

**St Mary's Hospital Pharmacy Services  
Request form for unlicensed and off license medicines**

Date.....

Drug.....Route.....

Dose.....

Indication.....

Patients name..... IW number.....

- a) The intended use is not included in the product license
- b) It does not have a UK Product Licence (delete as appropriate)

I understand that

- Prescribing this medicine in this way may have medico-legal implications and liability is carried by the Isle of Wight NHS Trust.
- Supply of medicines for use outwith the product licence or unlicensed medicines is restricted at the Isle of Wight NHS Trust to consultants or to doctors acting under a consultant's direction only.

Notes

*Section 9 of the Medicines Act (1968) permits the use by doctors of medicines for indications or in doses or by routes of administration outside the recommendations given in the Product Licence on a 'named patient basis'.*

*Responsibility for prescribing any medicine falls on the doctor but if the prescription is for an unlicensed medicine or for an unlicensed indication the prescriber may be particularly vulnerable. A doctor prescribing an unlicensed medicine does so entirely on his/her own responsibility, carrying the total burden for the patients welfare, and may be called upon to justify his/her actions in the event of an adverse reaction.*

*Unlicensed use may be justified if a responsible body of medical opinion supports its use in this way. In exceptional cases a pharmacist may refuse to supply a drug if in his/her professional opinion its use is deemed inappropriate or if the product requested is not of an appropriate quality. In this case the matter may be referred to the Medical Director who in turn may refer to the Board. The Board may refuse to accept liability for such prescribing in which case the prescriber has no protection from the Trust.*

**It is important that the patient is informed of the implications of the drug's licensed status and of any contraindications, warnings and precautions associated with use of the drug, before consent to treatment is obtained.**

Please fill in the reverse of this form as far as you can before returning it to pharmacy

I have read the above and it is my clinical judgement that use of the medication in this way is appropriate in this patient. I accept responsibility for the use of this medicine.

Consultant.....Signature.....Date.....

## Risk assessment for the supply of an unlicensed or off license medicine

Product.....

Indication.....

References:

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Alternative treatments

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Why are alternatives not suitable? give full supporting information if possible

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How urgent is the clinical need?

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Will treatment continue in primary care?

If so, has the GP been informed?

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Is an equivalent licensed product available? Y/N  
Give details

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If no licensed alternative - is there a known source of supply in common use?

The Board of the Isle of Wight NHS Trust accepts liability for the use of this drug which does not have the appropriate product licence.

Medical Director's Signature.....Date.....

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### PHARMACY ONLY

Where has product been sourced?

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Licensed/ special/ extemporaneous?

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Comments

Authority to proceed with supply.

Pharmacist Signature.....Date.....

Please send a copy of completed form to Directorate Board for information