

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 set out in the Schedule hereto:

Schedule

Product:	Besponsa
<i>Active Ingredient:</i>	Inotuzumab ozogamicin 1mg
<i>Dosage Form:</i>	Powder for injection
<i>New Zealand Sponsor:</i>	Pfizer New Zealand Limited
<i>Manufacturer:</i>	Wyeth Pharmaceutical Division of Wyeth Holdings LLC, New York, United States of America
Product:	Buprenorphine/Naloxone multichem
<i>Active Ingredients:</i>	Buprenorphine hydrochloride 2.16mg equivalent to buprenorphine 2mg Naloxone hydrochloride dihydrate 0.61mg equivalent to naloxone 0.5mg
<i>Dosage Form:</i>	Sublingual tablet
<i>New Zealand Sponsor:</i>	Multichem NZ Limited
<i>Manufacturer:</i>	Ethypharm Industries, Grand Quevilly, France
Product:	Buprenorphine/Naloxone multichem
<i>Active Ingredients:</i>	Buprenorphine hydrochloride 8.64mg equivalent to buprenorphine 8mg Naloxone hydrochloride dihydrate 2.44mg equivalent to naloxone 2mg
<i>Dosage Form:</i>	Sublingual tablet
<i>New Zealand Sponsor:</i>	Multichem NZ Limited
<i>Manufacturers:</i>	Ethypharm Industries, Grand Quevilly, France Ethypharm Industries, Chateauneuf-en-Thymerais, France
Product:	Cyclizine Lactate
<i>Active Ingredient:</i>	Cyclizine 37.35mg/mL equivalent to cyclizine lactate 50mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Max Health Limited
<i>Manufacturer:</i>	HBM Pharma s.r.o, Martin, Slovakia
Product:	Elerhin Tablets
<i>Active Ingredient:</i>	Levocetirizine hydrochloride 5mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	Ipca Pharma (NZ) Pty Limited
<i>Manufacturer:</i>	Ipca Laboratories Limited, Silvassa, India
Product:	Erlyand
<i>Active Ingredient:</i>	Apalutamide 60mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	Janssen-Cilag (New Zealand) Limited
<i>Manufacturer:</i>	Janssen Ortho LLC, Gurabo, Puerto Rico
Product:	Ipca-Levocetirizine
<i>Active Ingredient:</i>	Levocetirizine hydrochloride 5mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	Ipca Pharma (NZ) Pty Limited
<i>Manufacturer:</i>	Ipca Laboratories Limited, Silvassa, India
Product:	Parecoxib Mylan
<i>Active Ingredient:</i>	Parecoxib sodium 42.36mg equivalent to parecoxib 40mg
<i>Dosage Form:</i>	Powder for injection
<i>New Zealand Sponsor:</i>	Mylan New Zealand Limited
<i>Manufacturer:</i>	Mylan Laboratories Limited, Hosur, India

NEW ZEALAND GAZETTE

Product:

Active Ingredient:

Dosage Form:

New Zealand Sponsor:

Manufacturer:

Selcet Tablets

Levocetirizine hydrochloride 5mg

Film coated tablet

Ipca Pharma (NZ) Pty Limited

Ipca Laboratories Limited, Silvassa, India

Product:

Active Ingredient:

Dosage Form:

New Zealand Sponsor:

Manufacturers:

Teriflunomide Sandoz

Teriflunomide 14mg

Film coated tablet

Novartis New Zealand Limited

AET Laboratories Private Limited, Hyderabad, India

Combino Pharm (Malta) Limited, Birzebbuga, Malta

Dated this 14th day of October 2019.

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

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