NHS
Borders

Patient Group Direction for the supply and/or administration of Ibuprofen 100mg/5ml suspension SF to children requiring relief of mild to moderate pain with an inflammatory component attending NHS Borders services

This document authorises the supply and/or administration of Ibuprofen 100mg/5ml suspension by registered nurses to children requiring relief of mild to moderate pain with an inflammatory component who meet the criteria for inclusion under the terms of the document

The registered nurses seeking to supply or administer Ibuprofen 100mg/5ml suspension must ensure that all patients have been screened and meet the criteria before supply takes place.

The purpose of this Patient Group Direction is to help patients by providing them with more convenient access to pain relief in an efficient manner in the absence of medical cover.

This PGD was initially approved: September 2006

This direction was authorised on: April 2011

The direction will be reviewed by: April 2013

Clinician Responsible for Training and Review: Emergency Department Consultant/CNM Primary and Community Services

PGD Reviewed by: Jacques Kerr, Beverly Meins, Clare Ketteridge, Gavin Gorman

NHS Borders

Patient Group Direction for administration of Ibuprofen 100mg/5ml SF Suspension without a prescription for a named individual by registered nurses employed by NHS Borders

1. This Patient Group Direction relates to the following specific preparation:

Name of medicine, Strength, Formulation	Ibuprofen 100mg/5ml SF Suspension
Legal status	Pharmacy Medicine (P)
Storage	Store below 25°C and protect from light.
Dose	**Not licensed for use in children under 3 months or body weight under 5kg**
	Child 1 to 3 months: 5mg/kg 3 to 4 times daily
	Child 3 to 6 months: 50mg 3 times daily: Max 30mg/kg daily in 3-4 divided doses
	Child 6 to 12 months: 50mg three to four times daily with a minimum of 6 hours between doses.
	Child 1 to 3 years: 100mg three times daily with a minimum of 6 hours between doses.
	Child 4 to 6 years: 150mg three times daily with a maximum of 6 hours between doses.
	Child 7 to 9 years: 200mg three times daily with a maximum of 6 hours between doses.
	Child 10 to 12 years: 300mg three times daily with a minimum of 6 hours between doses.
Route/method	Oral
Frequency	As above
Total dose Quantity (Maximum/Minimum)	For total daily dose see age ranges above. Total supply:150ml in original pack
Advice to Patients	❖ Take with or just after food.

	❖ Stop taking and seek medical advice if any side effect occurs especially indigestion. ❖ Advise patient to contact doctor for any worsening of symptoms or lack of improvement of condition ❖ No products containing ibuprofen, or another NSAID should be used simultaneously
Follow up Arrangements	Seek medical advice if the patient fails to respond to treatment or condition deteriorates or as indicated in protocol.
Relevant Warnings	❖ Gastrointestinal: The most commonly-observed adverse events are gastrointestinal in nature. Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis and gastrointestinal haemorrhage have been reported following ibuprofen administration. Less frequently, gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation have been observed. Epidemiological data indicate that of the seven most widely-used oral, non-aspirin NSAIDs, ibuprofen presents the lowest risk of upper gastrointestinal toxicity. ❖ Hypersensitivity: Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme). ❖ Cardiovascular: Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high dose (2400 mg/ daily), and in long term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke)

	Other adverse events reported less commonly and for which causality has not necessarily been established include: ❖ Renal: Nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndrome and renal failure. ❖ Hepatic: Abnormal liver function, hepatitis and jaundice. ❖ Neurological & special senses: Visual disturbances, optic neuritis, headaches, paraesthesia, depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue and drowsiness. ❖ Haematological: Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia. ❖ Dermatological: Photosensitivity

2. Clinical condition

Clinical Condition to be treated	Relief of mild to moderate pain in children.
Criteria for inclusion	Pain and inflammation of soft tissue injuries Pyrexia with discomfort Pain not responsive to paracetamol.
Criteria for exclusion	❖ Know hypersensitivity to any other NSAID (non steroidal anti-inflammatory drug) (e.g. when NSAID has previously precipitated asthma, angiodema, urticaria or rhinitis). ❖ Active, suspected or history of GI ulceration or bleeding ❖ Asthma ❖ Renal impairment ❖ Hepatic impairment ❖ Severe cardiac disease (heart failure, oedema or hypertension) ❖ Current use of interactive drugs ❖ Coagulation defects
Action if excluded	The patient must be referred to a doctor. The reason for referral should be documented.
Action if declines	The patient must be referred to a doctor. The reason for referral should be documented.
Interactions with other medicaments and other forms of interaction	Antihypertensives: Reduced antihypertensive effect. Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs. Cardiac glycosides (Digoxin): NSAIDs may

	exacerbate cardiac failure, reduce renal function and increase plasma cardiac glycoside levels. Lithium: Decreased elimination of lithium. Methotrexate: Decreased elimination of methotrexate. Cyclosporin: Increased risk of nephrotoxicity with NSAIDs. Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effects of mifepristone. Other analgesics: Avoid concomitant use of two or more NSAIDs. Corticosteroids: Increased risk of gastrointestinal bleeding. Anticoagulants: Enhanced anticoagulant effect. Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
Point of referral	Patients may be referred to a prescribing practitioner at any stage. Patients should be referred if the treatment proves to be ineffective in relieving the symptoms.

3. Records: As per department protocol

a) The following records should be kept (either paper or computer based)

The GP practice, clinic, hospital, and ward or department
The patient name and CHI number
The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
Drug batch number and expiry
The signature and printed name of the approved healthcare professional that supplied or administered the medicine
The patient group direction title and/or number
If patient met the inclusion criteria and if the exclusion criteria was assessed
Quantity supplied / received and current stock balance

b) Preparation, audit trail, data collection and reconciliation-

Stock balances should be reconcilable with receipts, administration, records and disposals on a patient by patient basis.

c) Storage-Store below 25°C. Standards must be consistent with the Summary of Product Characteristics.

4. Professional Responsibility

- All Health Professionals will ensure they have the relevant training and are competent in all aspects of medication use, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate. For those involved in immunization, regular anaphylaxis updates are mandatory.
- Nurses will have due regard for the NMC – The Code, standards of conduct, performance and ethics (2008) and NMC Standards for Medicines Management (2007)

5. References

- British National Formulary (BNF) current edition
  http://bnf.org/bnf/index.htm
- British National Formulary (BNF) Children edition
  http://bnfc.org/bnfc/bnfc/current/
- Borders Joint Formulary (BJF)
  http://intranet/new_intranet/microsites/index.asp?siteid=65&uid=1
- Ibuprofen SPC www.medicines.org.uk

Patient Group Direction for the supply and/or administration of Ibuprofen 100mg/5ml SF Suspension by registered nurses employed by NHS Borders

This Patient Group Direction is approved for use by the under-signed :			
Job Title	**Name**	**Signed**	**Date**
Senior Doctor/Dentist for relevant clinical area	Ross Cameron		9/5/11
NHS Borders Director of Pharmacy	Alison Wilson		10/5/11
NHS Borders Senior Health Professional for Clinical Area	Sheena Wright		10/5/11

PGD AUTHORISED ON ..11../..5.../.....2011
Signed by ADTC CHAIRPERSON: .....
Name: ...John Hammond.....

The Health Professionals named below, being employees of NHS Borders are authorised to provide and/or administer this medication under this Patient Group Direction and agree to provide and/or administer this medication in accordance with this Patient Group Direction

Name of Health Professional	Job Title	Signed	Date