Cyclomydril
Newborn use only

2020

Alert	Unapproved medicine in Australia and New Zealand. Available only through Special Access Scheme Category C Pathway. For topical ophthalmic use only.
Indication	Mydriatic (dilates the pupil) and cycloplegic (prevents accommodation of the eye) for ophthalmic examinations and therapeutic procedures
Action	Contains cyclopentolate hydrochloride 0.2% and phenylephrine hydrochloride 1%. Cyclopentolate hydrochloride is an anticholinergic drug and phenylephrine hydrochloride is an adrenergic drug. This combination induces mydriasis that is greater than that of either drug alone at its respective concentration. The concentrations of cyclopentolate and phenylephrine have been selected to induce mydriasis with little accompanying cycloplegia.
Drug type	Antimuscarinic (cyclopentolate) and sympathomimetic (phenylephrine).
Trade name	Cyclomydril
Presentation	2 mL DROP-TAINER® dispenser. Each mL contains: Cyclopentolate hydrochloride 0.2%, phenylephrine hydrochloride 1%.
Dose	One drop into each eye 30–60 minutes prior to procedure, may be repeated up to three times (maximum of four drops), at least 5 minutes apart. Dark irises may require additional drops
Dose adjustment	Therapeutic hypothermia – Not applicable. ECMO – Not applicable. Renal impairment – Not applicable. Hepatic impairment – Not applicable.
Maximum dose	Four drops into each eye.
Total cumulative dose	
Route	Topical instillation into the eyes.
Preparation	Not applicable
Administration	Instil one drop in each eye. Apply pressure to the lacrimal sac during and for 2 minutes after instillation of eye drop to minimise systemic absorption. Wipe away excess medication.
Monitoring	Observe infants for at least 30 minutes up to 120 minutes. Blood pressure, heart rate and oxygen saturation. Signs of ileus.
Contraindications	Concurrent use with beta-blockers. Acute stage of necrotising enterocolitis (NEC).
Precautions	To minimise systemic absorption, apply pressure over the nasolacrimal sac for 2 to 3 minutes following instillation. Bronchopulmonary dysplasia. Feeding intolerance. Severe neurological impairment.
Drug interactions	Propranolol: An enhanced pressor response to phenylephrine has been shown in patients on propranolol (blocks the beta-adrenergic vasodilation that normally reduces the blood pressure effect).
Adverse reactions	These usually only occur with excess dosing. Anticholinergic side effects include fever, tachycardia, vasodilation, dry mouth, restlessness, delayed gastric emptying and decreased gastrointestinal motility, and urinary retention. Alpha-adrenergic side effects include decreased pulmonary compliance, tidal volume and peak airflow in babies with bronchopulmonary dysplasia. Increased heart rate and blood pressure.
Compatibility	N/A
Incompatibility	N/A
Stability	Single use only. Discard after use.
Storage	Store at room temperature < 25°C.
Excipients	Preservative: Benzalkonium chloride 0.01%. Inactives: Edetate disodium, boric acid, hydrochloric acid and/or sodium carbonate (to adjust pH), purified water.
Special comments	Cyclomydril is an unapproved medicine in Australia and New Zealand.
Evidence	Refer to full version.
Practice points	Refer to full version.
References	Refer to full version.

VERSION/NUMBER	DATE
Original 1.0	**24/08/2017**
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