



TT50-4821, TT50-4821a, TT50-4821b

<<Date>>

«Title» «Initials» «Surname» «BusinessName» «BuildingName» «StreetAddress» «Locality» «State» «PostCode»

Dear Healthcare Professional

## This letter is to inform you of the following:

- Changes to COVERSYL 4mg tablet appearance
- Changes to COVERSYL packaging

**COVERSYL (perindopril erbumine) became the only funded brand of perindopril tablets in New Zealand in 2021**.<sup>1</sup> At that time, Medsafe determined that Canadian-labelled COVERSYL could be supplied until supply of New Zealand-labelled COVERSYL was available.

**New Zealand COVERSYL packs are now available** and currently transitioning into wholesalers. By April 2024, it is expected that all COVERSYL product in wholesalers will be New Zealand-labelled product.

Patients, prescribers and pharmacists can be assured that the brand name, active ingredient and doses remain the same.<sup>2,3</sup> Patients who are currently taking Canadian COVERSYL should continue to do so until they run out. Once wholesaler stock of the Canadian COVERSYL has been depleted, pharmacy will receive New Zealand COVERSYL for dispensing.

Information you may find useful.

	Canadian COVERSYL <sup>2</sup>	New Zealand COVERSYL <sup>3</sup>
Coversyl 4mg tablet		
	Green rod-shaped biconvex scored tablets.1	White rod-shaped biconvex scored tablets. <sup>2</sup>

## New Zealand COVERSYL 4mg tablets differ in colour from Canadian COVERSYL 4mg tablets:

The 2mg & 8mg New Zealand COVERSYL tablets do not differ from the Canadian COVERSYL tablets.

## New Zealand COVERSYL packaging is different and now includes: <sup>3</sup>

• a blister strip, **inside a sealed aluminium foil envelope** containing a desiccant disc, inside a carton box. Please see below examples:



Once-daily Coversyl (perindopril erbumine) 2mg, 4mg & 8mg is indicated and fully funded for the treatment of:  $^{\rm 1-3}$ 

Hypertension
Heart Failure

• Established Coronary Artery Disease

See information overleaf for full indication.

Please report any suspected adverse events to the Centre for Adverse Reactions Monitoring (CARM) online at <u>https://nzphvc.otago.ac.nz/reporting</u> or by email to carmnz@otago.ac.nz . Alternatively, suspected adverse events and / or medical enquiries may be reported to Healthcare Logistics (HCL) via telephone on +(64 9) 969 0705 or email at <u>mtaylor@healthcarelogistics.co.nz</u>.

Yours sincerely

Au

**Chelsea Burchall** Franchise Lead (Cardiology)

References: 1. Coversyl (New Zealand Stock) Data Sheet 2. Coversyl (Canadian Stock) Data Sheet 3. www.bpac.org.nz/2021/ace.aspx

Please review Data Sheet before prescribing. Coversyl is a fully funded medicine. To access a copy of the Data Sheet please go to <a href="https://www.medsafe.govt.nz/profs/datasheet/c/coversyltabCanadian.pdf">https://www.medsafe.govt.nz/profs/datasheet/c/coversyltabCanadian.pdf</a>

Minimum Data Sheet. COVERSYL (2 mg, 4 mg, 8mg tablets). Each tablet contains perindopril erbumine. Contains lactose. Therapeutic Indications: Hypertension, heart failure - recommended in combination with a diuretic and/or digoxin (safety/efficacy in NYHA IV not demonstrated), established coronary artery disease in patients stable on concomitant therapy and no heart failure, to reduce the risk of non-fatal myocardial infarction or cardiac arrest. Dose and Method of Administration: Once daily taken in the morning. Hypertension - usual starting dose 4mg/day. NB 2mg starting dose recommended for patients at risk of ACE inhibitor-induced hypotension (including elderly and diuretic-treated patients). Titrate to maximum 8mg/day (4mg/day in elderly). Congestive heart failure - initiate therapy under close medical supervision. Usual starting dose 2mg once daily given with a diuretic and/or digitalis. Maintenance dose 4mg/day. Stable coronary artery disease - usual starting dose 4mg daily for 2 weeks, then increasing to 8mg daily. NB 2mg starting dose for elderly for first week of treatment, then 4mg daily the next week, before increasing to 8mg daily. All dose increases in CAD depend on tolerance and renal function. Renal impairment - adjust dose according to CrCl, consult full Data Sheet. Contraindications: Hypersensitivity to perindopril, ACE inhibitors or excipients; pregnancy; lactation; renal artery stenosis; history of hereditary and/or idiopathic angioedema or angioedema associated with previous ACE inhibitor treatment; extracorporeal treatment with high-flux membranes (e.g. "AN 69") and LDL apheresis with dextran sulfate; combined with aliskiren-containing products in patients with diabetes or renal impairment; combined use with sacubitril/valsartan fixed dose combinations - must not initiate Coversyl earlier than 36hrs after last sacubitril/valsartan dose. Special Warnings and Precautions for Use: Hyperkalaemia: diabetes (see interactions): lithium: potassium-sparing medicines, potassium supplements or potassium-containing salt substitutes; angioedema (+/- urticaria); anaphylactoid reactions during LDL apheresis, haemodialysis or desensitisation; renal impairment; renovascular hypertension; hepatic failure; hepatic impairment; ethnicity; cough; proteinuria; hypotension; neutropenia/agranulocytosis/thrombocytopenia/anaemia; dermatological reactions; taste disturbances; medicines causing renin release; dual blockade of the RAAS; surgery; anaesthesia; aortic or mitral valve stenosis/hypertrophic cardiomyopathy; stable coronary artery disease; lactose intolerance; primary aldosteronism; elderly, paediatric use; kidney transplantation; laboratory tests. Interactions: Dual blockade of the RAAS, medicines inducing hyperkalaemia, aliskiren, extracorporeal treatments, sacubitril/valsartan, lithium, co-trimoxazole, potassium-sparing medicines, NEP inhibitors, mTOR inhibitors, gliptins, antidiabetic medicines, baclofen, non-potassium sparing diuretics, NSAIDs, aspirin >3g/day, ciclosporin, combination of ACE-I+NSAID/COX2+thiazide diuretic (additive effects), gold, antihypertensives, vasodilators, tetracycline and medicines interacting with magnesium, medicines affecting sympathetic activity, tricyclic antidepressants/ antipsychotics/ anaesthetics, heparin. Ability to drive and use machines: May be impaired. Caution is recommended at initiation. Adverse Effects: Very Common: dizziness, cough, oedema peripheral. Common: headache, paresthaesia, vertigo, tinnitus, visual disturbance/impairment, palpitations, drowsiness, hypotension (and related effects), vasculitis, flushing, impaired peripheral circulation, dyspnoea, epistaxis, discomfort on exertion, abdominal pain, constipation, diarrhoea, dysgeusia, dyspepsia, nausea, vomiting, pruritus, rash, muscle cramps/spasms, asthenia, eczema, erectile dysfunction, atypical chest pain, lethargy, epigastric pain, dry mouth, exanthema, somnolence. Uncommon: eosinophilia, hypoglycaemia, hyperkalaemia, hyponatraemia, mood disturbances/altered, sleep disorder (insomnia, dream abnormality), syncope, tachycardia, bronchospasm, urticaria , angioedema of face/extremities/lips/mucous membranes/tongue/glottis and / or larynx, hyperhidrosis, photosensitivity reactions, pemphigoid, arthralgia, myalgia, renal/urinary disorders, renal insufficiency, chest pain, malaise, pyrexia, sweating, blood urea increased, blood creatinine increased, fall, hypersensitivity, peripheral coldness, rhinitis, leukopenia, thrombocytopenia, depression, arrhythmia, pancreatitis. Rare: psoriasis aggravation, blood bilirubin elevation, hepatic enzyme increases, confusion, angina pectoris, MI, hepatitis (cytolytic or cholestatic), erythema multiforme, acute renal failure, anuria/oliguria, SIADH. Very rare: agranulocytosis/pancytopenia, decreases in haemoglobin and haematocrit, neutropenia, unexplained change in prothrombin ratio, haemolytic anaemia with congenital G-6PDH deficiency, SIADH, hallucinations, stroke possibly secondary to excessive hypotension in high-risk patients, eosinophilic pneumonia, hepatitis either cytolitic or cholestatic. Frequency not known: Raynaud's Phenomenon. Overdosage: Consult full Data Sheet. Pharmacological Properties: Perindopril is an angiotensin converting enzyme (ACE) inhibitor and lowers blood pressure by reducing the conversion of angiotensin I to angiotensin II. Date of most recent amendment to the Data Sheet: 16 February 2023. Sponsor: Servier Laboratories (New Zealand) Ltd. Level 4 Zurich House, 21 Queen street, Auckland Central, Auckland 1010. For more information or to report an adverse event for a Servier product please contact Medical Information on 0800 293 139.

## Privacy Statement: Servier Laboratories (Aust.) Pty Ltd is bound by the Australian Privacy Act 1988 (Cth) and New Zealand Privacy Act 2020. We collect and use your personal (including sensitive) information necessary to carry out our business including for the purposes of sales and marketing, providing starter packs, information and promotional material about our products and services or those of third parties which may be of interest to you, planning educational events and performing any other functions and activities relating to our business (refer to our Privacy Policy for full details). If you do not wish to provide us with your personal information, we may not be able to provide you with our services. Your personal information may be disclosed to third parties such as data verification providers (who may disclose your personal

information to their clients), mailing houses, conference organisers or to our related entities including Servier Head Office in France. Our full privacy policy (which includes details of how to request access to or correct your personal information or make a privacy complaint) can be found at <u>www.servier.com.au</u>. If you do not wish to receive marketing information, please contact our Privacy Officer by phone: 0800 293 139 (New Zealand), in writing: P.O. Box 196, Hawthorn VIC 3122 or by email: <u>privacy.au@servier.com</u>. Material prepared February 2024.