



European Medicines Agency
Evaluation of Medicines for Human Use

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**ASSESSMENT OF THE PAEDIATRIC NEEDS
CARDIOVASCULAR PRODUCTS**

DISCLAIMER

The Paediatric Working Party (PEG) is working to identify the needs in the different therapeutic areas where there should be research and development of medicinal products for children, either old (i.e. off patent) or new ones (including those under development). Products on the list are not in any order of priority.

The lists should not be viewed as a prescription tool nor as recommendations for treatment. Accuracy of data including in particular authorised doses cannot be guaranteed.

Information on existing marketing authorisations is very limited and therefore information under “authorised” includes the indication in broad term (only related to cardiology), the lower age group authorised in at least one Member State, the authorised dose(s) (if authorised for use in patients less than 18 years of age) and formulation(s) in at least in one Member State.

Please refer to the EMEA/PEG procedure for identifying the paediatric needs for further information.

Comments from third parties are expected especially to complete and or update the list as necessary.

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INOTROPES, PHOSPHODIESTERASE INHIBITORS, INODILATORS, VASODILATORS	
LEVOSIMENDAN	
<i>Authorised indication</i>	Heart failure
<i>Authorised age group</i>	> 15 years
<i>Authorised dose</i>	12-24 µg/kg, followed by 0.1 µg/kg/min
<i>Authorised formulation</i>	2.5 mg/ml intravenous solution
<i>Needs¹</i>	Extension of the indication (efficacy, long term safety data and dose) < 15 years Age appropriate formulation
MILRINONE	
<i>Authorised indication</i>	Heart failure, low cardiac output following cardiac surgery
<i>Authorised age group</i>	> 12 years
<i>Authorised dose</i>	0.3-0.75 µg/kg/min
<i>Authorised formulation</i>	Intravenous solution
<i>Needs</i>	Extension of the indication (efficacy, long term safety data and dose) < 12 years Age appropriate formulation
ENOXIMONE	
<i>Authorised indication</i>	Heart failure
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	100mg/ml, 150mg/ml solution for injection
<i>Needs</i>	Extension of the indication (efficacy, long term safety data and dose) to all age groups Age appropriate formulation
INHALED NITRIC OXIDE	
<i>Authorised indication</i>	Pulmonary hypertension
<i>Authorised age group</i>	Preterms ≥ 34 weeks of gestational age, neonates and infants
<i>Authorised dose</i>	5-20 ppm
<i>Authorised formulation</i>	400 ppm mol/mol Inhalation gas
<i>Needs</i>	Extension of the indication to preterms < 34 weeks (efficacy and safety data) and in post-operative use in all age groups
BOSENTAN	
<i>Authorised indication</i>	Pulmonary arterial hypertension
<i>Authorised age group</i>	> 12 years
<i>Authorised dose</i>	62.5 mg b.i.d for 4 weeks, maintenance 125 mg b.i.d
<i>Authorised formulation</i>	62.5 mg tablet
<i>Needs</i>	Although there are some dosing regimen mentioned in the SPC for children ≥ 10 kg, additional data on efficacy and safety needed Data on efficacy, safety and dose < 3 years Age appropriate formulation
SILDENAFIL	
<i>Authorised indication</i>	Pulmonary hypertension
<i>Authorised age group</i>	Adults

¹ The list will specify which kind of data would be needed but neither the design, nor the number of studies (e.g. PK, efficacy). The lists will indicate the need for 'age-appropriate' formulations, without specifying which one, to keep options open and room for innovation.

<i>Authorised dose</i>	-
<i>Authorised formulation</i>	20, 25, 50 and 100 mg film-coated tablet
Needs	Extension of the indication (efficacy, long term safety data and dose) to all age groups Age appropriate formulation
ILOPROST	
<i>Authorised indication</i>	Pulmonary hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Nebuliser solution 10 micrograms/ml
Needs	Extension of the indication (efficacy, long term safety data and dose) to all age groups Age appropriate formulation
DOPAMINE	
<i>Authorised indication</i>	Cardiogenic shock, acute heart failure
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Intravenous solution
Needs	Extension of the indications to all age groups, including neonates (efficacy, safety data and dose) Age appropriate formulation
DOBUTAMINE	
<i>Authorised indication</i>	Cardiogenic shock, acute heart failure
<i>Authorised age group</i>	Children (<i>Spain, Germany</i>)
<i>Authorised dose</i>	1-15 µg/kg/min
<i>Authorised formulation</i>	Intravenous solution
Needs	Define the lower age limit based on data on efficacy and safety and investigate where needed. Age appropriate formulation
ARGININE-VASOPRESSIN	
<i>Authorised indication</i>	Cardiogenic shock
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Intravenous solution
Needs	Extension of the indication (safety, efficacy and dose) to all age groups Age appropriate formulation
DIHYDRALAZINE	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Powder and solvent for injection 25 mg/2 ml
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
NITROPRUSSIDE	
<i>Authorised indication</i>	Heart failure, hypertensive crisis
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Intravenous solution

Needs	Extension of the indications (efficacy, safety data and dose) to all groups Age appropriate formulation
EPINEPHRINE	
<i>Authorised indication</i>	Cardiac arrest
<i>Authorised age group</i>	Adults and children (unspecified lower age group)
<i>Authorised dose</i>	0,01-0,03 mg/kg
<i>Authorised formulation</i>	Intravenous solution
Needs	To define lower age group and investigate where there is a need
NOREPINEPHRINE	
<i>Authorised indication</i>	Acute hypotension
<i>Authorised age group</i>	Adults and children (unspecified lower age group)
<i>Authorised dose</i>	0,01-0,03 mg/kg
<i>Authorised formulation</i>	Intravenous solution
Needs	To define lower age group and investigate where there is a need
INDOMETACIN (IV)	
<i>Authorised indication</i>	Patent Ductus Arteriosus (PDA) closure
<i>Authorised age group</i>	Preterms (<i>United Kingdom and Belgium</i>)
<i>Authorised dose</i>	0,2 mg/kg every 12 hours x 3
<i>Authorised formulation</i>	Intravenous solution
Needs	Age appropriate formulation Availability in all Member States
ACE-INHIBITORS	
CAPTOPRIL	
<i>Authorised indication</i>	Hypertension, heart failure
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	12.5 mg tablet, 25 mg tablet
Needs	Re-analysis of the benefit/risk in children based on existing data, Define lower age limits in both indications and investigate where needed Age appropriate formulation
RAMIPRIL	
<i>Authorised indication</i>	Hypertension, heart failure
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	1,25 mg, 2,5 mg, 5 mg, and 10 mg tablet
Needs	Re-analysis of the benefit/risk in children based on existing data Define lower age limit in both indications and investigate where needed Age appropriate formulation
ENALAPRIL	
<i>Authorised indication</i>	Hypertension, heart failure
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	2.5 mg tablet, 5 mg tablet, 10, 20, 40 mg tablet

Needs	Re-analysis of the benefit/risk in children based on existing data Define lower age limits in both indications and investigate where needed Liquid formulation known to be technically challenging – Need for information on extemporaneous formulation in Summary of Product Characteristics
CALCIUM-ANTAGONISTS	
NIFEDIPINE	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	20 mg sustained release tablet, oral solution (drops) in some Member States, Capsules
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation, including prolonged release form
VERAPAMIL	
<i>Authorised indication</i>	Arrhythmias
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	40 mg, 80 mg and 120 mg tablets, 40 mg capsule, 2.5 mg/ml intravenous solution
Needs	Extension of the indication (data on efficacy, safety and dose) to all age groups Age appropriate formulation
AMLODIPINE	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	5 mg and 10 mg capsule
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
NICARDIPINE	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	50 mg prolonged release capsule, 20 mg tablet, 10 mg/10 ml intravenous solution
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
HYPERTENSION CENTRAL ACTION MECHANISM	
CLONIDINE	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	100, 150, 300 µg capsules, 25 µg tablets, intravenous solution (Norway, Finland, United Kingdom)

Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate oral formulation IV formulation to be made available in all Member States
α - AND β -BLOCKERS	
LABETALOL	
<i>Authorised indication</i>	Hypertension emergencies, hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	50, 100 mg and 200 mg scored tablet, 5, 10 mg/ml intravenous solution
Needs	Extension of the indications (efficacy, safety data and dose) Age appropriate formulation
PRAZOSIN	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Children > 12 years
<i>Authorised dose</i>	2.5 mg per day up to 5 mg/day
<i>Authorised formulation</i>	1 mg and 5 mg scored tablet, 2.5 and 5 mg prolonged release tablet
Needs	Extension of the indication to children < 12 years (efficacy, safety data and dose) Age appropriate formulation
β - BLOCKERS	
PROPRANOLOL	
<i>Authorised indication</i>	Arrhythmias, hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	20 mg tablet, 40 mg scored tablet, 160 mg prolonged release tablet, intravenous solution (5 mg/5 ml), oral liquid formulation (<i>United Kingdom</i>)
Needs	Extension of the indication for arrhythmias only (efficacy, safety data and dose) to all age groups Age appropriate formulation and intravenous solution to be made available in all Member States
SOTALOL	
<i>Authorised indication</i>	Supraventricular and ventricular arrhythmias
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	40 and 80 mg tablet, 160 mg tablet, intravenous solution
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
CARVEDILOL	
<i>Authorised indication</i>	Hypertension, heart failure, Angina
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	3.125 mg, 6.25 mg, 12.5 mg, 25 mg tablet

Needs	Extension of the indication (efficacy, safety data and dose) in both indications for hypertension and heart failure to all age groups Age appropriate formulation
ATENOLOL	
<i>Authorised indication</i>	Hypertension, arrhythmias
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	25 mg tablet, 50 mg and 100 mg tablet, intravenous solution, oral solution (<i>United Kingdom</i>)
Needs	Extension of the indications (efficacy, safety data and dose) to all age groups Age appropriate formulation in all Member States
METOPROLOL	
<i>Authorised indication</i>	Hypertension, arrhythmias
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	10 mg and 50 mg tablet, 200 mg prolonged tablet, 1 mg/ml intravenous solution
Needs	Extension of the indications (efficacy, safety data and dose) to all age groups Age appropriate formulation
ACEBUTOLOL	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults and Children
<i>Authorised dose</i>	10 mg/kg/day
<i>Authorised formulation</i>	200 mg, 400 mg coated tablet, 500 mg prolonged release tablet, 40 mg/ml oral solution (<i>France</i>)
Needs	Indication and age appropriate formulation to be made available in all Member States
ESMOLOL	
<i>Authorised indication</i>	Hypertension, arrhythmias
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	10 mg/ml intravenous solution, 250 mg/ml concentrate for intravenous solution
Needs	Extension of the indications (efficacy, safety data and dose) to all age groups Age appropriate formulation
OTHER ANTI-ARRHYTHMICS	
AMIODARONE	
<i>Authorised indication</i>	Arrhythmias
<i>Authorised age group</i>	> 3 years (<i>United Kingdom</i>)
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	100 mg tablet, 200 mg tablet, intravenous solution

Needs	Extension of the indication (efficacy, safety data and dose) < 3 years. Lower age limit to be defined in children due to iodine intoxication and thyroid adverse effects Age appropriate formulation (benzyl alcohol in current iv formulation)
FLECAINIDE	
<i>Authorised indication</i>	Arrhythmias
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	100 mg scored tablet, 50 mg tablet (<i>France</i>) intravenous solution
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
ADENOSINE TP	
<i>Authorised indication</i>	Reduction of supraventricular tachycardia - Cardioversion
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Intravenous solution
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
PROPAFENONE	
<i>Authorised indication</i>	Arrhythmias
<i>Authorised age group</i>	Infants and children (<i>Germany</i>)
<i>Authorised dose</i>	10-20 mg/kg (<i>Germany</i>) 6-12mg/kg/d in divided doses (<i>Malta</i>)
<i>Authorised formulation</i>	10 mg coated tablets, 300 mg scored tablets, (<i>Germany, Italy</i>)
Needs	Safety data especially on the risk of thrombopenia and arrhythmia Re-analysis of the benefit/risk in children based on existing data to define lower age limit
LIDOCAINE	
<i>Authorised indication</i>	Ventricular fibrillation, tachycardia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	20 mg/ml intravenous solution
Needs	Extension of the indications (efficacy, safety data and dose) to all age groups Age appropriate formulation
DIURETICS	
FUROSEMIDE	
<i>Authorised indication</i>	Hypertension, heart failure, oedema
<i>Authorised age group</i>	Children (for treatment of oedema in Sweden, hypertension in France)
<i>Authorised dose</i>	1 to 2 mg/kg/day (oral) for oedema 0.5 to 1 mg/kg/day (iv)
<i>Authorised formulation</i>	20 mg scored tablet, 40 mg tablet, 10 mg/ml intravenous solution, 10 mg/ml oral solution in some Member States (<i>France</i>)

Needs	Indications for oedema and hypertension and age appropriate formulation to be made available in all Member States
SPIRONOLACTONE	
<i>Authorised indication</i>	Hypertension, heart failure
<i>Authorised age group</i>	Adults and Children (<i>United Kingdom</i>)
<i>Authorised dose</i>	3 mg/kg/day (<i>United Kingdom</i>)
<i>Authorised formulation</i>	25 mg, 50 mg and 100 mg tablet
Needs	Age appropriate formulation Availability in all Member States
HYDROCHLOROTHIAZIDE/ CHLOROTHIAZIDE	
<i>Authorised indication</i>	Hypertension, heart failure
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	25 mg and 50 mg tablet
Needs	Extension of the indications for hypertension and heart failure (efficacy, safety data and dose) to all age groups Data on efficacy, safety and dose in oedema of bronchopulmonary dysplasia Age appropriate formulation
AT II-RECEPTOR ANTAGONISTS	
IRBESARTAN	
<i>Authorised indication</i>	Hypertension, Renal disease
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	75 mg tablet, 150 and 300 mg tablet and 75 mg, 150 mg, 300 mg film-coated tablet
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
CANDESARTAN	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	4 mg, 8 mg and 16 mg tablet
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
VALSARTAN	
<i>Authorised indication</i>	Hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	80 mg tablet

Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
TELMISARTAN	
<i>Authorised indication</i>	Essential hypertension
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	80 mg tablet
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
HYPO LIPIDAEMICS	
STATINS	
ATORVASTATIN	
<i>Authorised indication</i>	Dyslipidemia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	10 mg, 20 mg, 40 mg and 80 mg tablet
Needs	Extension of the indications (efficacy, safety data and dose) Age appropriate formulation Data on efficacy, safety and dose in secondary dyslipidaemia Lower age limit to be defined
FLUVASTATIN	
<i>Authorised indication</i>	Dyslipidemia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	20 mg, 40 mg and 80 mg tablet
Needs	Lower age limit to be defined Extension of the indications (efficacy, safety data and dose) as per lower age limit defined Age appropriate formulation Data on efficacy, safety and dose in secondary dyslipidaemia
PRAVASTATIN	
<i>Authorised indication</i>	Heterozygous hypercholesterolemia
<i>Authorised age group</i>	> 8 years
<i>Authorised dose</i>	10 to 20 mg daily
<i>Authorised formulation</i>	10, 20 mg and 40 mg tablet
Needs	Data on clinical outcome and safety in long term use Data on efficacy, safety and dose in secondary dyslipidaemia
LOVASTATIN	
<i>Authorised indication</i>	Dyslipidemia
<i>Authorised age group</i>	> 12 years
<i>Authorised dose</i>	10-80 mg daily
<i>Authorised formulation</i>	10 mg, 20 mg and 40 mg tablet

Needs	Data on clinical outcome and safety in long term use Data on efficacy, safety and dose in secondary dyslipidaemia
SIMVASTATIN	
<i>Authorised indication</i>	Prevention of cardiovascular complications, hypercholesterolemia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	5, 10, 20 and 40 mg, 80 mg tablet
Needs	Lower age limit to be defined Extension of the indications (efficacy, safety data and dose) as per lower age limit defined Age appropriate formulation Data on efficacy, safety and dose in secondary dyslipidaemia
COLESEVELAM	
<i>Authorised indication</i>	Primary hypercholesterinaemia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Tablets
Needs	Extension of the indications (efficacy, safety data and dose) Define lower age limit Age appropriate formulation Data on efficacy, safety and dose in secondary dyslipidaemia
ANTITHROMBOTICS	
UROKINASE	
<i>Authorised indication</i>	Thrombotic events
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Intravenous solution
Needs	Data on efficacy, safety and dose on catheter obstruction, vascular access in all age groups Age appropriate formulation
OTHERS	
CLOPIDOGREL	
<i>Authorised indication</i>	Prevention of atherothrombotic events
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Oral solution, 75 mg film-coated tablets
Needs	Extension of the indication (efficacy, safety data and dose) in all age groups Age appropriate formulation
ALTEPLASE	
<i>Authorised indication</i>	Thrombolysis
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Intravenous solution

Needs	Data on efficacy, safety and dose in thrombotic events in all age groups Age appropriate formulation
ENOXAPARINE	
<i>Authorised indication</i>	Prevention and treatment of deep venous thrombosis
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	100 mg/ml, 150 mg/ml solution for injection
Needs	Extension of the indication (efficacy, safety data and dose) to all age groups Age appropriate formulation
DALTEPARINE	
<i>Authorised indication</i>	Prevention and treatment of deep venous thrombosis, Myocardial Infarction, anticoagulation for hemodialysis and hemofiltration
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	10000-25000 IU antiX/ml solution for injection
Needs	Extension of the indications (efficacy, safety data and dose) to all age groups Age appropriate formulation
Acetylsalicylic acid (aspirin)	
<i>Authorised indication</i>	Prevention of arterial thrombosis Kawasaki disease
<i>Authorised age group</i>	> 6 months (for fever in some Member States)
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	50 mg powder and tablet, 75 mg tablet, 100 mg tablet, 100 mg/ml solution for injection
Needs	Age appropriate IV formulation Indication for Kawasaki disease in all Member States
DIPYRIDAMOLE	
<i>Authorised indication</i>	Prevention of arterial thrombosis
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	25, 50, 75 mg 100 mg tablet
Needs	Re-analysis of benefit risk in children based on existing data to define age lower limit
HEPARIN	
<i>Authorised indication</i>	Prevention and treatment of venous and arterial thrombosis
<i>Authorised age group</i>	Adults and children (unspecified age limit)
<i>Authorised dose</i>	20 UI/kg.h (initial dose)
<i>Authorised formulation</i>	IV formulation
Needs	Availability in all Member States
LOW MOLECULAR WEIGHT HEPARINS	
<i>Authorised indication</i>	Prevention and treatment of thrombosis
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-

<i>Authorised formulation</i>	Injectable (SC) formulation, 150mg/ml solution for injection
<i>Needs</i>	Extension of the indications (efficacy, safety data and dose) to all age groups Age appropriate formulation
WARFARIN	
<i>Authorised indication</i>	Prevention and treatment of thrombosis
<i>Authorised age group</i>	Adult and children (unspecified lower age limit)
<i>Authorised dose</i>	< 12 months: 0.32 mg/kg/d (mean stable dose) 12 months – 10 yrs: no data 11- 18 yrs: 0.09 mg/kg/d
<i>Authorised formulation</i>	Scored Tablet 2 mg, 5 mg
<i>Needs</i>	Data on dose in all age groups Age appropriate formulation