

Bulletin Pharmacy

For Healthcare Professional Only



EDITORIAL BOARD

ZARENA BT ZAINUL ABIDIN

NURUL AISYAH BINTI AMRAN

NAZIFA HUMAIRA BINTI ABDUL RAZAK

FUHKKB

NEW DRUG IN FUHKKB

Ubat Kelulusan Khas (UKK)

MEDSAFETY

Golden Hour with
Fibrinolytic

MEDICATION

ACUTE PAIN MANAGEMENT
IN PEADIATRIC

PAIN MANAGEMENT IN
PREGNANCY & LACTATION

NEW DRUG

JKUT BIL 2-2025



- **Acyclovir 250mg Injection**
- **Prescriber Category A***
- **Medical Department**



- **Perindopril 4mg and Indapamide 1.25mg Tablet**
- **Prescriber Category B**
- **Quota Medical & NCD**



- **Amlodipine 10mg and Valsartan 160mg Tablet**
- **Prescriber Category A/KK**
- **Quota Medical & NCD**



- **Dapagliflozin 10mg Tablet**
- **Prescriber Category A/KK**
- **Medical & Quota NCD**



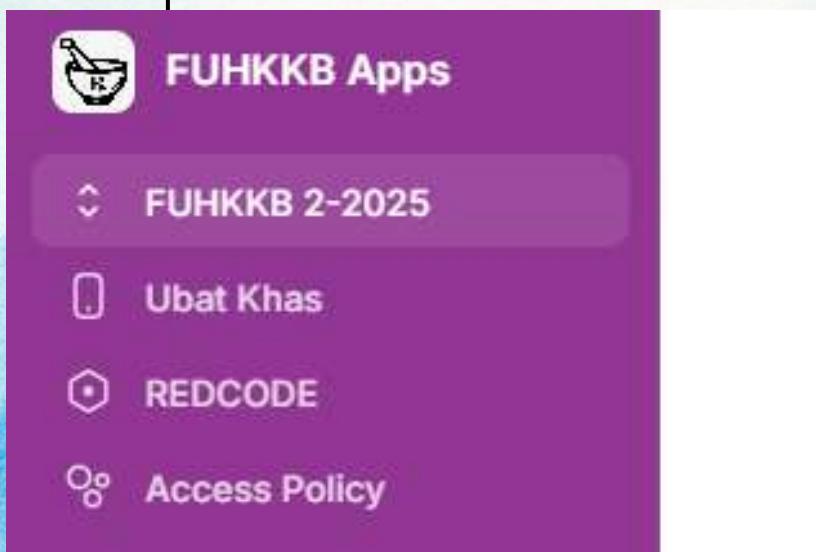
NEW DRUG



- **Betamethasone 17-valerate 0.1% Ointment**
- **BVC 1:2**
- **Prescriber Category B**
- **Medical Department**



- **Meclozine HCL 25mg and Pyridoxine 50mg Tablet**
- **Veloxin**
- **Prescriber Category B**
- **Obstetric & Gynaecology**



Ubat Kelulusan Khas

PF NURUL AISYAH BINTI AMRAN

Amalan mempreskrib ubat-ubatan yang tersenarai **FUKKM** adalah selaras dengan "Good Clinical Practice". Namun, terdapat pesakit yang memerlukan rawatan ubat-ubatan di luar senarai / indikasi **FUKKM** yang memerlukan kelulusan khas.



UKK adalah ubat:

- Ubat tidak tersenarai dalam **FUKKM**,
- Di luar indikasi **FUKKM** dan / atau di luar indikasi Pihak Berkuasa Kawalan Dadah (PBKD),
- Tidak berdaftar dengan PBKD di Malaysia

Kriteria dan Justifikasi Permohonan UKK

1. Pesakit telah dirawat menggunakan semua ubat-ubatan yang disenaraikan dalam **FUKKM** (bagi indikasi yang sama) tetapi **tidak berkesan**



2. Pesakit mengalami **kesan advers** atau **tidak dapat bertoleransi** dengan ubat-ubatan yang disenaraikan dalam **FUKKM** (perlu kemukakan salinan laporan kesan advers)

3. Ubat **penyelamat nyawa** yang **tiada alternatif** lain dalam **FUKKM**



4. Ubat dengan **indikasi spesifik** yang **tiada alternatif** lain dalam **FUKKM**

5. Ubat untuk kes-kes epidemik



RARE DISEASE



6. Ubat orphan (Orphan Medicine)
(Ubat yang digunakan untuk merawat, mencegah atau mendiagnos penyakit jarang jumpa (rare disease))

Ubat Kelulusan Khas

Proses permohonan UKK



Borang permohonan UKK (stok /individu/ulangan) diisi oleh **Pegawai perubatan/Pakar/Ketua Jabatan/Unit**



Borang permohonan diserahkan kepada **Pegawai Farmasi Pusat Maklumat Ubat (PF PMU)** untuk **semakan**.



Permohonan yang lengkap dan disokong oleh Ketua Pegawai Farmasi dan Pengarah Hospital akan dihantar kepada BAPF melalui sistem **PhIS**



Perolehan ubat dilakukan mengikut jumlah yang telah diluluskan (**Tidak melebihi setahun**)



Sekiranya lulus, **“Import permit”** akan diberikan bagi ubat yang tiada di pasaran Malaysia.

“Import permit” hanya sah untuk **setahun**.

Ketua Pengarah Kesihatan (KPK) atau **Pengarah Kanan Perkhidmatan Farmasi (PKPF)** akan meluluskan/menolak permohonan



RUJUKAN



Permohonan Ulangan

- **Permohonan ulangan untuk ubat berdaftar** akan diproses di fasiliti masing-masing (Tidak perlu kelulusan KPK/PKPF)
- **Permohonan ulangan bagi ubat tidak berdaftar** perlu dihantar kepada Seksyen Ubat Khas, Cawangan Pengurusan Formulari, Bahagian Amalan & Perkembangan Farmasi, KKM untuk diproses

Untuk maklumat lanjut sila layari:-

<https://sites.google.com/moh.gov.my/gppukk/utama>

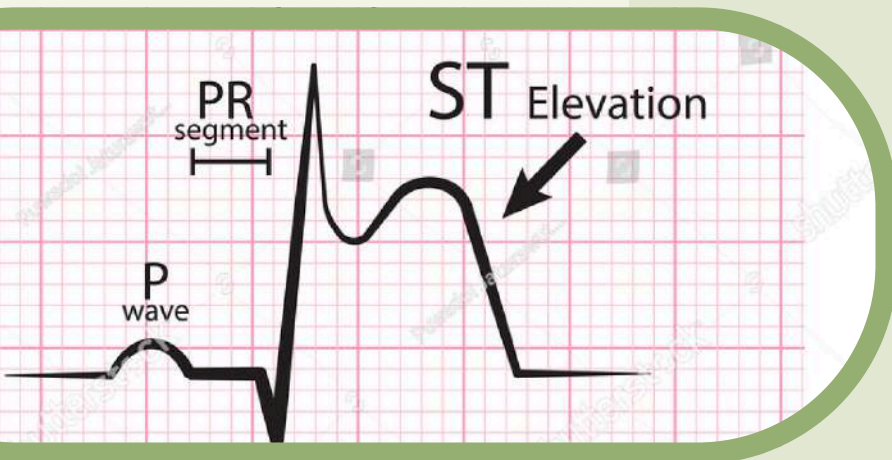
GOLDEN HOUR

FIBRINOLYTIC THERAPY



Golden Hour

Fibrinolytic therapy when given within **2 hours** from time of onset of symptoms, it is most beneficial and has been shown to be able to abort the infarction and reduce mortality by up to 50%



Indication

Only be given to patients with STEMI

Choice of Fibrinolytic

1. Streptokinase
2. Tenecteplase

Absolute Contraindication

Risk of intracranial haemorrhage

- History of intracranial bleed
- History of ischaemic stroke within 3 months
- Known structural cerebral vascular lesion (e.g. arteriovenous malformation)
- Known intracranial neoplasm

Risk of bleeding

- Active bleeding or bleeding diathesis (excluding menses)
- Significant head trauma within 3 months
- Suspected aortic dissection



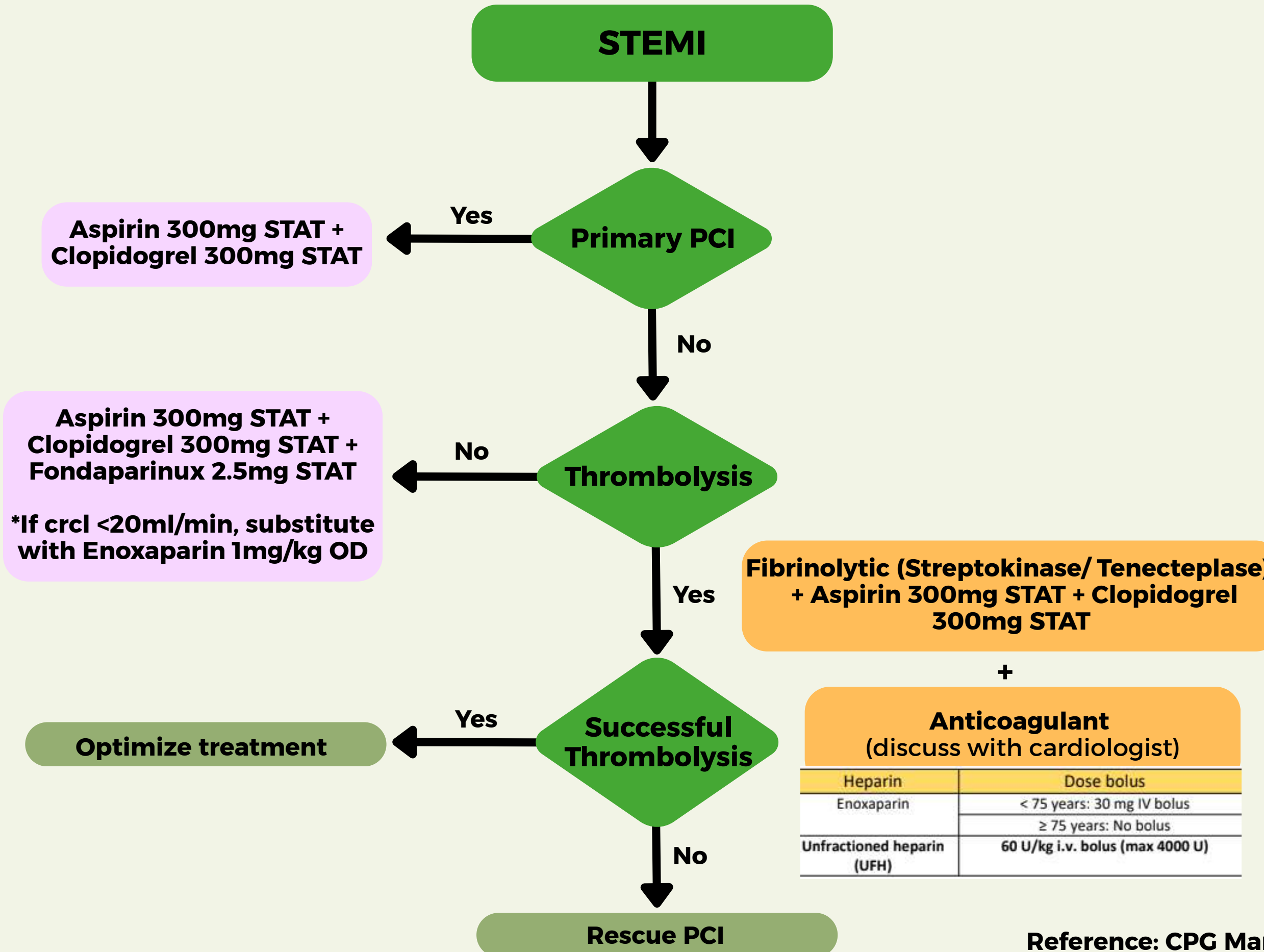
STREPTOKINASE VS TENECTEPLASE

Streptokinase		Tenecteplase
Group C streptococcus	Source	Recombinant
Yes thereby less effective if given between 3 days and 1 or even 4 years after the first administration	Antigenic	No
Less specific to fibrin	Fibrin specificity	More Fibrin specific thereby lowering bleeding complication
RM 1,00.77/ vial	Cost	RM 4,276.55/ vial
1.5 mega units in 100 ml normal saline or 5% dextrose over 1 hour	Dose	iv Tenecteplase weight-based regimen (refer below) over 5-10 seconds

Tenecteplase Dosing

BODY WEIGHT	SINGLE IV BOLUS OVER 5 SECS	VOLUME TNK TO BE ADMINISTERED
< 60 kg	30 mg	6
60 to < 70 kg	35 mg	7
70 to < 80 kg	40 mg	8
80 to < 90 kg	45 mg	9
> 90 kg	50 mg	10

ANTI-THROMBOTIC GUIDELINES FOR STEMI IN ED



Optimize treatment

- 1) Anticoagulant**
 - s/c Fondaparinux 2.5mg OD
 - s/c Enoxaparin 1mg/kg BD

*If crcl <20ml/min, substitute with Enoxaparin 1mg/kg OD
- 2) Antiplatelet**
 - T. Clopidogrel 75mg OD
 - T. Cardiprin 100mg OD/ Aspirin 150mg OD
- 3) Beta-blocker**
- 4) ACEi/ARBs**
- 5) Statin**
- 6) s/l GTN 0.5mg PRN**

Fibrinolytic (Streptokinase/ Tenecteplase) + Aspirin 300mg STAT + Clopidogrel 300mg STAT

Anticoagulant (discuss with cardiologist)

Heparin	Dose bolus
Enoxaparin	< 75 years: 30 mg IV bolus
	≥ 75 years: No bolus
Unfractionated heparin (UFH)	60 U/kg i.v. bolus (max 4000 U)

ACUTE PAIN MANAGEMENT IN PEADIATRIC

BY: NAZIFA HUMAIRA

PAIN SCORE

Observational-based Pain Score: The Alder Hey Triage Pain Score

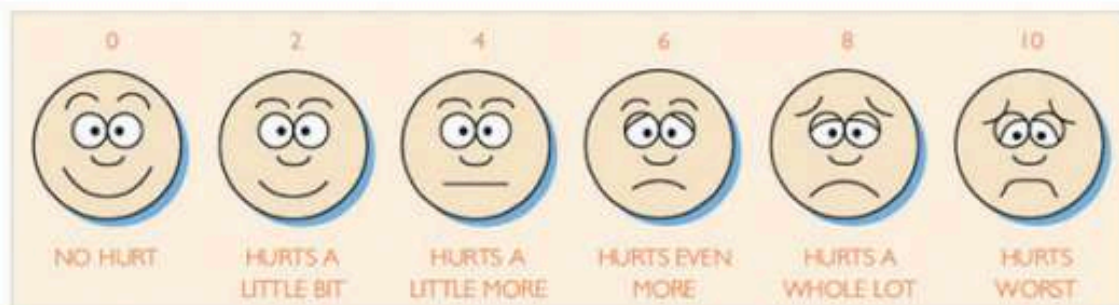
No.	Response	Score 0	Score 1	Score 2
1	Cry or voice	No complaint or cry Normal conversation	Consolable Not talking negative	Inconsolable Complaining of pain
2	Facial expression -grimace*	Normal	Short grimace <50% time	Long grimace >50% time
3	Posture	Normal	Touching / rubbing / sparing / limping	Defensive / tense
4	Movement	Normal	Reduced or restless	Immobile or thrashing
5	Colour	Normal	pale	Very pale / 'green'

*grimace – open mouth, lips pulled back at corners, furrowed forehead and /or between eye-brows, eyes closed, wrinkled at corners. Score range from 0 to 10

Self Assessment Pain Score:

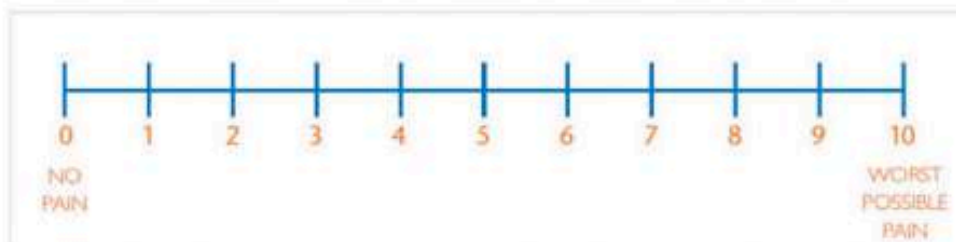
The two examples are FACES Pain Scale (Wong & Baker) and Verbal Pain Assessment Scale (Likert Scale).

FACES Pain Scale - The child is more than 3 years old and he or she is asked to choose a face on the scale which best describes his / her level of pain. Score is 2, 4, 6, 8, or 10.



Verbal Pain Assessment Scale

A child who is more than 8 years old is asked to rate his or her pain by circling on any number on the scale of 0 to 10.



ACUTE PAIN MANAGEMENT IN PEADIATRIC

ANALGESIC LADDER

		MODERATE		SEVERE		UNCONTROLLED
				7-10		
MILD 1-3		4-6		Regular IV/SC Morphine 5-10mg 4H	PRN IV/SC Morphine 5-10mg	To refer to APS For: PCA or Epidural or other forms of analgesia
				Or	Or	
Regular No Medication Or PCM 1g QID	PRN PCM &/or NSAID/ COX2 Inhibitor	Regular Opioid Tramadol 50-100mg TDS-QID ± PCM 1g QID ± NSAID/ COX2 Inhibitor	PRN Additional Tramadol 50-100mg (max total Dose: 400mg/day)	Aqueous Morphine 5-10mg 4H	Aqueous Morphine 5-10mg	
				Or	Or	
				IR Oxycodone 5-10mg 4-6H	IR Oxycodone 5-10mg	
				± PCM 1g QID ± NSAID/ COX2 Inhibitor		

Ref:

1. Shann, F. (2017). Drug Doses (17th ed.). Collective Pty Ltd.
2. Joint Formulary Committee & Royal Pharmaceutical Society. (2024).
3. British National Formulary for Children (BNFC). Pharmaceutical Press.
4. Malaysian Paediatric Association. (2019). Paediatric Protocols for Malaysian Hospitals (4th ed.). Malaysian Paediatric Association.
5. Ministry of Health Malaysia. (2023). Paediatric Pain Management Guidelines 2023. Medical Development Division, Ministry of Health Malaysia. ISBN 978-967-2469-53-7.



ACUTE PAIN MEDICATION FOR PEDIATRIC IN HKKB



PARACETAMOL

Available Preparation	Dose	Remarks
ORAL <ul style="list-style-type: none"> Paracetamol 500mg Tablet Paracetamol 250mg/5 ml Syrup 	0-3 months <ul style="list-style-type: none"> 15mg/kg/dose 6-8 H Max: 60mg/kg/day > 3 months <ul style="list-style-type: none"> 15mg/kg/dose 4-6 H Max: 75mg/kg/day or 4 grams/day 	<ul style="list-style-type: none"> First line Safe in all ages
PER RECTAL <ul style="list-style-type: none"> Paracetamol 125mg Suppository Paracetamol 250mg Suppository 	<12 years old <ul style="list-style-type: none"> 10-20mg/kg/dose every 4-6 H Do not exceed 4 doses in 24 hours Max: 75mg/kg/day 	Recommended in: <ul style="list-style-type: none"> High grade fever If child vomits Refuses oral meds Unable to swallow

NSAIDS

<ul style="list-style-type: none"> Ibuprofen 200mg Tablet 	> 6 months <ul style="list-style-type: none"> 4-10mg/kg/dose every 6-8 H Max: 40mg/kg/day or 2400mg/day, whichever is less 	<ul style="list-style-type: none"> Freshly prepared Reserve in patient contraindicated/ not responding to PCM
<ul style="list-style-type: none"> Diclofenac 50mg Tablet 	> 12 years old <ul style="list-style-type: none"> Refer adult dosing 	<ul style="list-style-type: none"> Use the lowest effective dose for shortest duration IV Diclofenac NOT RECOMMENDED
<ul style="list-style-type: none"> Mefenamid Acid 250mg Capsule 	> 14 years old <ul style="list-style-type: none"> Refer adult dosing 	

OPIOIDS

<ul style="list-style-type: none"> Tramadol 50mg Capsule 	> 12 years old <ul style="list-style-type: none"> 1-2 mg/kg/dose every 4-6 H Max: 100mg/dose, not to exceed 400mg/day 	<ul style="list-style-type: none"> Not recommended for children in whom respiratory function might be compromised
<ul style="list-style-type: none"> Tramadol 50mg/ml Injection 	> 12 years old <ul style="list-style-type: none"> Refer adult dosing 	<ul style="list-style-type: none"> It may worsen the opioid toxicity

PAIN MANAGEMENT IN PREGNANCY & LACTATION

BY: NAZIFA HUMAIRA

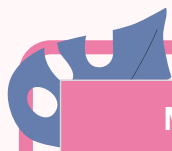


FDA Pregnancy Category

FDA DRUG RISK CATEGORIES IN PREGNANCY*	
Category	Description
A	Safest, well-controlled studies in pregnant women have not shown an increased risk of fetal abnormalities
B	No risk shown in animal studies and no adequate human studies or risk to fetus in animal studies but no harm to fetus in human studies
C	Risk to fetus in animal studies and no adequate human studies or no animal or adequate human studies
D	Risk to fetus has been shown in well-controlled or observational studies in pregnant patients; the benefits of therapy may outweigh the potential risk in human studies
E	Evidence of fetal abnormalities in well-controlled studies in animals or humans; contraindicated in pregnancy

DRUG & LACTATION DATABASE





Medicine	FDA category	Pregnancy	Lactation	Dose / Remarks
Antipyretic				
Paracetamol 500mg Tablet	B	✓	✓	Dose: 500-100mg every 4-6 hours Max: 4g daily
NSAIDS				
Ibuprofen 200mg Tablet	C	✗	✓	Dose: 200-400mg TDS Max: 3.2g daily <ul style="list-style-type: none">• Risk in 1st & 3rd trimester• For short-term use
Diclofenac 50mg Tablet	C	✗	✓	Dose: 75-150mg daily in 2-3 divided dose. Max: 3mg/kg/day (150mg/day) <ul style="list-style-type: none">• Risk in 1st & 3rd trimester• For short-term use
Mefenamic Acid 250mg Capsule	C	✗	✓	Dose: 250-500mg TDS <ul style="list-style-type: none">• Risk in 1st & 3rd trimester• For short-term use
Celecoxib 200mg Capsule	C	✗	✓	Dose: 200mg OD/BD <ul style="list-style-type: none">• Risk in 1st & 3rd trimester• Use only if benefit > risk
Opioid analgesic				
Tramadol HCL 50mg Capsule	C	✗	✗	Dose: 50mg TDS/PRN <ul style="list-style-type: none">• Risk in 1st & 3rd trimester• Prolonged use can result in neonatal opioid withdrawal syndrome and risk of respiratory depression



Additional notes:

- Paracetamol is first-line for pregnancy and breastfeeding
- NSAIDs avoid after 20 weeks; short-term use before then may be considered.
- Tramadol = last-line, only if safer options fail, and monitor neonate if breastfeeding.
- For lactation, Medication best taken immediately after breastfeeding to give the maximum time gap before the next feed, reducing drug exposure to the baby.

