Health Newsflash

A Quarterly Publication

New Drugs and Pipeline News Reviewed at the October to December 2016 DEC Meetings

The Drug Evaluation Committee (DEC) of Express Scripts Canada conducts monthly reviews of all new drugs receiving their Notice of Compliance from Health Canada, to ascertain their place in therapy and their possible impact on the private payer sector. The prices quoted in this document are approximations for general information purposes only, and are not intended, nor should they be relied upon, for purposes of any actual claims adjudication or reimbursement. This publication, describing new drugs of significance, is provided to our customers on a quarterly basis as a value-added service. We hope that you will find this Health Newsflash informative, timely, and useful.

NEW DRUGS

Alecensaro™ (alectinib)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Capsule	02458136 – 150mg	Hoffmann-La Roche Ltd.	10:00.00 – Antineoplastic Agents

Indication(s)

Alecensaro™ (alectinib) is indicated as monotherapy for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib (Xalkori®). [Notice of Compliance with Conditions (conditional marketing approval, NOC/c]

Dose

The recommended dose of Alecensaro is 600 mg (four 150 mg capsules) given orally, twice daily with food (total daily dose of 1200 mg). Dosage reductions due to adverse drug effects may be required.

Therapeutic Alternatives

Xalkori (crizotinib); Zykadia (ceritinib)

Clinical Notes

Lung cancer is the most commonly diagnosed cancer in Canada (excluding non-melanoma skin cancers). It is the leading cause of death from cancer for both men and women in Canada. In 2015, it was estimated that 26,600 Canadians would be diagnosed with lung cancer, representing 14% of all new cancer cases in 2015. An estimated 20,900 Canadians will diewill have died from lung cancer, representing 27% of all cancer deaths in 2015. About 80% of all lung cancers are NSCLC. There are several subtypes of NSCLC including: squamous cell (epidermoid) carcinoma (30% of all NSCLC), adenocarcinoma (40-50%), large cell carcinoma (10%), and less common subtypes such as adenosquamous carcinoma and sarcomatoid carcinoma.

Anaplastic lymphoma kinase (ALK) is a member of the insulin receptor tyrosine kinase family (RTK). ALK rearrangements occur in 3-7% of patients with NSCLC and are more common among patients with a never/light smoking history, adenocarcinoma histology, a younger age, female gender and in tumours with few other mutations. The first-generation ALK inhibitor, crizotinib, showed excellent response rates and progression free survival in both first-line and second-line (post-chemotherapy) settings. Unfortunately, as seen with other targeted therapies, such as the first-generation epidermal growth factor receptor (EGFR) inhibitors in EGFR-mutated NSCLC, despite initial major responses to crizotinib, the majority of patients develop crizotinib resistance within the first 12 months.

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Second-generation ALK inhibitors were developed to enhance anti-ALK activity, to overcome crizotinib-resistant mutations and to improve activity in CNS disease. CNS metastases are a major concern in patients with ALK+ NSCLC as this has been reported to be the primary site of treatment failure in 46% of patients treated with crizotinib.

Alectinib is a highly selective and CNS-active oral second-generation ALK inhibitor. Alectinib has demonstrated activity against a broad range of ALK mutations, including mutations responsible for resistance to crizotinib, and has prospectively demonstrated durable responses in CNS lesions.

Place in Therapy

Alecensaro is an ALK inhibitor which is a second- or third-line agent which can be used in patients who have progressed after therapy with crizotinib (Xalkori). In particular, patients with CNS metastases may respond better with Alecensaro compared to the other second-generation ALK inhibitor, ceritinib (Zykadia).

Comparative Pricing

Drug	Estimated Monthly Cost
Alecensaro	$10,800
Xalkori	$8,200
Zykadia	$10,700

Impact/Plan Management Suggestions

Intermediate impact – high cost but cost shift from other similar high cost alternatives. Manage utilization to ensure appropriate use of drug.

Lixiana® (edoxaban tosylate)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Tablet	02458640 – 15mg 02458659 – 30mg 02458667 – 60mg	Daiichi Sankyo Inc.	20:12.04 – Anticoagulants

Indication(s)

Lixiana (edoxaban) is indicated for:

- Prevention of stroke and systemic embolic events in patients with atrial fibrillation, in whom anticoagulation is appropriate.
- Treatment of venous thromboembolism (VTE) (deep vein thrombosis [DVT], pulmonary embolism [PE]) and the prevention of recurrent DVT and PE.

Dose

Stroke Prevention in Atrial Fibrillation (SPAF)

The usual recommended dose of Lixiana is 60 mg once daily.

Treatment of VTE and Prevention of Recurrent DVT and PE

The recommended dose of Lixiana is 60 mg once daily following initial use of a parenteral anticoagulant for 5-10 days.

Lixiana dose may be reduced in patients with renal impairment (CrCl 30-50ml/min), low body weight (≤ 60kg), or concomitant use of P-glycoprotein inhibitors, or in certain cases of switching to another anticoagulant (bridging therapy).

Therapeutic Alternatives

Direct-acting oral anticoagulants:

Factor Xa inhibitors: Eliquis (apixaban); Xarelto (rivaroxaban)

Direct Thrombin Inhibitor: Pradaxa (dabigatran)

Clinical Notes

Lixiana (edoxaban) is a select, direct and reversible inhibitor of factor Xa. It inhibits free factor Xa, and prothrombinase activity. Inhibition of factor Xa in the coagulation cascade reduces thrombin generation and prolongs clotting time and reduces the risk of formation or provoked thrombus formation. Lixiana is the third factor Xa inhibitor to be approved in Canada after Xarelto and Eliquis. Pradaxa is a direct thrombin inhibitor that is used similarly to these drugs. All agents are indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, as well as for the treatment of VTE. Of note, Xarelto and Eliquis are indicated for initial treatment of VTE (e.g., no use of an initial parenteral anticoagulant is required) as well as prophylaxis of DVT, which may lead to PE, in patients undergoing knee or hip replacement surgery.

The efficacy and safety of Lixiana was demonstrated in two pivotal multinational, double-blind, double-dummy, non-inferiority trials. Warfarin was used as a comparator in both studies. The ENGAGE AF-TIMI 48 study evaluated the prevention of stroke and systemic embolism in patients with atrial fibrillation (AF), while the Hokusai-VTE Study evaluated the effectiveness of Lixiana for the treatment of VTE and the prevention of recurrent DVT and PE. Both trials showed Lixiana to be non-inferior to warfarin.

Place in Therapy

Lixiana is the third direct factor Xa inhibitor and the fourth direct-acting anticoagulant to become available in Canada. It has similar advantages to the other newer oral anticoagulant agents (i.e., Pradaxa, Xarelto and Eliquis) over warfarin; such as, no requirement for continuous monitoring of blood tests (INR). There is no comparative data available between the different direct-acting anticoagulants. Of note, unlike Xarelto, Eliquis and Pradaxa,

Lixiana does not have an indication for the prophylaxis of DVT/PE in patients undergoing knee or hip replacement surgery. With the available clinical data, Lixiana does not fill an unmet medical need amongst the new anticoagulant medications. It can be considered to be an alternative to the other direct-acting oral anticoagulant agents.

Comparative Pricing

Drug	Estimated Annual Cost
Lixiana	$1,100
Eliquis	$1,200
Xarelto	$1,100
Pradaxa	$1,300

Impact/Plan Management Suggestions

Minimal impact – cost shift from similarly priced alternatives.

MDK-Nitisinone (nitisinone) and Nitisinone Tablets (nitisinone)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Capsule	MDK-Nitisinone : 02457717 – 2mg 02457725 – 5mg 02457733 – 10mg	Mendelikabs Inc.	92:92.00 – Other Miscellaneous Therapeutic Agents
Tablet	Nitisinone Tablets: 02458616 – 2mg 02458624 – 5mg 02458632 – 10mg	Cycle Pharmaceuticals Ltd.	

Indication(s)

MDK-Nitisinone (nitisinone) and Nitisinone Tablets (nitisinone) are indicated for the treatment of patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

Treatment with MDK-Nitisinone or Nitisinone Tablets should be initiated and supervised by a physician experienced in the treatment of HT-1.

Dose

The recommended initial dose of MDK-Nitisinone or Nitisinone Tablets in the pediatric and adult population is 1 mg/kg body weight/ day divided in 2 doses administered orally. The dose of nitisinone should be adjusted individually.

Therapeutic Alternatives

No pharmacologic alternatives; only other treatment alternatives are dietary management and liver transplantation.

Clinical Notes

Tyrosinemia is a genetic disorder characterized by disruptions in the multistep process that breaks down the amino acid tyrosine. There are three types of tyrosinemia, which are each distinguished by their symptoms and genetic cause. Tyrosinemia type I, the most common and most severe form of this disorder, is characterized by signs and symptoms that begin in the first few months of life. Type I tyrosinemia is most common among children of French-Canadian or Scandinavian descent. Tyrosinemia type I is inherited as an autosomal recessive genetic condition that is caused by mutations in the fumarylacetoacetate hydrolase (FAH) gene that is responsible for the production of the FAH enzyme. Deficiency of this enzyme leads to an accumulation of fumarylacetoacetate and accumulation of tyrosine and its metabolites in the liver, kidney, and central nervous system. Children with Type I become ill within the first year of life with dysfunction of the liver, kidneys, and nerves, resulting in irritability, rickets, or even liver failure and death. Restriction of tyrosine in the child's diet is of little help. Often, children with type I tyrosinemia require a liver transplant.

Nitisinone is a competitive inhibitor of 4-hydroxyphenyl-pyruvate dioxygenase, an enzyme the tyrosine catabolic pathway. By inhibiting the normal catabolism of tyrosine in patients with HT-1, nitisinone prevents the accumulation of the catabolic intermediates maleylacetoacetate and fumarylacetoacetate. In patients with HT-1, these catabolic intermediates are converted to the toxic metabolites (succinylacetone and succinylacetoacetate), which are responsible for the observed liver and kidney toxicity. Succinylacetone can lead to the accumulation of 5-aminolevulinate, a neurotoxin responsible for the porphyric crises characteristic of HT-1.

Nitisinone inhibits catabolism of the amino acid tyrosine and can result in elevated plasma levels of tyrosine. As such patients taking nitisinone require a tyrosine and phenylalanine restricted diet to prevent the toxicity associated with elevated plasma levels of tyrosine.

Place in Therapy

Tyrosinemia type I affects males and females in equal numbers. The prevalence of is estimated to be 1 in 100,000 to 120,000 births worldwide. In Quebec, Canada, the birth prevalence is estimated to be 1 in 16,000, and the estimated prevalence in the Saguenay-Lac Saint-Jean region of Quebec is 1 in 1,850 births. In Norway, the birth prevalence is estimated to be 1 in 60,000 births.

MDK-Nitisinone require storage under refrigeration while Nitisinone Tablets can be stored at room temperature.

Pricing

Pricing not available.

Impact/Plan Management Suggestions

High Impact – anticipated high cost, lifetime use despite rare disease prevalence.

Movapo™ (apomorphine HCl)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Subcutaneous injection	02459132 – 30mg/3ml Pen 02459140 – 20mg/2ml Ampoule	Paladin Labs Inc.	28:36.20 – Dopamine Receptor Agonists

Indication(s)

Movapo is indicated for the acute, intermittent treatment of hypomobility, “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) in patients with advanced Parkinson’s disease.

Dose

0.2 mL (2 mg) up to a maximum recommended dose of 0.6 mL (6 mg). Movapo is given as an intermittent subcutaneous injection, and as an adjunct to oral medications used for the treatment of Parkinson’s disease. The average frequency of dosing in clinical trials was 3 times per day, with the majority of patients using ≤ 3 injections per day. The total daily dose should not exceed 2 mL (20 mg).

Therapeutic Alternatives

There are no true therapeutic alternatives to Movapo. Other dopamine agonists may be considered; however, their onset of effect prevent them from being suitable substitutes.

Clinical Notes

Apomorphine as is a dopamine agonist that appears to relieve the symptoms of parkinsonism for patients who experience severe motor fluctuations after chronic levodopa therapy. It has been approved for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes). Apomorphine hydrochloride is a potent non-ergoline D1-D2 dopamine agonist that is relatively non-selective for dopamine D1, D2, D3, D4, and D5 receptors. The precise mechanism of action of Movapo as a treatment for Parkinson’s disease is not known, but it is believed to be due to stimulation of post-synaptic D2-type receptors in the brain.

Place in Therapy

In the past, apomorphine has had tolerance issues because it is a strong vomiting inducing and blood pressure lowering effects, but it has a rapid onset of action and short duration of action, that make it advantageous during "off" episodes. Small studies have shown apomorphine to be more effective then levodopa/benserazide, levodopa/carbidopa for "off" episodes, primarily due to its rapid onset.

Pricing

Pricing not available.

Impact/Plan Management Suggestions

Insufficient information.

Venclexta™ (venetoclax)			
Dosage Form	**DIN & Strength**	**Manufacturer**	**AHFS Class**
Tablet	02458039 – 10mg 02458047 – 50mg 02458055 – 100mg 02458063 – 10/50/100mg Starter Kit	AbbVie Corp.	10:00.00 – Antineoplastic Agents

Indication(s)

Venclexta (venetoclax) is indicated as monotherapy for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options. [NOC/c]

Dose

The starting dose of Venclexta is 20 mg once daily for 7 days. The Venclexta dose must be administered according to a weekly ramp-up schedule to the recommended daily dose of 400 mg over a period of 5 weeks as shown in Table below. The 5-week ramp-up dosing schedule is designed to gradually reduce tumour burden (debulk) and decrease the risk of tumour lysis syndrome (TLS). The recommended steady daily dose is 400 mg thereafter.

Week	Venclexta Daily Dose
1	20mg (2x10mg)
2	50mg (1x50mg)
3	100mg (1x100mg)
4	200mg (2x100mg)
5 and beyond	400mg (4x100mg)

The Starting Pack provides the first 4 weeks of Venclexta according to the ramp-up schedule.

Therapeutic Alternatives

Imbruvica (ibrutinib)

Clinical Notes

Venclexta is only available through specialty pharmacies and/or retail oncology pharmacies that are part of AbbVie's managed distribution program.

Venclexta is a B-cell lymphoma-2 (BCL-2) inhibitor. The BCL-2 protein is overexpressed in the cells of many patients with CLL and is involved in tumour cell survival and resistance to chemotherapeutic agents. Venclexta assists to restore the process of apoptosis by binding directly to the BCL-2, displacing pro-apoptotic proteins such as BIM (BCL-2 interacting mediator of cell death or BCL-2-like protein 11), triggering mitochondrial outer membrane permeabilizaiton and the activation of caspases. Additionally, some data suggest Venclexta had demonstrated cytotoxic activity in tumor cells that overexpress BCL-2. Venclexta's apoptotic activity is so pronounced that there is a significant risk for TLS in the initial phase of treatment necessitating a five-week ramp-up of therapy.

Venclexta received conditional approval on the basis of one pivotal Phase II open-label, single-arm, multicenter trial in 106 patients with relapsed or refractory CLL with 17p deletion who had received at least one prior therapy. Efficacy was assessed by overall response rate (defined as partial remission or better). 85 patients experienced a response for an ORR of 80.2%. The median duration of response had not been met at approximately 12-months of median follow-up, but the range of duration of response was from 2.9 to over 19 months. Similarly, progression-free survival and overall survival had not yet been achieved at the data cut-off, but the estimated 12-month progression-free survival and overall survival rates were 72.0% and 86.7% respectively. In a non-pivotal dose-escalation and expansion Phase I trial of 116 patients, the overall response rate was 79%. The median duration of progression-free survival was 25 months in the dose-escalation cohort while PFS could not be estimated in the expansion cohort at the end of the data collection period. The 2-year overall survival estimate for all patients was 84%.

Chronic lymphocytic leukemia is a blood and bone marrow disease that usually gets worse over time. CLL is the most common type of leukemia in adults, often occurring in or after middle age. Normally, the body makes blood stem cells that slowly develop into mature blood cells, becoming a myeloid stem cell or a lymphoid stem cell. In CLL, too many blood stem cells develop into abnormal lymphocytes and don't result in healthy cells. The abnormal lymphocytes may also be called leukemic cells. The lymphocytes aren't able to fight infection properly. Also, as the number of lymphocytes increases in the blood and bone marrow, there is less room for healthy white blood cells, red blood cells, and platelets.

The Canadian Cancer Society's estimates for leukemia in Canada for 2016 is approximately 5,900 new cases. CLL is the most common type of leukemia in adults. It accounts for about one-third of all cases of leukemia with 1,600 new cases every year. Approximately 8,400 patients are currently living with CLL. The average age at diagnosis is 67 years and it is rarely seen in children.

Place in Therapy

Venclexta is the first BCL-2 inhibitor and the targeted therapy had an excellent overall response rate in patients with 17p deletion CLL who had relapsed or refractory disease after receiving at least one prior line of treatment (e.g., fludarabine-based chemotherapy). Venclexta is an alternative to Imbruvica and other agents recommended to treat 17p deletion CLL. Further studies involving patients with CLL, updated guidelines, clinical use, and longer-term safety information will more strongly define its place in therapy.

Pricing

Drug	Estimated Monthly Cost
Venclexta	$8,600
Imbruvica	$8,600

Impact/Plan Management Suggestions

Intermediate impact – high cost but similarly priced to other potential therapeutic alternatives.

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FIRST TIME GENERICS

First Time Generic Drugs (Notices of Compliance (NOCs) from August 31, 2016 to November 30, 2016)

Generic Name	Reference Drug (Brand)	Rank by ingredient cost in 2015	Manufacturer	Route of Administration	Approved Indications/ Comments
oseltamivir	Tamiflu	—	Natco Pharma (Canada) Inc.	Oral	Influenza

NEW DRUGS AND PRODUCT LINE EXTENSIONS

New Drugs and Product Line Extensions (Notices of Compliance (NOCs) from August 31, 2016 to November 30, 2016)

Brand name	Chemical name	Manufacturer	Dosage form	Type of Line Extension	Specifics/Comments
Zemaira	alpha-1 proteinase inhibitor (human)	CSL Behring Canada Inc.	Intravenous injection	New brand	Zemaira is the second alpha-1 proteinase inhibitor (A1-PI, also known as alpha-1 antitrypsin) to be available in Canada after Prolastin-C. They are indicated for use in the maintenance treatment of alpha-1 antitrypsin deficiency in patients with clinical evidence of emphysema.
Izba	travoprost	Alcon Canada Inc.	Ophthalmic solution	New brand and strength	Izba is a brand of ophthalmic travoprost in a 0.003% strength versus Travatan Z 0.004% (and generics).
Hemangiol	propranolol	Pierre Fabre Dermo-Cosmetique Canada Inc.	Oral solution	New dosage form.	Hemangiol is a new oral solution dosage form of propranolol indicated for the treatment of infants 5-weeks to 5-months of age with proliferating infantile hemangioma requiring systemic therapy.
Enstilar	betamethasone-calcipotriol	Leo Pharma Inc.	Topical foam	New brand and formulation	Topical foam formulation used to treat psoriasis. Ointment and gel formulations available as Dovobet.
Rituxan SC	rituximab	Hoffmann-La Roche Ltd.	Subcutaneous injection	New dosage form	New subcutaneous dosage form indicated for the treatment of non-Hodgkin's lymphoma.
Somavert	pegvisomant	Pfizer Canada Inc.	Subcutaneous injection	New indication	New indication removes requirement of use of other medical therapies prior to use of Somavert; i.e., potential for first-line use.

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NEW DRUGS AND PRODUCT LINE EXTENSIONS (continued)

New Drugs and Product Line Extensions (Notices of Compliance (NOCs) from August 31, 2016 to November 30, 2016)

Brand name	Chemical name	Manufacturer	Dosage form	Type of Line Extension	Specifics/Comments
Grastofil	filgrastim	Apotex Inc.	Subcutaneous or Intravenous injection	New strength	New strength of 480µg/0.8ml. Grastofil is now available in matching strengths to Neupogen.
Vyvanse	lisdexamfetamine dimesylate	Shire Pharma Canada ULC	Capsule	New strength and new indication.	New strength of 70mg to support a new indication of moderate to severe binge eating disorder (BED). Existing indication: attention deficit hyperactivity disorder (ADHD).
Naloxone Hydrochloride Nasal Spray	naloxone hydrochloride	Adapt Pharma Operations Ltd.	Metered-dose nasal spray	New dosage form	New easier to administer dosage form for the emergency treatment of known or suspected opioid overdose. Available without prescription. Intended for out-of-hospital use by non-healthcare professionals.
Opdivo	nivolumab	Bristol-Myers Squibb Canada	Intravenous injection	New indications	Two new indications for the treatment of patients with unresectable or metastatic melanoma in previously untreated adults: • For BRAF V600 mutation-positive patients. • In combination with ipilimumab (Yervoy) in patients with low tumour PD-L1 expression (expression level of < 5%).
Humira	adalimumab	AbbVie Corp.	Subcutaneous injection	New strength, new formulation, new indication	New strength delivers the same dose with a lower volume injection. New formulation contains fewer excipients. These changes have to potential to reduce patient injection discomfort due to lower volume of injection and reduce sensitivity reactions due to fewer excipients in new formulation. New indication: non-infectious uveitis (intermediate, posterior or panuveitis) in adults.
Octagam 10%	immune globulin (human)	Octapharma Canada Inc.	Intravenous injection	New indications	• Primary Immunodeficiency (PID) Syndromes • Secondary Immunodeficiency (SID) Syndromes • Guillain-Barré Syndrome in adults

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NEW DRUGS AND PRODUCT LINE EXTENSIONS (continued)

New Drugs and Product Line Extensions (Notices of Compliance (NOCs) from August 31, 2016 to November 30, 2016)

Brand name	Chemical name	Manufacturer	Dosage form	Type of Line Extension	Specifics/Comments
Qtern	saxagliptin/ dapagliflozin	AstraZeneca Canada Inc.	Tablet	New drug combination	Fixed-dose combination of the DPP-4 inhibitor saxagliptin, available as Onglyza, and the SGLT2 inhibitor dapagliflozin, available as Forxiga.
Adynovate	antihemophilic factor (recombinant), pegylated	Baxalta Canada Corp.	Intravenous injection	New drug	Pegylated version of Advate which will allow for less frequent administration – twice a week vs. 3-4 times per week.
Arepanrix	AS03-adjuvanted Quebec H5N1 influenza vaccine	GlaxoSmithKline Inc.	Intramuscular injection	New indication	Extension of indication to include children 6-months of age and older (previously indicated only in adults).
Dotarem	gadoterate meglumine	Guerbet	Intravenous injection	New drug	New MRI contrast medium for use in patients 2 years of age and older.
Zytiga	abiraterone acetate	Janssen Inc.	Tablet	New strength	500mg tablet – will allow for simplified dosing.
Flonase Allergy Relief	fluticasone propionate	GlaxoSmithKline Consumer Healthcare Inc.	Nasal Spray	New schedule	Non-prescription version of previously prescription only product (NAPRA Schedule III).
Nexium 24HR	esomeprazole magnesium	Pfizer Consumer Healthcare, a Division of Pfizer Canada Inc.	Capsule (delayed release)	New formulation	Non-prescription version of previously prescription only product (NAPRA Schedule II).
Advil 12 Hour	ibuprofen	Pfizer Consumer Healthcare, a Division of Pfizer Canada Inc.	Tablet (extended release)	New formulation	Non-prescription version of previously prescription only product (NAPRA Schedule III) – regular-release 600mg tablets remain prescription requiring.

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