**Request Form and Treatment Protocol for Use of New Unlicensed Medicine or new off-label indication**

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| This form should be completed by the consultant wishing to use a new unlicensed product or off-label purpose. The form can be sent to the as part of the submission for approval to use the product.  Before completing this form, you should be familiar with your jurisdiction’s, practising organisation and professional indemnity insurance’s practises, policies and procedures for the use of unlicensed medicines and must be aware of your responsibilities.   |  |  | | --- | --- | | Generic name |  | | International non-proprietary name | Metformin Sustained Release | | Pharmaceutical form | Pill | | Dose | 500 mg (**or 250 mg if over age 80**) (delete as appropriate) | | Route | Oral | | Frequency | Daily after meals  May not want to take on days with intense exercise | | Dose increase | Start with 250 mg daily for 2 weeks then increase to 500 mg daily | | Duration of treatment | 3 months then review for side effects: if intestinal side effects advise stopping for 2 weeks and restarting at lowest dose, taking after meals, taking with daily lactobacillus probiotic supplements or psyllium husk, or with peppermint tea | | Indication |  | | Why is use of this unlicensed medicine being considered? |  | | Please outline the clinical evidence of efficacy to support the use of this product in this manner? | See - <https://www.londonhealthmanager.com/blog/metformin-longevity-review-weight-loss-side-effects-aging-and-cancer> | | Please outline the safety risks | See - <https://www.londonhealthmanager.com/blog/metformin-longevity-review-weight-loss-side-effects-aging-and-cancer> | | In what situations should you stop this medication | * During days doing intense exercise (may prevent mitochondrial benefits) * During acute illness such as hospital admission (check with clinician) * During diarrheoa and vomiting (increased risk of lactic acidosis) * At least 2 days before having imaging scans that use injected contrast (contrast CT, MRI, PET etc.) | | What monitoring is required and at what frequency and reason? | * Annually 🡪 Creatinine and estimated glomerular filtration rate (eGFR) (for increased risk of lactic acidosis) * Total B12 (for risk of metformin induced B12 deficiency) * Full blood count (for B12 deficiency anaemia) | | Co-prescriptions required | * Around 100 micrograms daily of methylcobalamin B12, or around 1000 micrograms weekly, as part of an orally taken B12 complex (pills are fine unless client has condition that has causes poor gut absorption, injections and sublingual sprays have no benefit otherwise) * Good to supplement other B vitamins in concert with B12 so as not to cause secondary B vitamin deficiencies (as recommended by Biolab UK) * We recommend HALF A PILL ONLY of Igennus B12 complex from Amazon ([**click to buy**](https://www.amazon.co.uk/Super-B-Complex-Strength-Vitamins-vitamin/dp/B01787EPEE) ) (no affiliation); this costs around £27 or $35 a year. | | Name of prescriber |  | | Registration number |  | | Signature |  | | Date of prescription |  |  PATIENT CONSENT I confirm that I understand that metformin is not licensed for marketing in this country and that I consent for it to be used as part of my treatment plan. The Doctor supervising this treatment has satisfactorily answered all the questions I have about this medication and its status.   |  |  | | --- | --- | | Name of prescribee |  | | Signature of prescribe |  | | Date |  | |