



## NHS South of Tyne and Wear

serving Gateshead Primary Care Trust, South Tyneside Primary Care Trust and  
Sunderland Teaching Primary Care Trust

# SHARED CARE GUIDELINE

For

**Naltrexone for the management of agitation and / or self injurious  
behaviour in patients with autism or learning disabilities.**

**Implementation Date: 1.12.09**

**Review Date: 1.10.09**

**This guidance has been prepared and approved for use within Gateshead, South  
Tyneside and Sunderland in consultation with Primary and Secondary Care Trusts and  
Local Medical Committees.**

**The guideline sets out the details of the transfer of prescribing and respective  
responsibilities of GPs and specialist services within shared care prescribing  
arrangements. It is intended to provide sufficient information to allow GPs to prescribe  
these treatments within a shared care setting**

### Further copies are available from

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### Approved by:

Committee	Date
Gateshead Medicines Management Committee	
South Tyneside Prescribing Committee	
Sunderland Primary Care Prescribing Group	
South of Tyne and Wear Medicines Management Committee	5.11.09

## Transfer of prescribing responsibilities

Name of drug:	<b>Naltrexone</b>	Form and strength:	50mg tablets (tablets are scored)
Brand name:	Nalorex and Opizone	BNF Code:	4.10. Please note this is an unlicensed or “off label” use of a licensed product.
Conditions(s) to be treated  <b>Agitation and / or self injurious behaviour in patients with autism or learning disabilities.</b>  <b>This shared care guideline does not cover the licensed use of naltrexone as an adjunct to prevent relapse in detoxified formerly opioid-dependent patients.</b>		Aim of treatment  <b>To reduce agitation and / or self injurious behaviour</b>	
Excluded patients	<b>Unstable disease state, patients currently dependent on opioids, pregnancy and lactation</b>		
Eligibility criteria for shared care	<b>Following dose and drug stabilisation for at least 1 month</b>		
Initiation	Initiation of treatment will take place in secondary care by a medical specialist in the care of people with autism or learning disabilities.		
Duration of treatment	For as long as benefit is maintained. The specialist team will be responsible for treatment discontinuation		
Usual Maintenance Dose	25 - 50mg daily (prescribed BD, daily or alternate days)		
Usual Dose Range	12.5mg – 100mg daily		
Maximum Dose	100mg daily		
Available Strengths (Colours)	Nalorex 50mg tablets are yellow Opizone 50mg tablets are beige		
Preparations	50 mg film coated, scored tablets		
Cost 28 days (Drug Tariff)	£23.72		
Adverse effects	Adverse effects are taken from SPC for the licensed indication. Clinical experience suggests adverse effects in this patient group may be less.		
	Very Low	Hallucinations, tremor, idiopathic thrombocytopenia.	
Incidence	Low	Hepatic dysfunction, suicidal ideation, speech disorders	
	Moderate	Loss of appetite, diarrhoea, constipation, increased thirst, increased energy, feeling down, irritability, dizziness, skin rash, delayed ejaculation, decreased potency, chills, chest pain, increased sweating and increased lacrimation.	
	High	Difficulty sleeping, anxiety, nervousness, abdominal pain/cramps, nausea and/or vomiting, low energy, joint and muscle pain, and headache	
Contra-indications	Known hypersensitivity to the product, acute hepatitis, liver failure, patients currently dependent on opioids.		
Renal impairment and liver	Naltrexone is contraindicated in severe renal or hepatic		

## Transfer of prescribing responsibilities

disease	impairment.	
Pregnancy and breast feeding	Because of absence of documented clinical experience naltrexone should only be given to pregnant or breast-feeding women when, in the judgement of the physician, the potential benefits outweigh the possible risks.	
Monitoring	Liver function tests should be carried out by the specialist team in obese and elderly patients. 6 monthly reviews by specialist team to determine response to treatment.	
Responsibilities	Consultant	Initiate and determine response to treatment. Review patient until stable and suitable for shared care. Complete section 1 of shared care request form. 6 monthly reviews of patient's management and response to treatment. Any required liver function tests.
	G.P.	Complete and return section 2 of shared care request form if declining to accept the shared care arrangement. Prescribe medication at monthly intervals. To liaise with the specialist regarding any adverse drug reaction, including the reporting of any serious adverse drug reaction to the MHRA.
Communications	Consultant	Inform patient and carers that this is an unlicensed or "off label" use of a medicinal product. Notification to GP of patients suitable for shared care. The GP should also be informed that this is an unlicensed or "off label" use of a medicinal product. Notification to GP of patients who fail to attend 6 monthly reviews within one month, plus specific information on the planned course of action.
	G.P.	Acceptance of patients for shared care. Inform consultant of any relevant problems with patient, or medication
Circumstances in which Consultant should be informed include	<ul style="list-style-type: none"> <li>• Sudden deterioration in patients condition</li> <li>• Patient intolerance or adverse side effects of medication</li> <li>• Non-compliance</li> <li>• Unusual prescribing circumstances e.g. initiation of potentially interacting medication, such as opioid analgesics for pain.</li> <li>• Communications failure</li> </ul>	
Supporting evidence for the	The use of naltrexone to reduce agitation and / or self	

## Transfer of prescribing responsibilities

<p>unlicensed or “off label” use of naltrexone</p>	<p>injurious behaviour is an established treatment for patients with autism or learning disabilities. However due to the limited evidence base it should be initiated by a specialist only when other measures have proven to be ineffective. Its use in this area is supported by a body of physicians and withstands logical analysis, satisfying the Bolam / Bolitho criteria in principle. The use of naltrexone under this shared care arrangement is supported by Northumberland, Tyne and Wear NHS Trust Medicines Management Committee. Further evidence of naltrexone’s use in this indication is also documented in: The Psychotropic Drug Directory, the Maudsley Prescribing Guidelines, the Frith Prescribing Guidelines for Adults with Learning Disabilities.</p>
<p>Contact details</p>	<p>Consultant:</p>
<p><b>Agreed Date</b></p>	<p><b>Insert date</b></p>

For full prescribing information on naltrexone, please refer to the Summary of Product Characteristics available from the electronic medicines compendium at:  
[www.medicines.org.uk](http://www.medicines.org.uk)

**Appendix 1 Shared Care Request Form**

- **Consultant to complete FIRST SECTION of form**
- **GP to complete SECOND section and RETURN to SECONDARY CARE TRUST CLINICIAN TEAM if transfer declined.**

**Section 1**

Consultant	
Hospital address	
Contact Phone Number	

Patient's name	
Address	
This patient is stabilised on	
Dose	
Prescription for 28 days supply given on	

Compliance aid	YES/NO
Monitored by	
Designated community pharmacy	

Their treatment has been explained to them and a review has been arranged for

.....

Appointments to continue every ..... months

**Section 2**

Patient's name	
Address	

I do **NOT ACCEPT** the proposed Shared-Care Agreement for this patient

My reasons for not accepting: <b>Please complete this section</b>

Signed .....date.....

Please return to the Secondary Care Trust Clinician team at :

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