

Consent to the Distribution of New Medicines

Pursuant to section 20 of the Medicines Act 1981, the Minister of Health hereby consents to the distribution in New Zealand of the new medicines which were referred to the Minister of Health under the provisions of section 24(5) of the Act and are set out in the Schedule hereto:

Schedule

Product:	APO-Paracetamol 665mg
<i>Active Ingredient:</i>	Paracetamol 665mg
<i>Dosage Form:</i>	Modified release tablet
<i>New Zealand Sponsor:</i>	Arrotex Pharmaceuticals (NZ) Limited
<i>Manufacturers:</i>	Sri Krishna Pharmaceuticals Limited, Hyderabad, India Gracure Pharmaceuticals Limited, Bhiwadi, India
Product:	Fasenra
<i>Active Ingredient:</i>	Benralizumab 30mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	AstraZeneca Limited
<i>Manufacturers:</i>	AstraZeneca Pharmaceuticals LP, Maryland, United States of America Catalent Indiana LLC, Indiana, United States of America
Product:	Fasenra Pen
<i>Active Ingredient:</i>	Benralizumab 30mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	AstraZeneca Limited
<i>Manufacturers:</i>	AstraZeneca Pharmaceuticals LP, Maryland, United States of America AstraZeneca AB, Sodertalje, Sweden Catalent Indiana LLC, Indiana, United States of America
Product:	IPCA-Enalapril
<i>Active Ingredient:</i>	Enalapril maleate 5mg
<i>Dosage Form:</i>	Tablet
<i>New Zealand Sponsor:</i>	Ipca Pharma (NZ) Pty Limited
<i>Manufacturer:</i>	Ipca Laboratories Limited, Silvassa, India
Product:	IPCA-Enalapril
<i>Active Ingredient:</i>	Enalapril maleate 10mg
<i>Dosage Form:</i>	Tablet
<i>New Zealand Sponsor:</i>	Ipca Pharma (NZ) Pty Limited
<i>Manufacturer:</i>	Ipca Laboratories Limited, Silvassa, India
Product:	IPCA-Enalapril
<i>Active Ingredient:</i>	Enalapril maleate 20mg
<i>Dosage Form:</i>	Tablet
<i>New Zealand Sponsor:</i>	Ipca Pharma (NZ) Pty Limited
<i>Manufacturer:</i>	Ipca Laboratories Limited, Silvassa, India
Product:	Osteo Relief Paracetamol
<i>Active Ingredient:</i>	Paracetamol 665mg
<i>Dosage Form:</i>	Modified release tablet
<i>New Zealand Sponsor:</i>	Arrotex Pharmaceuticals (NZ) Limited
<i>Manufacturers:</i>	Sri Krishna Pharmaceuticals Limited, Hyderabad, India Gracure Pharmaceuticals Limited, Bhiwadi, India
Product:	Paracetamol 665mg
<i>Active Ingredient:</i>	Paracetamol 665mg
<i>Dosage Form:</i>	Modified release tablet
<i>New Zealand Sponsor:</i>	Arrotex Pharmaceuticals (NZ) Limited

NEW ZEALAND GAZETTE

Manufacturers: Sri Krishna Pharmaceuticals Limited, Hyderabad, India
Gracure Pharmaceuticals Limited, Bhiwadi, India

Dated this 3rd day of September 2024.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

2024-go4440

05-09-2024 16:29
