

## 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

<i>Product:</i>	<b>3TC</b>
<i>Active Ingredient:</i>	Lamivudine 150mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	GlaxoSmithKline (NZ) Limited
<i>Manufacturers:</i>	Glaxo Operations UK Limited t/a Glaxo Welcome Operations, Ware, United Kingdom GlaxoSmithKline Pharmaceuticals SA, Poznan, Poland
<i>Product:</i>	<b>3TC</b>
<i>Active Ingredient:</i>	Lamivudine 300mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	GlaxoSmithKline (NZ) Limited
<i>Manufacturers:</i>	Glaxo Operations UK Limited t/a Glaxo Welcome Operations, Ware, United Kingdom GlaxoSmithKline Pharmaceuticals SA, Poznan, Poland
<i>Product:</i>	<b>3TC</b>
<i>Active Ingredient:</i>	Lamivudine 10mg/mL
<i>Dosage Form:</i>	Oral solution
<i>New Zealand Sponsor:</i>	GlaxoSmithKline (NZ) Limited
<i>Manufacturer:</i>	GlaxoSmithKline (Canada) Inc, Mississauga, Canada
<i>Product:</i>	<b>Fosamax</b>
<i>Active Ingredient:</i>	Alendronate sodium trihydrate 6.53mg equivalent to alendronic acid 5mg
<i>Dosage Form:</i>	Tablet
<i>New Zealand Sponsor:</i>	Merck Sharp & Dohme (New Zealand) Limited
<i>Manufacturer:</i>	Savio Industrial Srl, Pavia, Italy
<i>Product:</i>	<b>Fosamax</b>
<i>Active Ingredient:</i>	Alendronate sodium trihydrate 52.21mg equivalent to alendronic acid 40mg
<i>Dosage Form:</i>	Tablet
<i>New Zealand Sponsor:</i>	Merck Sharp & Dohme (New Zealand) Limited
<i>Manufacturers:</i>	Savio Industrial Srl, Pavia, Italy Aesica Pharmaceuticals GmbH, Zwickau, Germany
<i>Product:</i>	<b>Fosamax</b>
<i>Active Ingredient:</i>	Alendronate sodium trihydrate 91.37mg equivalent to alendronic acid 70mg
<i>Dosage Form:</i>	Tablet
<i>New Zealand Sponsor:</i>	Merck Sharp & Dohme (New Zealand) Limited
<i>Manufacturers:</i>	Savio Industrial Srl, Pavia, Italy Aesica Pharmaceuticals GmbH, Zwickau, Germany
<i>Product:</i>	<b>Neutrafluor 5000 Plus</b>
<i>Active Ingredient:</i>	Sodium fluoride 1.105%w/w equivalent to 5000 ppm fluoride ion
<i>Dosage Form:</i>	Toothpaste
<i>New Zealand Sponsor:</i>	Colgate-Palmolive Limited (NZ)
<i>Manufacturer:</i>	Colgate-Palmolive Company, Tennessee, United States of America
<i>Product:</i>	<b>Nurofen Quickzorb (General sale)</b>
<i>Active Ingredient:</i>	Ibuprofen lysine 342mg equivalent to ibuprofen 200mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	Reckitt Benckiser (New Zealand) Limited
<i>Manufacturer:</i>	Reckitt Benckiser Healthcare International Limited, Nottingham, United Kingdom
<i>Product:</i>	<b>Nurofen Quickzorb (Pharmacy only)</b>
<i>Active Ingredient:</i>	Ibuprofen lysine 342mg equivalent to ibuprofen 200mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	Reckitt Benckiser (New Zealand) Limited
<i>Manufacturer:</i>	Reckitt Benckiser Healthcare International Limited, Nottingham, United Kingdom

## NEW ZEALAND GAZETTE

<i>Product:</i>	<b>Praluent</b>
<i>Active Ingredient:</i>	Alirocumab 75mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Sanofi-Aventis New Zealand Limited
<i>Manufacturers:</i>	Sanofi Winthrop Industrie, Le Trait, France Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany Sanofi Pasteur Inc, Pennsylvania, United States of America
<i>Product:</i>	<b>Praluent</b>
<i>Active Ingredient:</i>	Alirocumab 150mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Sanofi-Aventis New Zealand Limited
<i>Manufacturers:</i>	Sanofi Winthrop Industrie, Le Trait, France Sanofi-Aventis Deutschland GmbH, Frankfurt am Main, Germany
<i>Product:</i>	<b>Ropivacaine Kabi</b>
<i>Active Ingredient:</i>	Ropivacaine hydrochloride 2mg/mL equivalent to ropivacaine 1.77mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Fresenius Kabi New Zealand Limited
<i>Manufacturer:</i>	Fresenius Kabi Norge AS, Halden, Norway
<i>Product:</i>	<b>Ropivacaine Kabi</b>
<i>Active Ingredient:</i>	Ropivacaine hydrochloride 5mg/mL equivalent to ropivacaine 4.43mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Fresenius Kabi New Zealand Limited
<i>Manufacturer:</i>	Fresenius Kabi Norge AS, Halden, Norway
<i>Product:</i>	<b>Ropivacaine Kabi</b>
<i>Active Ingredient:</i>	Ropivacaine hydrochloride 7.5mg/mL equivalent to ropivacaine 6.64mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Fresenius Kabi New Zealand Limited
<i>Manufacturer:</i>	Fresenius Kabi Norge AS, Halden, Norway
<i>Product:</i>	<b>Ropivacaine Kabi</b>
<i>Active Ingredient:</i>	Ropivacaine hydrochloride 10mg/mL equivalent to ropivacaine 8.85mg/mL
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Fresenius Kabi New Zealand Limited
<i>Manufacturer:</i>	Fresenius Kabi Norge AS, Halden, Norway
<i>Product:</i>	<b>ZolaCos CP (Combination Product)</b>
<b>Component 1:</b>	
<i>Active Ingredient:</i>	Goserelin acetate 3.8mg equivalent to goserelin 3.6mg
<i>Dosage Form:</i>	Subcutaneous implant
<i>Manufacturer:</i>	AstraZeneca UK Limited, Macclesfield, United Kingdom
<b>Component 2:</b>	
<i>Active Ingredient:</i>	Bicalutamide 50mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	AstraZeneca Limited
<i>Manufacturer:</i>	Corden Pharma GmbH, Plankstadt, Germany
<i>Product:</i>	<b>ZolaCos CP (Combination Product)</b>
<b>Component 1:</b>	
<i>Active Ingredient:</i>	Goserelin acetate 11.34mg equivalent to goserelin 10.8mg
<i>Dosage Form:</i>	Subcutaneous implant
<i>Manufacturer:</i>	AstraZeneca UK Limited, Macclesfield, United Kingdom
<b>Component 2:</b>	
<i>Active Ingredient:</i>	Bicalutamide 50mg
<i>Dosage Form:</i>	Film coated tablet
<i>New Zealand Sponsor:</i>	AstraZeneca Limited
<i>Manufacturer:</i>	Corden Pharma GmbH, Plankstadt, Germany
<i>Product:</i>	<b>Zoladex 3.6mg</b>
<i>Active Ingredient:</i>	Goserelin acetate 3.8mg equivalent to goserelin 3.6mg
<i>Dosage Form:</i>	Subcutaneous implant
<i>New Zealand Sponsor:</i>	AstraZeneca Limited
<i>Manufacturer:</i>	AstraZeneca UK Limited, Macclesfield, United Kingdom

## NEW ZEALAND GAZETTE

*Product:* **Zoladex 10.8mg**  
*Active Ingredient:* Goserelin acetate 11.34mg equivalent to goserelin 10.8mg  
*Dosage Form:* Subcutaneous implant  
*New Zealand Sponsor:* AstraZeneca Limited  
*Manufacturer:* AstraZeneca UK Limited, Macclesfield, United Kingdom

Dated this 13th day of May 2019.

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

2019-go2232

16-05-2019 09:03

---