RALTEGRAVIR

Read in conjunction with Disclaimer

Formulary: Restricted
For HIV prophylaxis as part of combination therapy in high-risk neonates ≥ 37 weeks and weighing ≥ 2 kg born to HIV positive mothers. Treatment must be under the direction of an Infectious Disease Consultant.

Special Access Scheme (SAS): Category A

Presentation	**Granules for oral suspension**: 100 mg sachets.
Classification	Integrase inhibitor.
Indication	Post exposure propylaxis for high risk infants in combination with zidovudine and lamivudine.
Special Considerations	• Raltegravir is only indicated for neonates born at 37 weeks gestation or greater and weighing at least 2000 g. • Raltegravir competes with bilirubin for albumin protein-binding sites and may increase unconjugated bilirubin concentrations.
Monitoring	• Bilirubin and liver function tests (LFTs) at baseline. • Bilirubin, LFTs and platelets periodically if indicated by clinical presentation.
Interactions	• **Calcium** supplements may reduce raltegravir concentration if taken at the same time, which may affect its efficacy; try to avoid combination, if this is not possible consider separating administration by as long as possible (eg by at least 4 hours) and monitor for loss of efficacy. • **Iron** supplements theoretically may reduce raltegravir absorption and effectiveness; separate administration by at least 2 hours.
Side Effects	**Common or infrequent:** Headache, increased unconjugated bilirubin, insomnia, nausea, diarrhoea, fatigue. **Rare:** Psychomotor hyperactivity, rash (including Stevens-Johnson syndrome, hypersensitivity reaction, and toxic epidermal necrolysis), creatine phosphokinase elevation, muscle weakness, and rhabdomyolysis, liver enzyme elevations, particularly ALT.
Storage & Stability	Store at room temperature, between 20 and 25ºC.
Comments	Raltegravir is also known as RAL.

ORAL

Presentation

Granules for oral suspension: 100 mg sachets

Dosage

Only to be prescribed in conjunction with zidovudine and lamivudine.

Continue for the first 4 weeks of life as per dosing tables below, then stop.

For the first 7 days of life:

Approximately 1.5 mg/kg/dose once daily as per following recommended dose bands:

Corrected Gestation Age	Weight	Dose	Frequency
37 weeks or greater	2 kg to less than 3 kg	4 mg/dose	Every 24 hours
	3 kg to less 4 kg	5 mg/dose	Every 24 hours
	4 kg to less than 5 kg	7 mg/dose	Every 24 hours

For days 8 to 28 of life:

Approximately 3 mg/kg/dose every 12 hours as per following recommended dose bands:

Corrected Gestation Age	Weight	Dose	Frequency
37 weeks or greater	2 kg to less than 3 kg	8 mg/dose	Every 12 hours
	3 kg to less 4 kg	10 mg/dose	Every 12 hours
	4 kg to less than 5 kg	15 mg/dose	Every 12 hours

Dose adjustment

- **Renal impairment:** No dose adjustment necessary.
- **Hepatic impairment:** The effect of hepatic impairment on raltegravir pharmacokinetics has not been studied.

Preparation

Granules for oral suspension: 100 mg sachets

Reconstitution:

- Add 10 mL of sterile water to a syringe.
- Add the entire contents of a raltegravir sachet (100 mg) to the syringe.
- Using a gentle circular motion, mix contents of syringe for 45 seconds. Do not shake.

Concentration now equal to **10 mg/mL.**

Administration

- Draw prescribed dose into oral/enteral syringe.
- May be given anytime in relation to feeds.
- Suspension must be used within 30 minutes of preparation. Discard any remaining suspension.

Related Policies, Procedures, and Guidelines

CAHS Neonatology Guidelines:

HIV Prevention In Infants Born To HIV Positive Women

Newborn Care of the Infant Born to a Mother receiving Minical or No Antenatal Care

Pharmaceutical and Medicines Management Guidelines:

CAHS Neonatology – Medication Administration Guideline

References

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