

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: **Adempas**
Active Ingredient: Riociguat 0.5mg
Dosage Form: Film coated tablet
New Zealand Sponsor: Bayer New Zealand Limited
Manufacturer: Bayer AG, Leverkusen, Germany

Product: **Adempas**
Active Ingredient: Riociguat 1mg
Dosage Form: Film coated tablet
New Zealand Sponsor: Bayer New Zealand Limited
Manufacturer: Bayer AG, Leverkusen, Germany

Product: **Adempas**
Active Ingredient: Riociguat 1.5mg
Dosage Form: Film coated tablet
New Zealand Sponsor: Bayer New Zealand Limited
Manufacturer: Bayer AG, Leverkusen, Germany

Product: **Adempas**
Active Ingredient: Riociguat 2mg
Dosage Form: Film coated tablet
New Zealand Sponsor: Bayer New Zealand Limited
Manufacturer: Bayer AG, Leverkusen, Germany

Product: **Adempas**
Active Ingredient: Riociguat 2.5mg
Dosage Form: Film coated tablet
New Zealand Sponsor: Bayer New Zealand Limited
Manufacturer: Bayer AG, Leverkusen, Germany

Product: **Gadovist 1.0**
Active Ingredient: Gadobutrol 604.72mg equivalent to 1mmol/mL
Dosage Form: Solution for injection
New Zealand Sponsor: Bayer New Zealand Limited
Manufacturer: Bayer AG, Berlin, Germany

Product: **Keytruda**
Active Ingredient: Pembrolizumab 25mg/mL
Dosage Form: Concentrate for infusion
New Zealand Sponsor: Merck Sharp & Dohme (New Zealand) Limited
Manufacturers: MSD International GmbH (Singapore Branch), Singapore
 MSD International GmbH, t/a MSD Ireland (Carlow), Carlow, Ireland

Dated this 31st day of January 2025.

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