

This applies to adult patients only

Loading Dose Worksheet for Intravenous Argatroban

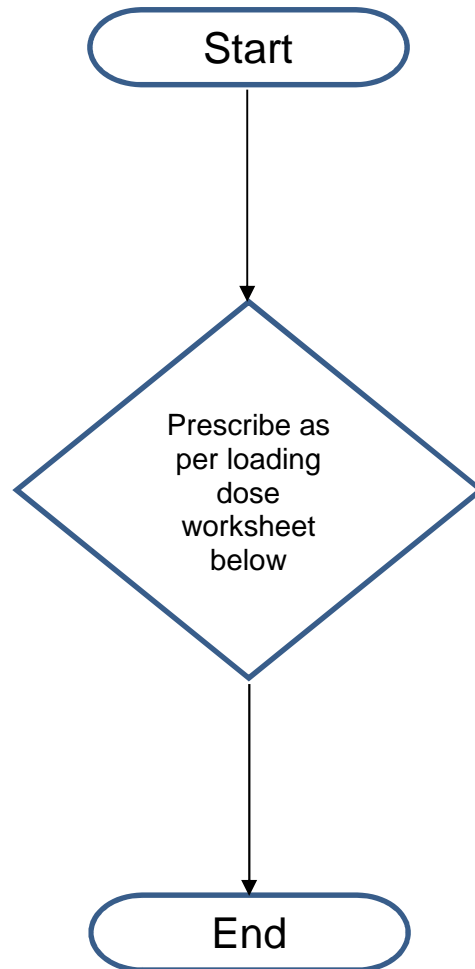
Key:

General Notes

GP/SWASFT

ED/MAU/SRU/Acute GP/Amb-Care

In-patient wards



1. Aim/Purpose of this Guideline

1.1. This loading dose worksheet is intended to guide medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of intravenous argatroban loading doses in adults

2. The Guidance

2.1. See the next page(s)

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Loading dose worksheet for IV Argatroban

Administration

Dose

- Anticoagulation in patients with heparin-induced thrombocytopenia type II with normal hepatic function:
 - ◊ Initial infusion of **2mcg/kg/min**
- **Please note:** reduce initial infusion to **0.5mcg/kg/min** in patients with **moderate hepatic impairment** (Child-Pugh Class B), after **cardiac surgery** and in **critically ill** patients.
- Maintenance doses are based on **aPTT** levels (see **Monitoring**).
- The maximum recommended dose is 10mcg/kg/min.
- The maximum recommended duration of treatment is 14 days.

Instructions for dilution

- Argatroban comes as a 250mg/2.5mL vial that must be diluted to make a final concentration of 1mg/mL:
 - ◊ Dilute one 2.5mL vial to a total volume of 250mL with glucose 5%, sodium chloride 0.9%, or sodium lactate compound.
- Mix thoroughly after dilution by repeated inversion of the solution container for one minute. Slight haziness may form due to transient micro-precipitation, but the solution should clear with adequate mixing. If the solution is cloudy, or if precipitate is noted, it should be discarded.

Example Prescription (see overleaf for dose table)

- Based on a 70kg Adult with normal hepatic function

EPMA Supplementary intravenous therapy prescription sheet										att:patient label		
All infusions, infusion fluids, blood and plasma must also be prescribed in EPMA												
Date	Infusion solution	Name and dose of additive	Infusion volume	Duration of infusion	Infusion rate	Proposed start time	Prescriber signature	Infusion bag batch no.	Time actually started	Given by	Time finished	Pharma use
										Checked by		
1/8 /17	Sodium Chloride 0.9%	Argatroban 250mg	250 mL	Continuous	8.4 mL/hr		Doctor (bleep)					

Monitoring

- **aPTT** at baseline and 2 hours after the start of the infusion to confirm aPTT is within the desired therapeutic range (1.5 to 3.0 times the initial baseline value but not exceeding 100 seconds).
- See overleaf for guidance table on rate adjustments according to aPTT and when further aPTT levels are required.
- Monitor LFTs (argatroban is contraindicated in severe liver impairment).
- Monitor for signs of bleeding as major adverse effect of argatroban.
- No dose adjustment is necessary in renal impairment or the elderly.

Disclaimer: This worksheet is a guideline—there may be other safe ways of prescribing and administering this drug

Argatroban— Dose tables

Infusion Rate (ml/hr)						
Weight (kg)	2mcg/kg/min (Standard dosing schedule)			0.5mcg/kg/min (Moderate hepatic impairment/ critically ill patients)		
	Dose (mcg/min)	Infusion rate (mL/hr)	<i>Incremental increase in infusion rate if aPTT is <1.5 x baseline (0.5mcg/kg/min) mL/hr</i>	Dose (mcg/min)	Infusion rate (mL/hr)	<i>Incremental increase in infusion rate if aPTT is <1.5 x baseline (0.1mcg/kg/min) mL/hr</i>
50	100	6.0	1.5	25	1.5	0.3
60	120	7.2	1.8	30	1.8	0.4
70	140	8.4	2.1	35	2.1	0.4
80	160	9.6	2.4	40	2.4	0.5
90	180	10.8	2.7	45	2.7	0.5
100	200	12.0	3.0	50	3.0	0.6
110	220	13.2	3.3	55	3.3	0.7
120	240	14.4	3.6	60	3.6	0.7
130	260	15.6	3.9	65	3.9	0.8
140	280	16.8	4.2	70	4.2	0.8

Infusion rate adjustment according to aPTT				
aPTT (seconds)	Initial Infusion rate: 2mcg/kg/min (Standard dosing schedule)		Initial Infusion rate: 0.5mcg/kg/min (Moderate hepatic impairment/ critically ill patients)	
	Infusion rate change	Next aPTT level	Infusion rate change	Next aPTT level
< 1.5 times baseline	Increase by 0.5mcg/kg/min (see above table)	2 hours	Increase by 0.1 mcg/kg/min (see above table)	4 hours
1.5-3.0 times baseline (not exceeding 100 seconds)	No change	2 hours; after 2 consecutive aPTT's within target range, check at least once a day	No change	4 hours; after 2 consecutive aPTT's within target range, check at least once a day
> 3.0 times baseline or > 100 seconds	Stop infusion until aPTT is 1.5-3.0 times baseline; resume at half the previous rate	2 hours	Stop infusion until aPTT is 1.5-3.0 times baseline; resume at half the previous rate	4 hours

3. Monitoring compliance and effectiveness

Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice).
Lead	Medications Safety Pharmacist.
Tool	No specific tool. Datix will be used to identify clinical incidents.
Frequency	As required according to clinical incident reports.
Reporting arrangements	Via Medicines Practice Committee. Clinical incidents on Datix will be reported to the senior nurse/manager in that area and will also be reported to the Medication Safety Group.
Acting on recommendations and Lead(s)	Actions from incident reports will be at a local level and may also result in broader actions, co-ordinated by the Medication Safety Group. Matrons/ward managers
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within the time frame specified in the action plan.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Diversity & Human Rights Policy'](#) or the [Equality and Diversity website](#).

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Loading Dose Worksheet for Intravenous Argatroban.			
Date Issued/Approved:	November 2017			
Date Valid From:	November 2017			
Date Valid To:	November 2020			
Directorate / Department responsible (author/owner):	Bronwin Staple, Medicines Information Lisa Thomas, Medicines Information Ann Cardell, Medication Safety			
Contact details:	01872 252587			
Brief summary of contents	Guidance on the prescribing and administration of intravenous argatroban in adults.			
Suggested Keywords:	'Argatroban', 'Loading Dose', 'Anticoagulant', 'Heparin-induced Thrombocytopenia'.			
Target Audience	RCHT	PCH	CFT	KCCG
	✓			
Executive Director responsible for Policy:	Chief Pharmacist.			
Date revised:	October 2017			
This document replaces (exact title of previous version):	Clinical Guideline for Argatriban in Adults – Loading Dose Worksheet.			
Approval route (names of committees)/consultation:	Medication Practice Committee.			
Divisional Manager confirming approval processes	<i>Head of relevant Division.</i>			
Name and Post Title of additional signatories	Not required.			
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}			
	Name:			
Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy	Internet & Intranet		Intranet Only	✓

on Policies – Approvals and Ratification):				
Document Library Folder/Sub Folder	Clinical / Pharmacy			
Links to key external standards	None			
Related Documents:	N/A			
Training Need Identified?	N/A			

Version Control Table

Date	Version No	Summary of Changes	Changes Made by (Name and Job Title)
October 2011	V1.0	Initial Issue.	Ian Nicholls, Medication Safety Pharmacist
October 2012	V2.0	Clinical update.	Ian Nicholls, Medication Safety Pharmacist
August 2014	V3.0	Update to include EPMA changes and review practice.	Ian Nicholls, EPMA and governance Pharmacist
October 2017	V4.0	Clinical update.	Lisa Thomas, Medicines Information Pharmacist; Bronwin Staple, Medicines Information Lead Pharmacist.

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Initial Equality Impact Assessment Form

Name of the strategy / policy /proposal / service function to be assessed (hereafter referred to as <i>policy</i>) (Provide brief description): Loading Dose Worksheet for Intravenous Argatroban.	
Directorate and service area: All clinical areas	Is this a new or existing Policy? Existing.
Name of individual completing assessment: Lisa Thomas	Telephone: 01872 252587
1. Policy Aim* Who is the strategy / policy / proposal / service function aimed at?	This loading dose worksheet is intended to guide medical, nursing and pharmacy staff in the safe and appropriate prescribing and administration of intravenous argatroban loading doses in adults.
2. Policy Objectives*	To ensure RCHT complies with the requirements of the NPSA RRR018: <i>Preventing fatalities from medication loading doses.</i>
3. Policy – intended Outcomes*	Reduction in the risk associated with the prescribing and administration of intravenous argatroban loading doses in adults.
4. *How will you measure the outcome?	Review of Clinical Incident Reports.
5. Who is intended to benefit from the policy?	All adult inpatients within the Trust.
6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b) If yes, have these *groups been consulted? C). Please list any groups who have been consulted about this procedure.	No. Medications Safety Group.

7. The Impact			
Please complete the following table.			
Are there concerns that the policy could have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		✓	Policy for all patients
Sex (male, female, trans-gender / gender reassignment)		✓	Policy for all patients
Race / Ethnic communities /groups		✓	Policy for all patients

Disability - Learning disability, physical disability, sensory impairment and mental health problems		✓	Policy for all patients
Religion / other beliefs		✓	Policy for all patients
Marriage and civil partnership		✓	Policy for all patients
Pregnancy and maternity		✓	Policy for all patients
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		✓	Policy for all patients
<p>You will need to continue to a full Equality Impact Assessment if the following have been highlighted:</p> <ul style="list-style-type: none"> You have ticked "Yes" in any column above and No consultation or evidence of there being consultation- this <u>excludes</u> any <i>policies</i> which have been identified as not requiring consultation. or Major service redesign or development 			
8. Please indicate if a full equality analysis is recommended.		Yes	No ✓
9. If you are not recommending a Full Impact assessment please explain why.			
It is not required as the guideline does not have a differential impact on any group.			
Signature of policy developer / lead manager / director		Date of completion and submission November 2017	
Names and signatures of members carrying out the Screening Assessment	1. Lisa Thomas 2. Bronwin Staple		

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead,
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,
Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust's web site.

Signed _____

Date _____