

Application Number	Application Date	Decision Date	Form Type	Product Profile	Product Presentation	Indication	Status Reason	Clinical Justification
MB18/0038214	30/04/2018	2/05/2018	SAS-B	Leuprorelin	Injection	Delayed puberty	Approved	
MB20/0274283	30/06/2020	1/07/2020	SAS-B	Leuprorelin	3.75mg Injection	Carcinoma	Approved	
MA22-0653240	28/02/2022		SAS-A	Leuprorelin	Injection	Delayed puberty	Completed	
								GnRH (also called LHRH) from the hypothalamus stimulates luteinising hormone (LH) and follicle stimulating hormone (FSH) release from the pituitary gland, which in turn stimulate oestradiol or testosterone production by the gonad. Leuprolide acetate (leuprorelin) is a GnRH analogue. Leuprolide stimulation testing has been shown to accurately predict pubertal progression in children with central precocious puberty (1, 2) and can therefore be used as an alternative to GnRH (which is no longer available in Australia).
MB22-0681166	19/04/2022	20/04/2022	SAS-B	Leuprorelin	Injection	Test	Approved	
MB22-0742702	21/07/2022	22/07/2022	SAS-B	Leuprorelin	Injection	Delayed puberty	Approved	
								To assess the pituitary and gonadal response in disorders of puberty or gonadal function where basal (unstimulated) gonadotrophin levels are low
MB22-0744823	25/07/2022	26/07/2022	SAS-B	Leuprorelin	Injection	Test	Approved	
MB22-0765195	18/08/2022	23/08/2022	SAS-B	Leuprorelin	Injection	IVF	Approved	
MA22-0789000	19/09/2022		SAS-A	Leuprorelin	Injection	Delayed puberty	Completed	
MB22-0793851	29/09/2022	30/09/2022	SAS-B	Leuprorelin	Injection	Test	Approved	Once off test to help with and investigate prior to/ as part of pubertal induction
								For use with stimulation test, to confirm diagnosis and plan management. Best guidelines for LHRH stimulation test are with Lucrin 5mg/mL formulation.
MB22-0795145	3/10/2022	5/10/2022	SAS-B	Leuprorelin	Injection	Test	Approved	
								Basal biochemistry not confirmatory of central vs peripheral cause - needs LHRH stimulation test to ascertain
MB22-0802515	13/10/2022	17/10/2022	SAS-B	Leuprorelin	Injection	Test	Approved	
MB22-0802522	13/10/2022	17/10/2022	SAS-B	Leuprorelin	Injection	Test	Approved	To assess whether central in origin - will impact treatment approach
MB22-0825067	17/11/2022	21/11/2022	SAS-B	Leuprorelin	Injection	Test	Approved	For stimulation test to confirm diagnosis and target appropriate management
MA23-0860950	22/01/2023		SAS-A	Leuprorelin	Injection	Test	Completed	Pubertal failure
MA23-0896266	20/03/2023		SAS-A	Leuprorelin	Injection	Test	Completed	Pubertal delay
MA18-0019528	22/01/2018		SAS-A	Goserelin	Injection	Carcinoma	Completed	
MA18/0053762	29/06/2018		SAS-A	Goserelin	Injection	Carcinoma	Completed	
MA20/0221535	26/01/2020		SAS-A	Goserelin	Implant	Carcinoma	Completed	
								planned to commence cyclophosphamide- for application for zoladex for fertility preservation
MB21-0610059	17/12/2021	20/12/2021	SAS-B	Goserelin	Injection	Fertility preservation	Approved	