report any suspected adverse events to the TGA, the sponsor and either the approving ethics committee or endorsing specialist college (as applicable); and
* comply with all relevant State/Territory legislation.

|  |
| --- |
| **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.** |
| **Medical practitioner’s signature**      | **Date**      |

List of medicines with an established history of use

HREC approval or specialist college endorsement is not required if the medicine,concentration (if any), dosage from, route of administration and indication match those listed below (as specified in regulation 12B(1B) of the *Therapeutic Goods Regulations 1990*).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Active ingredient | Dosage form | Route of administration | Indication | Code |
| Aciclovir | Eye ointment | Ophthalmic | Treatment of herpes simplex keratitis | AP1 |
| Allergens—multiple, various (including control solutions) | Drops | Intradermal | Confirmation of suspected allergic reactions | AP2 |
| Allergens – multiple, various (including control solutions) | Drops | Skin prick | Confirmation of suspected allergic reactions | AP3 |
| Amifampridine (3,4‑diaminopyridine) | Tablet | Oral | Treatment of Lambert‑Eaton Myasthenic Syndrome | AP4 |
| Betaxolol 0.25% (preservative free) | Eye drops  | Ophthalmic | Treatment of elevated intraocular pressure where other treatments are inappropriate | AP5 |
| Bismuth subcitrate | Tablet | Oral | Treatment of resistant *Helicobacter pylori* infection | AP6 |
| Buspirone | Tablet | Oral | Treatment of generalised anxiety disorders | AP7 |
| Calcitriol | Liquid | Oral | Prevention of hypophosphatemic rickets in children | AP8 |
| Calcitriol | Liquid | Oral | Treatment of hypoparathyroidism (with severe hypocalcaemia) | AP9 |
| Carbidopa | Tablet | Oral | Premedication for F‑18 DOPA imaging | AP10 |
| Cholecalciferol | Capsule | Oral | Treatment of severe vitamin D deficiency and prevention of osteoporosis | AP11 |
| Cholecalciferol | Injection  | Intramuscular | Treatment of severe vitamin D deficiency and prevention of osteoporosis | AP12 |
| Cinnarizine | Tablet | Oral | Treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere’s disease)  | AP13 |
| Clobetasol propionate 0.05% | Cream | Topical | Treatment, or prolongation of flare‑free intervals, of dermatitis/eczema where other treatments have failed | AP14 |
| Clobetasol propionate 0.05% | Lotion | Topical | Treatment, or prolongation of flare‑free intervals, of dermatitis/eczema where other treatments have failed | AP15 |
| Clobetasol propionate 0.05% | Ointment | Topical | Treatment, or prolongation of flare‑free intervals, of dermatitis/eczema where other treatments have failed | AP16 |
| Clofazimine | Capsule | Oral | Treatment of Leprosy | AP17 |
| Clofazimine | Capsule | Oral | Treatment of granulomatous cheilitis | AP18 |
| Clofazimine | Capsule | Oral | Treatment of Melkersson Rosenthal Syndrome | AP19 |
| Clofazimine | Capsule | Oral | Treatment of confirmed mycobacterium avium paratuberculosis in immunocompromised patients recommended by an infectious disease specialist | AP20 |
| Clofazimine | Capsule | Oral | Treatment of erythema nodosum leprosum | AP21 |
| Clofazimine | Capsule | Oral | Treatment of drug resistant tuberculosis | AP22 |
| Clofazimine | Capsule | Oral | Treatment of non-tuberculosis mycobacterial infections | AP23 |
| Clofazimine | Capsule | Oral | Treatment of other infections as recommended by an infectious diseases specialist | AP24 |
| Cyclopentolate, 0.2%, and phenylephrine, 1% | Eye drops | Ophthalmic | Production of mydriasis | AP25 |
| Cyclosporin, 0.05% | Eye drops, emulsion | Ophthalmic | Treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca (dry eye syndrome) | AP26 |
| Deflazacort | Tablet | Oral | Treatment of Duchenne muscular dystrophy | AP27 |
| Dehydrated ethanol (alcohol) 96% ‑ 100% | Ampoule | Topical | Treatment of progressive keratoconus and intra‑operative use in superficial keratectomy (single use per procedure) | AP28 |
| Dexamethasone (preservative free) | Eye drops | Ophthalmic | Treatment of inflammatory conditions of the eye that are non‑infected and steroid responsive in patients sensitive to preservative‑containing formulations | AP29 |
| Diazoxide | Capsule | Oral | Treatment of hypoglycaemia | AP30 |
| Diazoxide | Capsule | Oral | Treatment of hyperinsulinaemia  | AP31 |
| Diazoxide | Capsule | Oral | Treatment of Beckwith-Weiderman Syndrome | AP32 |
| Diazoxide | Capsule | Oral | Treatment of insulinoma | AP33 |
| Diazoxide | Suspension | Oral | Treatment of hypoglycaemia | AP34 |
| Diazoxide | Suspension | Oral | Treatment of hyperinsulinaemia | AP35 |
| Diazoxide | Suspension | Oral | Treatment of Beckwith-Weiderman Syndrome | AP36 |
| Diazoxide | Suspension | Oral | Treatment of insulinoma | AP37 |
| Diazoxide | Tablet  | Oral | Treatment of hypoglycaemia | AP38 |
| Diazoxide | Tablet  | Oral | Treatment of hyperinsulinaemia | AP39 |
| Diazoxide | Tablet  | Oral | Treatment of Beckwith-Weiderman Syndrome | AP40 |
| Diazoxide | Tablet | Oral | Treatment of insulinoma | AP41 |
| Diflunisal | Tablet | Oral | Treatment of amyloidosis | AP42 |
| Dimethyl sulfoxide (DMSO) | Solution | Intravesical | Symptomatic relief of interstitial cystitis | AP43 |
| Doxycycline | Injection | Intralesional | Sclerotherapy of lymphatic malformations | AP44 |
| F‑18 DCFPyl (PSMA) | Injection | Intravenous | Prostate cancer imaging study | AP45 |
| F‑18 myocardial perfusion tracer (18F flurpiridaz) | Injection | Intravenous | Myocardial perfusion study | AP46 |
| F‑18 NaF (sodium fluoride) | Injection | Intravenous | Bone study | AP47 |
| Flunarizine | Tablet | Oral | Treatment of vestibular disorders | AP48 |
| Flunarizine | Tablet | Oral | Prophylactic treatment of migraine | AP49 |
| Flunarizine | Capsule | Oral | Treatment of vestibular disorders | AP50 |
| Flunarizine | Capsule | Oral | Prophylactic treatment of migraine | AP51 |
| Furazolidone | Tablet | Oral | Treatment of resistant *Helicobacter pylori* infection | AP52 |
| Gallium‑68(Ga‑68) Galligas | Aerosol | Inhalation | Lung ventilation study | AP53 |
| Gallium‑68 (Ga‑68) ‑ MAA | Injection | Intravenous | Lung perfusion study | AP54 |
| Gallium‑68 prostate specific membrane antigen (PSMA) | Injection | Intravenous | Prostate cancer imaging study | AP55 |
| Glycopyrronium bromide | Tablet | Oral | Treatment of excessive salivation in patients with neurological conditions | AP56 |
| Hyoscine hydrobromide | Patch | Transdermal | Treatment of excessive salivation | AP57 |
| Hypertonic sodium chloride, 5 % | Eye ointment | Ophthalmic | Temporary relief of corneal oedema (hypertonicity) | AP58 |
| Hypertonic sodium chloride, 5% | Eye drops | Ophthalmic | Temporary relief of corneal oedema (hypertonicity) | AP59 |
| Indigo carmine | Injection | Intravenous | Intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures | AP60 |
| Indocyanine green dye | Injection | Intravenous | Intra‑operative diagnostic use | AP61 |
| Ketotifen | Tablet | Oral | Treatment of allergic conditions | AP62 |
| Levofloxacin | Tablet | Oral | Treatment of resistant *Helicobacter pylori* infection | AP63 |
| Levofloxacin | Tablet | Oral | Treatment of drug resistant tuberculosis | AP64 |
| Levomepromazine | Tablet | Oral | Treatment of nausea and vomiting | AP65 |
| Levomepromazine | Tablet | Oral | Treatment of agitation | AP66 |
| Levomepromazine | Injection | Subcutaneous | Treatment of nausea and vomiting | AP67 |
| Levomepromazine | Injection | Subcutaneous | Treatment of agitation | AP68 |
| Lorazepam | Injection | Parenteral | Treatment of acute severe behavioural episodes in the hospital setting | AP69 |
| Melatonin | Syrup | Oral | Treatment of sleep disorders | AP70 |
| Melatonin | Capsule | Oral | Treatment of sleep disorders | AP71 |
| Melatonin | Immediate release tablet | Oral | Treatment of sleep disorders | AP72 |
| Melatonin | Lozenge | Oral | Treatment of sleep disorders | AP73 |
| Mexiletine | Tablet | Oral | Treatment of ventricular arrhythmia | AP74 |
| Mexiletine | Tablet | Oral | Treatment of myotonic disorders | AP75 |
| Mexiletine | Capsule | Oral | Treatment of ventricular arrhythmia | AP76 |
| Mexiletine | Capsule | Oral | Treatment of myotonic disorders | AP77 |
| Moxifloxacin 0.5% | Eye drops | Ophthalmic | Treatment of refractory bacterial conjunctivitis | AP78 |
| Nadolol | Tablet | Oral | Treatment of ventricular tachycardia | AP79 |
| Nadolol | Tablet | Oral | Treatment of long QT Syndrome | AP80 |
| Natamycin 5% | Eye drops | Ophthalmic | Treatment of refractory fungal blepharitis, conjunctivitis or keratitis | AP81 |
| Neomycin | Tablet | Oral | Sepsis prevention for colorectal operation | AP82 |
| Nicotine in solution, salt or base form | Liquid or solid | Inhalation | Smoking cessation | AP83 |
| Nitazoxanide | Tablet | Oral | Treatment of giardiasis | AP84 |
| Nitazoxanide | Tablet | Oral | Treatment of cryptosporidiosis | AP85 |
| Nitazoxanide | Tablet | Oral | Treatment of blastocystis | AP86 |
| Nitazoxanide | Suspension | Oral | Treatment of giardiasis | AP87 |
| Nitazoxanide | Suspension | Oral | Treatment of cryptosporidiosis | AP88 |
| Nitazoxanide | Suspension | Oral | Treatment of blastocystis | AP89 |
| Paromomycin | Capsule | Oral | Antiprotozoal treatment of *Blastocystis hominis* | AP90 |
| Paromomycin | Capsule | Oral | Antiprotozoal treatment of *Dientomoeba fragilis* | AP91 |
| Paromomycin | Capsule | Oral | Antiprotozoal treatment of *Entamoeba histolytica* | AP92 |
| Paromomycin | Capsule | Oral | Antiprotozoal treatment of any of parasite infection | AP93 |
| Pimozide | Tablet | Oral | Treatment of schizophrenia | AP94 |
| Pimozide | Tablet | Oral | Treatment of chronic psychosis | AP95 |
| Pimozide | Tablet | Oral | Treatment of Tourette syndrome | AP96 |
| Pristinamycin | Tablet | Oral | Treatment of confirmed methicillin‑resistant *Staphylococcus aureus* or vancomycin‑resistant *enterococci* infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis | AP97 |
| Pristinamycin | Tablet | Oral | Treatment of refractory or resistant *Mycoplasma genitalium* infections | AP98 |
| Pristinamycin | Tablet | Oral | Treatment of other infections as prescribed by an infectious disease specialist | AP99 |
| Pyrazinamide | Tablet | Oral | Treatment of tuberculosis | AP100 |
| Riboflavin, 0.1% in 20% dextran | Eye drops | Ophthalmic | Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus | AP101 |
| Riboflavin, 0.1% in 1.1% hydroxylpropyl methylcellulose (HPMC) | Eye drops | Ophthalmic | Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus | AP102 |
| Riboflavin, 0.1% in sodium chloride | Eye drops | Ophthalmic | Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus | AP103 |
| Riboflavin, 0.22% in sodium chloride | Eye drops | Ophthalmic | Intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus | AP104 |
| Ripasudil 0.4% | Eye drops | Ophthalmic | Treatment of refractory corneal oedema | AP105 |
| Ripasudil 0.4% | Eye drops | Ophthalmic | Treatment of refractory glaucoma | AP106 |
| Sodium benzoate | Tablet | Oral | Treatment of urea cycle disorders | AP107 |
| Tacrolimus 0.03% | Ointment | Topical | Treatment, or prolongation of flare‑free intervals, of moderate to severe atopic dermatitis/eczema in children | AP108 |
| Tacrolimus 0.1% | Ointment | Topical | Treatment, or prolongation of flare‑free intervals, of moderate to severe atopic dermatitis/eczema in adults | AP109 |
| Tetracycline | Capsule | Oral | Treatment of resistant *Helicobacter pylori* infection | AP110 |
| Tetracycline | Tablet | Oral | Treatment of resistant *Helicobacter pylori* infection | AP111 |
| Tick‑borne encephalitis vaccine | Injection | Intramuscular | Prevention of tick‑borne encephalitis | AP112 |
| Tinidazole | Tablet | Oral | Treatment of *Trichomonas vaginalis* infections of the genito‑urinary tract in female and male patients | AP113 |
| Tinidazole | Tablet | Oral | Treatment of giardiasis | AP114 |
| Tinidazole | Tablet | Oral | Treatment of amoebic dysentery | AP115 |
| Tinidazole | Tablet | Oral | Treatment of amoebic liver abscess | AP116 |
| Tinidazole | Tablet | Oral | Treatment of acute giardiasis in children | AP117 |
| Tinidazole | Tablet | Oral | Treatment of acute amoebic dysentery in children | AP118 |
| Tinidazole | Tablet | Oral | Treatment of amoebic liver disease in children | AP119 |
| Tinidazole | Tablet | Oral | Prevention of infection of the surgical site | AP120 |
| Tizanidine | Capsule | Oral | Treatment of spasticity where other treatments have failed | AP121 |
| Tizanidine | Tablet | Oral | Treatment of spasticity where other treatments have failed | AP122 |
| Triamcinolone acetonide | Suspension for injection | Ophthalmic | Treatment of non‑infectious uveitis | AP123 |
| Triamcinolone acetonide | Suspension for injection | Ophthalmic | Visualisation during vitrectomy | AP124 |
| Triamcinolone acetonide | Suspension for injection | Ophthalmic | Treatment of diabetic macular oedema | AP125 |
| Triamcinolone acetonide | Suspension for injection | Ophthalmic | Treatment of cystoid macular oedema secondary to retinal vein occlusion | AP126 |
| Triamcinolone acetonide | Suspension for injection | Ophthalmic | Treatment of uveitic macular oedema | AP127 |
| Triamcinolone acetonide | Suspension for injection | Ophthalmic | Treatment of post‑operative macular oedema (cataract surgery) | AP128 |
| Verteporfin | Powder for injection | Intravenous infusion | Photosensitisation for photodynamic therapy | AP129 |
| Yttrium‑90 (Y‑90) Citrate | Injection | Intraarticular | Radiosynovectomy treatment | AP130 |