

# Patient Group Direction

for the supply of

## **Aspirin 150mg (2 x 75mg) Dispersible Tablets**

by registered midwives for

## **Women Considered At High Risk of Pre-eclampsia**

In Maternity services, Swansea Bay Health Board

Operational from: 1<sup>st</sup> July 2020

Review Date: 1<sup>st</sup> March 2023 Version

number: 3.0

## Change history

Version number	Change details	Date
2.0	Existing Patient Group Direction (PGD) reviewed and re-formatted into new Health Board template  References updated	15/05/2018
3.0	Change of dosage to 150mg in light of updated NICE guidance. <a href="#">Hypertension in pregnancy: diagnosis and management NICE guideline [NG133] Published date: 25 June 2019</a>  New Guideline for reduction of pre-eclampsia in Swansea Bay Health Board	1/7/2020

PGD for the Supply of:



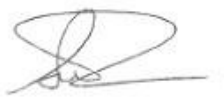

Aspirin 150mg Dispersible Tablets for Women Considered At High Risk of Pre-eclampsia v.3

Valid from: 1st July 2020

Review Date: 1st March 2023




Expiry date: 30th June 2023

## PGD development

Role	Name and Job title	Signature	Date
Lead author	Dr Louise-Emma Shaw, Consultant Obstetrician Singleton Hospital Swansea Bay Health Board		14/4/2020
Lead doctor (or dentist)	Marsham Moselhi, Consultant Obstetrician. Obstetrics and Gynaecology, Singleton Hospital		14/07/2020
Lead pharmacist	Stuart W Evans, Pharmacy Manager, Pharmacy, Singleton Hospital		14/4/20
Lead Midwife	Susan Jose Deputy Head of Midwifery		

## PGD authorisation

This PGD has been approved on behalf of Abertawe Bro-Morgannwg University Health Board by:

Designation	Name and Job title	Signature	Date
<b>Senior doctor (or dentist)</b>	<b>Myriam Bonduelle,</b> Consultant Obstetrician. Obstetrics and Gynaecologist, Maternity , Singleton Hospital		15/08/18
<b>Senior pharmacist</b>	<b>Judith Vincent,</b> Clinical Director for Integrated Pharmacy and Medicines Management		17/08/18
<b>Senior nursing representative</b>	<b>Gareth Howells,</b> Director of Nursing & Patient Experience		06/09/18
<b>Person signing on behalf of SBUHB</b>	<b>Richard Evans</b> Medical Director		

PGD for the Supply of:

Aspirin 150mg Dispersible Tablets for Women Considered At High Risk of Pre-eclampsia v.3

Valid from: 1st July 2020

Review Date: 1st March 2023

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## Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Midwives currently registered with the Nursing and Midwifery Council (NMC)
Additional requirements	Practitioners must: <ul style="list-style-type: none"> <li>➤ be employed by, or providing services on behalf of, Swansea Bay University Health Board</li> <li>➤ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it</li> <li>➤ must have access to the Patient Group Direction and associated online resources</li> </ul>
Initial training	<ul style="list-style-type: none"> <li>➤ Attended formal training for registered health professionals working within the speciality.</li> <li>➤ Demonstrates evidence of competency.</li> <li>➤ Has completed PGD training.</li> <li>➤ Familiar with the British National Formulary (BNF) and Summary of Product Characteristics (SmPC) entries for these products.</li> <li>➤ Recognises the adverse drug reactions associated with <b>Aspirin 75mg Dispersible tablets</b></li> </ul>
Competency assessment	Individual/s operating under the PGD are assessed as competent to administer and / or supply the medication as specified and detailed in the PGD by a suitably trained member of the relevant directorate

PGD for the Supply of:

Aspirin 150mg Dispersible Tablets for Women Considered At High Risk of Pre-eclampsia v.3

Valid from: 1st July 2020

Review Date: 1st March 2023

Expiry date: 30th June 2023

Ongoing training and competency	<ul style="list-style-type: none"> <li>➤ As specified by each individual directorate</li> <li>➤ Maintenance of personal education and competence as outlined by the by the NMC.</li> <li>➤ Attends relevant update training</li> <li>➤ Aware of any updates to relevant national guidelines</li> <li>➤ Aware of any updates made to the product in SmPC or BNF.</li> <li>➤ All registered professionals are professionally accountable and must work within their competence. A record of training and competence must be maintained in the individual's personal file</li> </ul>
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## Clinical Condition

<b>Clinical condition or situation to which this PGD applies</b>	Reducing the risk of hypertensive disorders in pregnancy
<b>Inclusion Criteria</b>	Women identified at moderate and high risk of pre-eclampsia, using the guidance outlined in Hypertension in pregnancy: diagnosis and management NICE guideline <a href="#">[NG133]</a>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>➤ Hypersensitivity/allergy to aspirin or other Non-Steroidal Anti-inflammatory Drugs (NSAIDs)</li> <li>➤ Asthma precipitated by NSAIDs in past.</li> <li>➤ Already on aspirin.</li> <li>➤ Active or history of recurrent peptic ulcer and / or gastric / intestinal haemorrhage, or other kinds of bleeding such as cerebrovascular haemorrhages.</li> <li>➤ Bleeding disorder e.g. Von Willebrand's disease.</li> <li>➤ Coagulation disorders such as haemophilia and thrombocytopenia.</li> <li>➤ Patients who are suffering from gout.</li> <li>➤ Severe hepatic impairment.</li> <li>➤ Severe renal impairment.</li> </ul>

PGD for the Supply of:

Aspirin 150mg Dispersible Tablets for Women Considered At High Risk of Pre-eclampsia v.3

Valid from: 1st July 2020

Review Date: 1st March 2023

Expiry date: 30th June 2023

<b>Cautions (including any relevant action to be taken)</b>	Refer to medical practitioner if patient is currently prescribed: <ul style="list-style-type: none"> <li>➤ Methotrexate</li> <li>➤ Uricosuric agents, e.g. probenecid</li> <li>➤ Anticoagulants e.g. coumarin, heparin, warfarin and</li> <li>➤ Phenindione</li> <li>➤ Anti-platelet agents</li> <li>➤ Selective serotonin re-uptake inhibitors (such as sertraline or paroxetine)</li> <li>➤ Antidiabetics, e.g. sulphonylureas</li> <li>➤ Digoxin</li> <li>➤ Lithium</li> <li>➤ Diuretics</li> <li>➤ Antihypertensives</li> <li>➤ Carbonic anhydrase inhibitors (acetazolamide)</li> <li>➤ Systemic corticosteroids</li> <li>➤ Other NSAIDs (e.g. ibuprofen, naproxen, diclofenac)</li> <li>➤ Ciclosporin, tacrolimus</li> <li>➤ Valproate</li> <li>➤ Phenytoin (an antiepileptic)</li> </ul>
	For a full list of special warnings and precautions for use, interactions etc., consult the <a href="#">Summary of Product Characteristics</a>
<b>Arrangements for referral for medical advice</b>	Refer to a consultant obstetrician.
<b>Action to be taken if patient is excluded</b>	<ul style="list-style-type: none"> <li>➤ Document reason for exclusion in hand held maternity record and refer to the consultant obstetrician.</li> </ul>
<b>Action to be taken if patient declines treatment</b>	<ul style="list-style-type: none"> <li>➤ Document reason for refusal, if given, in the hand held maternity record and discuss with the relevant obstetrician.</li> <li>➤ Document the action taken.</li> </ul>

### Details of the Medicine

<b>Name, form and strength of medicine</b>	Aspirin 75mg Tablets
<b>Legal category</b>	Prescription Only Medicine

PGD for the Supply of:

Aspirin 150mg Dispersible Tablets for Women Considered At High Risk of Pre-eclampsia v.3

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Expiry date: 30th June 2023

<b>Indicate any off-label use (if relevant)</b>	This use of aspirin 75mg tablets is off-label. Administration in accordance with the <a href="#">NICE guideline Hypertension in pregnancy: diagnosis and management [NG133]</a>
<b>Route / Method of Administration</b>	Oral
<b>Dose and frequency</b>	150mg (2x75mg tablets) daily from 12 weeks until birth
<b>Quantity to be supplied</b>	<ul style="list-style-type: none"> <li>➤ An initial supply of 28 days treatment</li> <li>➤ It is intended that the GP will continue the treatment or mother will purchase a supply</li> <li>➤ However, further instalments of 28 days duration may be supplied under this PGD if required.</li> </ul>
<b>Maximum or minimum treatment period</b>	From 12 weeks gestation until birth.
<b>Adverse effects</b>	<ul style="list-style-type: none"> <li>➤ Side effects are not common and are mainly gastrointestinal e.g. dyspepsia, nausea, vomiting,</li> </ul>
	<p>diarrhoea and gastrointestinal bleeding which can lead to haemorrhage and perforation.</p> <ul style="list-style-type: none"> <li>➤ Aspirin may precipitate bronchospasm and induce asthma attacks or other hypersensitivity reactions in susceptible individuals.</li> <li>➤ Due to the effect on platelet aggregation, aspirin may be associated with an increased risk of bleeding.</li> <li>➤ Isolated cases of liver function disturbances and skin reactions have been reported. Aspirin and other NSAIDs may cause salt and water retention as well as a deterioration of renal function</li> </ul> <p>A detailed list of adverse reactions associated with <b>Aspirin 75mg tablets</b> can be found in the <a href="#">SmPC</a>.</p>

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<p><b>Reporting procedure for suspected adverse reactions</b></p>	<ul style="list-style-type: none"> <li>➤ If the medicine is a ▼ (black triangle) medicine, all suspected adverse effects should be reported to the Medicines and Health products Regulatory Agency (MHRA) using the yellow card system</li> <li>➤ For established medicines, serious adverse events in adults and all suspected adverse reactions in children that may be attributable to the product should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card system</li> <li>➤ Guidance on the yellow card system is available at the back of the BNF or can be accessed via the CHM website at <a href="http://www.yellowcard.gov.uk">www.yellowcard.gov.uk</a></li> <li>➤ Explain patients can self report any suspected adverse reactions directly to the MHRA</li> <li>➤ In the event of an unexpected adverse drug reaction: <ul style="list-style-type: none"> <li>• if necessary seek appropriate emergency advice and assistance</li> <li>• make a note in the individual's clinical record and inform appropriate doctor/independent nurse prescriber</li> <li>• Complete incident procedure if adverse reaction is severe (refer to local organisational policy).</li> </ul> </li> </ul>
<p><b>Records to be kept</b></p>	<ul style="list-style-type: none"> <li>➤ patient inclusion or exclusion from PGD</li> <li>➤ date and time of administration and / or supply</li> <li>➤ patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD</li> <li>➤ Whether patient consent to treatment was obtained.</li> <li>➤ details of medicine, such as name, form, strength, dose, frequency, quantity, route and site (if by injection) of administration</li> <li>➤ batch number and expiry date</li> </ul>
	<ul style="list-style-type: none"> <li>➤ A statement that administration or supply is by using a PGD including the PGD version number.</li> <li>➤ name and signature of the health professional administering or supplying the medicine</li> <li>➤ relevant information that was provided to the patient or their carer (including side effects)</li> <li>➤ details of any adverse drug reaction and actions taken ➤ referral arrangements (if any)</li> </ul>



## Patient information

<b>Written information to be given to the patient or carer</b>	<ul style="list-style-type: none"><li>➤ Full explanation of risks and benefits to the patients (including the unlicensed use of the medicine in order to obtain informed consent).</li><li>➤ Provide manufacturer's Patient Information Leaflet (PIL) supplied with the pack</li><li>➤ Counselling information to be given specific to the medication.</li><li>➤ Provide information on possible side effects and their management.</li><li>➤ Advise to contact the Doctor or nurse about any other severe side effects, if concerned about any reaction and / or if the treatment fails or the condition / symptoms worsen</li></ul>
<b>Follow- up advice to be given to the patient or carer</b>	Midwives to follow SBUHB Criteria list for consultant led care and timescales for referral.

## Appendices

### **Appendix A: Key references**

- Current edition of BNF. Available at: <http://bnf.org/bnf/index.htm>
- [Summary of Product Characteristics](#) for **Aspirin 75mg Tablets**
- NICE guidance. [Hypertension in pregnancy: diagnosis and management NICE guideline \[NG133\] Published date: 25 June 2019](#)

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Aspirin 150mg Dispersible Tablets for Women Considered At High Risk of Pre-eclampsia v.3

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**Appendix B: Healthcare Professionals Agreement to Practice**

Patient Group Direction for the Supply of **Aspirin 150mg (2x75mg) Tablets**  
to Women Considered At High Risk of Pre-eclampsia

**Patient Group Directions do not remove inherent professional obligations or accountability.**

It is the responsibility of each professional to practise only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this “Agreement to Practice”, you are indicating that you agree to its contents and that you will work within it

Note to Authorising Managers:

Managers should only authorise staff who have received the required training and have been assessed as competent to work to this PGD. Authorised staff should be provided with a copy of the clinical content of the PGD and a photocopy of this agreement confirming their authorisation. The authorising manager should retain the original signed copy within the practice / clinic / directorate and retained for access by the Health Board for audit purposes.

**Name and address of Practice / Clinic / Directorate:**

***I confirm that I have read and understood the content of this PGD and agree to supply and / or administer this medicine only in accordance with this PGD.***

<b>Name of health professional</b>	<b>Signature</b>	<b>Senior representative authorising health professional</b>	<b>Date</b>

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**Appendix C: Moderate and high risk of pre-eclampsia  
(NICE (2019) The management of hypertension in pregnancy)**

Name:	Hospital number;
Date of birth:	
Address:	

**Estimated date of delivery:**  
**By USS / LMP (delete as appropriate)**  
**Current gestation:**

<b>MODERATE RISK</b>	<b>Tick</b>	<b>HIGH RISK</b>	<b>Tick</b>
First Ongoing Pregnancy (excluding miscarriage etc)		Previous hypertensive disease in pregnancy	
Age 40 or more at booking		Chronic Kidney Disease	
Pregnancy Interval >10 years		Pre-existing Diabetes	
BMI 35-49.9 at booking		Autoimmune disorders (Systemic Lupus erythematosus or phospholipid syndrome)	
Family history of pre-eclampsia (either parent)		Pre-existing hypertension	
Twins or higher multiple pregnancy		BMI 50 or more at booking	

**TWO moderate or ONE high risk factors requires administration of aspirin 150mg from 12 weeks gestation.**

<b>Reasons to Not give Aspirin</b>	<b>Tick</b>
Known Allergy to aspirin	
Asthma triggered by Aspirin OR Ibuprofen	
Active Stomach ulcers	

**Record of Supply:**

<b>Drug</b>	<b>Dose</b>	<b>Quantity supplied</b>	<b>Batch number</b>	<b>Expiry date</b>
Aspirin	150mg daily			

**Midwife's signature:**

**Date:**

*File one copy in hand held maternity record / Store second copy for audit.*

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## Maternity Services

### Checklist for Clinical Guidelines being Submitted for Approval

Title of Guideline:	Aspirin in pregnancy
Name(s) of Author:	
Chair of Group or Committee approving submission:	PGD
Brief outline giving reasons for document being submitted for ratification	PGD update. New evidence suggesting change in dosage required.
Details of persons included in consultation process:	
Name of Pharmacist (mandatory if drugs involved):	
Issue / Version No:	3
Please list any policies/guidelines this document will supercede:	Aspirin 150mg (2 x 75mg) Dispersible Tablets by registered midwives for Women Considered At High Risk of Pre-eclampsia 2018
Date approved by Group:	1 July 2020
Next Review / Guideline Expiry:	1 March 2023
Please indicate key words you wish to be linked to document	Aspirin, pre-eclampsia
File Name: Used to locate where file is stores on hard drive	Aspirin, pregnancy

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