NHS Forth Valley

Patient Group Direction (PGD) Number 556

Supply of paracetamol for fever associated with coronavirus (COVID-19) for individuals aged 3 months or over to 11 years of age who are self-isolating by Community Pharmacists

Version – 2.0

The purpose of the PGD is to allow management of fever associated with coronoavirus (COVID-19) in individuals aged 3 months and older to 11 years of age who are self-isolating by registered pharmacists within Community Pharmacies.

This PGD authorises community pharmacists to supply paracetamol 500mg oral solid dosage form; paracetamol 250mg/5mL oral suspension or paracetamol 120mg in 5mL oral suspension to individuals who are self-isolating aged 3 months and older to 11 years of age with fever and who meet the criteria for inclusion under the terms of the document for a period limited to responding to COVID-19.

Change history

Version	Date	Summary of Changes
2	1/3/21	Action if excluded section updated to replace MAS with Pharmacy First
2	1/3/21	Specials warnings and precautions section updated to replace MAS with Pharmacy First
2	1/3/21	Authorisation page updated to local template

PGD for the supply of paracetamol 500mg oral solid dosage form, paracetamol 250mg in 5mL oral suspension or paracetamol 120mg in 5mL oral suspension, in response to coronavirus (COVID-19) for self-isolated individuals aged 3 months and over to 11 years of age with fever

Authorisation

This specimen PGD has been produced by the Area Drugs and Therapeutics Committee Collaborative and the Primary Care Community Pharmacy Group to assist NHS Boards provide uniform services across NHS Scotland. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply paracetamol 500mg oral solid dosage form or paracetamol 250mg in 5mL oral suspension or paracetamol 120mg in 5mL oral suspension under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the individual under the PGD.

This PGD has been reviewed for NHS Forth Valley by:

Doctor	David Herron	Signature	Signed by David Herron
Pharmacist	Kirstin Cassells	Signature	Signed by Kirstin Cassells
Nurse		Signature	

Approved on behalf of NHS Forth Valley by:

Medical Director	Andrew Murray	Signature	Signed by Andrew Murray
Director of Pharmacy/Senior Pharmacist	Scott Mitchell	Signature	Signed by Scott Mitchell
Clinical Governance Lead	Andrew Murray	Signature	Signed by Andrew Murray

Date Approved 06/04/2021

Effective from 06/04/2021 Review Date 31/03/2022

Clinical Situation

Indication/ Definition of situation	Symptomatic relief of fever associated with coronavirus (COVID-19) (suspected or confirmed) N.B. Supply under this PGD may be made to a representative as the individual with the fever will be unable to attend the pharmacy in person due to at home isolation. The act of making a supply to the individual's representative does not constitute delegation. The community pharmacist supplying the medicine must undertake the whole episode of care under the PGD. Fever can be defined as patient symptoms of fever OR recorded temperature over 37.8°C. Symptoms of fever may include sweating, shivering, headache, muscle aches. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC) and the individual Summary of Product Characteristics (SmPC).
Inclusion Criteria	• Individuals aged 3 months to 11 years of age with fever associated with coronavirus (COVID-19) • Valid consent by individual, individuals advocate/carer. Consent must be in line with current individual Boards consent policy • Individuals advocate/carer must be present at consultation
Exclusion Criteria	• Individual aged 12 years and over (see separate PGD) • Individuals with known or suspected hypersensitivity to paracetamol and/or other constituents– review Summary of Product Characteristics of the products under consideration • Individuals with severe hepatic impairment • Individuals with severe renal impairment • Individuals currently taking other medicines containing paracetamol • Where there is no valid consent
Precautions and Special Warnings	Paracetamol for supply under this PGD should only be used for individuals with the age range specified in the PGD and with fever. Individuals who are suffering from any other condition out with the PGD specification should be advised to consider other options for supply, e.g. Pharmacy First
Cautions /Need for further advice/	Individuals who have: • Fever with confusion and/or lethargy

Circumstances when further advice should be sought from a doctor	• Shortness of breath • Reduced urinary output • Cold hands and feet • Worsening of symptoms during home isolation • Symptoms have not improved after 7 days Should be told to contact GP surgery/NHS 24 111 service, or call 999 in an emergency e.g. suspected meningitis or sepsis. Individuals at increased risk of liver toxicity such as chronic malnutrition Check time and dosing of previous paracetamol doses, ensure 4 hours between doses and maximum daily dose is not exceeded.
Action if Excluded	Advice must be sought - Refer to GP practice (in hours)/NHS 24 111 service (out of hours) and document in Patient Medication Record (PMR) or Pharmacy Care Record (PCR). Individuals who are suffering from any other condition out with the PGD specification should be advised to consider other options for supply, e.g. Pharmacy First
Action if treatment is Declined	Advise on self-care to relieve symptoms and advise to check www.nhsinform.scot and use the COVID-19 Self Help Guide. Make it clear that if their fever shows no improvement after 7 days, or if any symptoms worsen, they should contact GP practice (in hours)/NHS 24 111 service (out of hours) for advice. Record outcome in Patient Medication Record (PMR) or Pharmacy Care Record (PCR) if appropriate.

Description of Treatment

Name of Medicine	Paracetamol		
Form/Strength	500mg tablets, caplets and capsules (POM) 500mg effervescent tablets and soluble tablets (P) 250mg in 5mL oral suspension (P) 120mg in 5mL oral suspension (GSL)		
Route of administration	Oral		
Dosage	Age Range (est. weight ranges)	Dose	Preferred Product
	10 – 11 years (32 -35kg)	500mg every 4 – 6 hours. Maximum 4 doses in 24 hours.	500mg tablet or 250mg in 5mL oral suspension if

			necessary
	8 -9 years (25 – 30 kg)	375mg (7.5mLs of 250mg in 5mL oral suspension) every 4 – 6 hours. Maximum 4 doses in 24 hours.	250mg in 5mL oral suspension
	6 – 7 years (20 – 23kg)	250mg (5mLs of 250mg in 5mL oral suspension) every 4 – 6 hours. Maximum 4 doses in 24 hours.	250mg in 5mL oral suspension
	4 – 5 years (15 -18kg)	240mg (10mLs of 120mg in 5mL oral suspension) every 4 – 6 hours. Maximum 4 doses in 24 hours.	120mg in 5mL oral suspension
	2-3 years (11 – 14 kg)	180mg (7.5mLs of 120mg in 5mL oral suspension) every 4 – 6 hours. Maximum 4 doses in 24 hours.	120mg in 5mL oral suspension
	6 months – 23 months (7.5 – 11kg)	120mg (5mLs of 120mg in 5mL oral suspension) every 4 – 6 hours. Maximum 4 doses in 24 hours.	120mg in 5mL oral suspension
	3 – 5 months	60mg (2.5mL of 120mg in 5mL oral suspension) every 4 – 6 hours. Maximum 4 doses in 24 hours.	120mg in 5mL oral suspension
Frequency	See Dosage section above		
Duration of treatment	See Dosage section above		
Maximum or minimum treatment period	Only one supply per individual should be made under this PGD		
Quantity to supply	500mg tablets/caplets/capsules/effervescent/soluble tablets [1 x 50] 250mg/5mL suspension [1-2 x 100mL or 1 x 200mL] 120mg/5mL suspension [1-2 x 100mL or 1 x 200mL]		
▼ additional monitoring	No		
Legal Status	Paracetamol in a 100 tablet/caplet/capsule pack is a Prescription-only Medicine (POM) Paracetamol in a 100 effervescent/soluble pack is a Pharmacy-only		

	Medicine (P) Paracetamol liquid oral suspension 120mg in 5mL and 250mg in 5mL is a Pharmacy-only Medicine (P) or General Sales List (GSL) medicine. In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions Tablets/caplets/capsules/soluble - Store below 25°C in a cool dry place Effervescent - Store below 30°C. Store in the original container to protect from the moisture and light. Suspension – Protect from light and store in original container Ensure preparation is within expiry date
Additional information	None

Warnings including possible adverse reactions and management of these	Hypersensitivity reactions including skin rashes and blood disorders have been reported rarely Speed of absorption may be increased by metoclopramide and domperidone N.B. Oral coumarin anticoagulants (prolonged regular use may enhance the anticoagulant effect. INR should be checked if individual continues to take paracetamol for more than 5 days) For a full list of side effects – refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on www.medicines.org.uk
Reporting procedure for adverse reactions	Pharmacists should document and report all adverse incidents through their own internal governance systems. All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded patient's medical

	record. Pharmacists should record in their PMR and send an SBAR to the GP as appropriate. Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/
Advice to Individual/carer including written information	• Do not take anything else containing paracetamol while taking this medicine • Do not exceed recommended dose • Talk to a doctor at once if the maximum dose is exceeded, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage • If symptoms of fever show no improvement after 7 days, or symptoms worsen, advise them to contact the NHS 24 111 service. • Inform of possible side effects and their management. The medicine Manufacturer Patient Information Leaflet should be given. • If taking oral coumarin anticoagulants to have INR checked if they continue to take paracetamol regularly for longer than 5 days • If taking cholestyramine not to take at the same as paracetamol as cholestyramine decreases the absorption of paracetamol. Take paracetamol one hour before or 4 – 6 hours after cholestyramine • Patients should be informed who to contact should they experience an adverse drug reaction
Monitoring	Not applicable
Follow-up	If symptoms worsen or there is no improvement in symptoms after 7 days, seek advice from the NHS 24 111 service.
Additional Facilities	The following should be available at sites where the medication is supplied: • Appropriate storage facilities • An acceptable level of privacy to respect individuals right to confidentiality and safety • Access to a working phone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of the current PGD in print or electronically • Access to current BNF (online version preferred)

Characteristics of staff authorised under the PGD

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration. ***Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the individual under this PGD.***
Specialist competencies or qualifications	Approved by the organisation as: Competent to assess the individual/person with parenteral responsibilities/individuals representatives' capacity to understand the nature and purpose of the medication supply in order to give or refuse consent. Aware of current treatment recommendations and be competent to discuss issues about the medication with the individual. Competent to make a supply of the medicine(s). Competent to work under this PGD. Must be familiar with the relevant paracetamol Summary of Product Characteristics (SPC).
Continuing education and training	All professional working under this PGD must: Have undertaken PGD training as required/set out by each individual Health Board Attends approved training and training updates as appropriate.

Documentation

Authorisation of supply	Pharmacist can be authorised to supply the medicine(s) specified in this PGD by their Director of Pharmacy. All authorised staff are required to read the PGD and sign the individual authorisation
Record/Audit Trail	All records must be clear, legible and in an easily retrieval format in order to allow audit of practice. Pharmacists must record in Patient Medication Record (PMR) or Pharmacy Care Record (PCR). The following records should be kept (paper or computer based): • Date and time of supply • Individuals name and Date of Birth (or CHI if available) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form of the medicines supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine

	• Record of any adverse effects (advise individuals GP/relevant medical practitioner) These records should be retained in accordance with local/national guidance.
Additional references	Electronic Medicines Compendium http://www.medicines.org.uk Paracetamol 500mg caplets SmPC (M & A Pharmachem Ltd) Paracetamol 500mg effervescent tablets SmPC (Accord Healthcare Limited) Paracetamol 500mg soluble tablets SmPC (Zentiva) Paracetamol 250mg/5mL Oral suspension sachets SmPC (Rosemont Brand) Paracetamol 120mg/5mL Oral suspension sachets SmPC (Rosemont Brand) British National Formulary (BNF) and British National Formulary for Children http://about.medicinescomplete.com/

NHS Forth Valley

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

PGD for the supply of paracetamol 500mg oral solid dosage form, paracetamol 250mg in 5mL oral suspension or paracetamol 120mg in 5mL oral suspension, in response to coronavirus (COVID-19) for self-isolated individuals aged 3 months or over to 11 years of age with fever protocol number 556 Version 2

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

I_____ (please print in capitals), confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which the supply of the medicine will take place and agree to provide this medicine only in accordance with this PGD.

I understand that it is the responsibility of the pharmacist to act in accordance with the Code of Ethics for Pharmacists and to keep an up to date record of training and competency. I understand it is also my responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and fully understand the Patient Group Direction for the supply of Paracetamol and agree to provide this medicine only in accordance with this PGD in NHS Forth Valley Community Pharmacies.

Name of Pharmacist (in block capitals)_____

GPhC Number _____ Employee ☐ Locum ☐ Relief Pharmacist ☐

If you are a locum please provide a contact email address:

_____

Normal NHS Forth Valley Pharmacy Location
(Please state contractor code)

_____

Signature_____Date_____

Note : A copy of this agreement must be signed by each pharmacy practitioner who wishes to be authorised to use the PGD for Supply of Paracetamol for fever associated with COVID 19 by Community Pharmacists working in Forth Valley Pharmacies. Please return this form to Community Pharmacy Services, Forth Valley Royal Hospital, Stirling Road, Larbert. FK5 4WR or email a copy to fv.communitypharmacysupport@nhs.scot and retain a copy in each pharmacy premises you wish to provide the medicine from. Each authorised pharmacy practitioner should be provided with an individual copy of the authorised PGD and a photocopy of the document showing their authorisation.

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Name of Premises & Contractor Code_____

Address of Premises_____

PROFESSIONAL AGREEMENT

I have read and confirm that I have understood the above named patient group direction. **The people below have been authorised to use this protocol.** I confirm that it is my professional responsibility to ensure all those signed below have had their professional registration confirmed as per normal company processes and have signed the necessary PGD paperwork* to enable them to work within the confines of this PGD.
*The professional signing the PGD paperwork accepts personal responsibility for having undertaken all the mandatory training requirements for the PGD.

Signature of **Lead Pharmacist** for the contractor code

Name (in block capitals)	Signature	Date

Name of Professional (IN BLOCK CAPITALS)	Registration Number	Signature	Date