# Health Newsflash — a Quarterly Publication

## New Drugs and Pipeline News Reviewed at the July to September 2012 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

### Dificid (fidaxomicin)

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Tablet | 02387174 – 200mg | Optimer Pharmaceuticals Inc. | 08:12.12 – Macrolide antibacterials |

**Indication(s)**
Dificid is a macrolide antibacterial drug indicated in adults (≥18 years of age) for treatment of *Clostridium difficile*-associated diarrhea (CDAD).

**Dose**
200mg twice daily for 10 days

**Therapeutic Alternatives**
metronidazole; Vancocin (vancomycin)

**Clinical Notes**
Dificid is a macrolide antibacterial agent that is bactericidal against Clostridia species, including *C. difficile,* in vitro by inhibiting RNA synthesis by RNA polymerases. Fidaxomicin and the OP-1118 metabolite have demonstrated synergistic interaction with rifampin and rifaximin against *C. difficile* (FIC values 0.5 or less) in vitro. Fidaxomicin has demonstrated a postantibiotic effect against *C. difficile* of 6 to 10 hours. Dificid has been shown to be non-inferior to vancomycin for cases of moderate to moderately severe CDAD. It has not been evaluated compared to metronidazole for mild to moderate CDAD.

**Place in Therapy**
Dificid is indicated in adults for the treatment of Clostridium difficile-associated diarrhea (CDAD). Dificid is not effective for systemic infections because fidaxomicin is minimally absorbed. The precise place in therapy for Dificid has not yet been defined.

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**Comparative Pricing**

| | Dificid | Apo-Metronidazole | Vancocin |
|---|---|---|---|
| **Unit price** | 200mg - $112 | 500mg - $0.70 | 125mg - $9 |
| **Cost for one course of treatment** | $2,240 | $20-$30 | $360-$500 |

**Impact/ Plan Management Suggestions**

Since the precise place in therapy for Dificid has not yet been defined and is substantially higher cost compared to existing therapies, this drug is recommended to t be listed on managed formularies with a higher coinsurance.

## Latuda (lurasidone hydrochloride)

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Tablet | 02387751 – 40mg<br>02387778 – 80mg<br>02377786 – 120mg | Sunovion Pharmaceuticals Canada Inc | 28:16.08 – Antipsychotic Agents |

**Indication(s)**

Latuda (lurasidone hydrochloride) is indicated for the acute treatment of schizophrenia.

**Dose**

The recommended dose of Latuda is 40 to 160 mg once daily.

**Therapeutic Alternatives**

Abilify (aripiprazole); Zyprexa (olanzapine)*; Invega (paliperidone); Seroquel (quetiapine)*; Risperdal (risperidone)*; Zeldox (ziprasidone)

* available in generic form

**Clinical Notes**

Latuda is an atypical (second generation) antipsychotic belonging to the chemical class of benzisothiazol derivatives. Although the mechanism of action of Latuda is unknown, the efficacy of Latuda in schizophrenia could be mediated through a combination of central dopamine Type 2 (D2) and serotonin Type 2 (5HT2A) receptor antagonism. Latuda has shown a favourable weight and metabolic profile in clinical trials compared to quetiapine XR, risperidone and olanzapine.

**Place in Therapy**

Latuda offers patients an effective treatment option possibly with improved tolerability relative to other atypical antipsychotics.

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**Comparative Pricing**

| | Latuda | Teva-Quetiapine | Zeldox | Abilify |
|---|---|---|---|---|
| **Unit cost** | $3.93 (all strengths) | range from $0.12 to $1.35 (25mg to 300mg) | $1.70 (20mg) $1.94 (40, 60, 80mg) | Range from $3.07 to $6.68 (2mg to 30mg) |
| **Annual cost** | $120 | $30 - $65 | $115 | $120 - $200 |

**Impact/Plan Management Suggestions**

Minimal impact. No specific plan management recommendations since this new drug will result in cost shift from other similarly priced drugs.

**Jakavi (ruxolitinib)**

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Tablet | 02388006 – 5mg<br>02388014 – 15mg<br>02388022 – 20mg | Novartis Pharmaceuticals Canada Inc. | 10:00.00 – Antineoplastic agents\JAK 1 JAK 2 inhibitor |

**Indication(s)**

Jakavi is indicated for the treatment of splenomegaly and/or its associated symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

**Dose**

The starting dose is between 15-20mg twice daily, depending on platelet count. These counts must be performed every 2 to 4 weeks until doses are stabilized, and then as clinically indicated. The maximum dose is 25mg twice daily. Treatment may be continued as long as the benefit: risk remains positive. However the treatment should be discontinued after 6 months if there has been no reduction in spleen size or improvement in symptoms since initiation of therapy.

**Therapeutic Alternatives**

None

**Clinical Notes**

Jakavi is a selective inhibitor of the Janus Kinases (JAKs) JAK1 and JAK2. These mediate the signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. JAK signaling involves recruitment of STATs (signal transducers and activators of transcription) to cytokine receptors, activation, and subsequent localization of STATs to the nucleus leading to modulation of gene expression. Dysregulation of the JAK-STAT pathway has been associated with several cancers and increased proliferation and survival of malignant cells. Myelofibrosis (MF) is a myeloproliferative neoplasm (MPN) known to be associated with the dysregulated JAK1 and JAK2 signaling. The basis for the dysregulation is believed to include high levels of circulating cytokines that activate the JAK-STAT pathway, gain-of function mutations such as JAK2, and silencing of negative regulatory mechanisms. MF patients exhibit dysregulated JAK signaling regardless of JAK2 mutation status.

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**Place in Therapy**

Jakavi is the first medication to receive Health Canada approval to treat patients with myelofybrosis. Jakavi offers a unique mechanism of action that targets what studies suggest is the underlying pathology of the disease, rather than using medications developed for treatment of other conditions. Jakavi is designed to specifically inhibit the biological activity of these JAK enzymes for the treatment of this patient population with MF.

**Pricing**

| | Jakavi |
|---|---|
| **Unit cost** | $82 (all strengths) |
| **Annual cost** | ~$60,000 |

**Impact/Plan Management Suggestions**

Intermediate impact. Recommend use of Prior Authorization to ensure drug used as indicated in the appropriate patient population.

## Inlyta (axitinib)

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Tablet | 02389630 – 1mg<br>02389649 – 5mg | Pfizer Canada Inc | 10:00.00 – Antineoplastic agents |

**Indication(s)**

For the treatment of patients with metastatic renal cell carcinoma (mRCC) of clear cell histology after failure of prior systemic therapy with either a cytokine or the VEGFR-TKI, sunitinib

**Dose**

The recommended oral starting dose of Inlyta is 5 mg twice daily. Dose increase or reduction is recommended based on individual safety and tolerability. Maximum recommended dose is 10mg twice daily.

**Therapeutic Alternatives**

While no true therapeutic alternatives exist, Afinitor (everolimus) is recommended after prior systemic therapy only with a TKI [NCCN (National Comprehensive Cancer Network) Category 1].

**Clinical Notes**

Axitinib was shown to inhibit tyrosine kinase vascular endothelial growth factor receptor (VEGFR)-1, VEGFR-2, and VEGFR-3. These receptors are implicated in pathologic angiogenesis, tumor growth, and metastatic progression of cancer.

The clinical effectiveness of Inlyta is based on progression-free survival (PFS) in patients with mRCC in a Phase 3, controlled clinical trial which compared Inlyta to sorafenib. The overall median PFS increased by 2 months in patients treated with Inlyta as compared to those treated with sorafenib (HR = 0.67 [95% CI: 0.54, 0.81]). The difference in median PFS for patients previously treated with a cytokine was 5.6 months (HR = 0.46 [95% CI: 0.32, 0.68]), whereas the difference in patients previously treated with sunitinib was 1.4 months (HR = 0.74 [95% CI: 0.57, 0.96]). The overall survival and quality of life were not significantly different in patients treated with Inlyta as compared to those treated with sorafenib.



**Place in Therapy**
Inlyta (axitinib) is recommended as a Category 1 therapy by the NCCN as a second line treatment in patients who have failed prior systemic therapy.

**Pricing**

| | Inlyta | | Afinitor | | |
|---|---|---|---|---|---|
| | 1mg | 5mg | 2.5mg | 5mg | 10mg |
| **Unit cost** | $20 | $100 | $195 | $195 | $195 |
| **Monthly cost** | ~$5,600 | | ~$5,900 | | |

**Impact/Plan Management Suggestions**
Intermediate impact. Recommend use of Prior Authorization to ensure drug used for indicated purpose in the appropriate patient population.

### Treanda (bendamustine hydrochloride)

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Intravenous injection | 02392550 – 25mg/vial<br>02392569 – 100mg/vial | Lundbeck Canada Inc. | 10:00.00 – Antineoplastic agent |

**Indication(s)**
Treanda is indicated for treatment of patients with:

- Relapsed indolent B-cell non-Hodgkin lymphoma (NHL) who did not respond to or progressed during or shortly following treatment with a rituximab regimen.
- Symptomatic chronic lymphocytic leukemia (CLL) who have received no prior treatment.

**Dose**
**NHL:** as a monotherapy at a dose of 120 mg/m$^2$ administered intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.
**CLL:** as a monotherapy at a dose of 100 mg/m$^2$ administered intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles.
Note: treatments are for maximum number of cycles described above. There is no on-going treatment beyond this.

**Therapeutic Alternatives**
Leukeran (chlorambucil)

**Clinical Notes**
Treanda contains bendamustine hydrochloride as the active ingredient. Bendamustine is an alkylating agent (nitrogen mustard derivative) with a benzimidazole ring (purine analog) which demonstrates only partial cross-resistance (*in vitro*) with other alkylating agents. It leads to cell death via single and double strand DNA cross-linking. Bendamustine is active against both quiescent and dividing cells. The primary cytotoxic activity is due to bendamustine (as compared to metabolites).


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**Place in Therapy**

For CLL bendamustine has shown higher ORR and longer PFS compared to chlorambucil. Efficacy compared to first-line therapies other than chlorambucil has not been established.
Bendamustine is indicated for the treatment of indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen. Clinical trials revealed that bendamustine improved overall response rates and provided durable of response

**Comparative Pricing**

| | | Treanda | Leukeran |
|---|---|---|---|
| Unit price | | 25mg/vial - $330<br>100mg/vial - $1,320 | 2mg tablet - $1.40 |
| Annual cost | NHL | $48,150* | < $2,030† |
| | CLL | $30,100* | $2,030 |

* represents cost for maximum number of treatment cycles; many patients will require fewer cycles; assumes 1.9m$^2$ average body surface area; note: this is a one-time treatment cost – no ongoing treatment is indicated.
† chlorambucil therapy for NHL is intermittent based on individual response.

**Impact/Plan Management Suggestions**

Intermediate impact. Recommend use of Prior Authorization to ensure drug used for indicated purpose in the appropriate patient population.

**NEW FORMULATION**

**Ondissolve ODF (ondansetron)**

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Oral soluble film | 02389983 – 4mg<br>02389991 – 8mg | Takeda Canada Inc | 56:22.20 – 5-HT$_3$ Receptor Antagonist Antiemetics |

**Indication(s)**

**Canadian Product Monograph not available; information from Zuplenz U.S. Prescribing Information**
Ondissolve ODF (ondansetron) oral soluble film is indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin ≥50 mg/m$^2$; for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (CINV); for the prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen (RTNV); for the prevention of postoperative nausea and/or vomiting (PONV).

**Dose**

Adult: dose ranges from 8mg to 24mg once to three times daily depending on indication;
Children 4-11 years: 4mg three times a day (only indicated for use with moderately emetogenic chemotherapy)

**Therapeutic Alternatives**

Zofran (ondansetron) tablets*, oral solution*, injection*, Zofran ODT Orally Disintegrating Tablets
* generic products available

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**Clinical Notes**

Ondansetron is a selective 5-$HT_3$ receptor antagonist. While its mechanism of action has not been fully characterized, ondansetron is not a dopamine-receptor antagonist. Serotonin receptors of the 5-$HT_3$ type are present both peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. It is not certain whether ondansetron's antiemetic action is mediated centrally, peripherally, or in both sites. However, cytotoxic chemotherapy appears to be associated with release of serotonin from the enterochromaffin cells of the small intestine. In humans, urinary 5-HIAA (5-hydroxyindoleacetic acid) excretion increases after cisplatin administration in parallel with the onset of emesis. The released serotonin may stimulate the vagal afferents through the $5HT_3$ receptors and initiate the vomiting reflex.

The pharmacokinetics of ondasetron after administration of as single 8mg dose of the oral soluble film was found to be comparable to that after administration of a single 8mg dose of the oral disintegrating tablet (ODT), specifically similar $C_{max}$ and AUC. Similar systemic exposures were also seen in fed and fasting conditions, and with and without water.

**Place in Therapy**

Ondissolve ODF oral soluble film is indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, moderately emetogenic cancer chemotherapy, radiotherapy, and post-operative nausea and vomiting. Its place in therapy is essentially the same as for Zofran ODT.

**Comparative Pricing**

| | | Ondissolve ODF | Zofran ODT |
|---|---|---|---|
| **Unit Price** | | Price not available | 4mg - $13<br>8mg - $20 |
| **Cost per treatment course** | **Chemotherapy Induced Nausea & Vomiting** | Price not available | $200-$300 |
| | **Radiotherapy associated Nausea & Vomiting** | Price not available | $300 |
| | **Post-operative Nausea & Vomiting** | Price not available | $40 |

**Impact/Plan Management Suggestions**

Insufficient information.

| Cipralex Meltz (escitalopram) | | | |
|---|---|---|---|
| **Dosage Form** | **DIN & Strength** | **Manufacturer** | **AHFS Class** |
| Orally disintegrating tablet | 02391449 – 10mg<br>02391457 – 20mg | Lundbeck Canada Inc | 28:16.04 - Antidepressants |


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**Indication(s)**
Cipralex Meltz is indicated for the symptomatic relief of:
• **Major Depressive Disorder (MDD)**
• anxiety causing clinically significant distress in patients with **Generalized Anxiety Disorder (GAD).**
• **Obsessive-Compulsive Disorder (OCD).** The obsessions and compulsions must be experienced as intrusive, markedly distressing, time consuming or interfering significantly with the person's social or occupational functioning.

**Dose**
Recommended dose for all indications is 10mg once daily. Dose may be increased to a maximum of 20mg daily depending on individual response.

**Therapeutic Alternatives**
Cipralex; Other selective serotonin reuptake inhibitors (SSRIs)

**Clinical Notes**
Escitalopram (S-citalopram) is the active enantiomer of the racemic drug citalopram. *In vitro* and *in vivo* studies have suggested that escitalopram is a highly potent and selective serotonin reuptake inhibitor (SSRI), which acts by specific competitive inhibition of the membrane transporter of serotonin (5-hydroxytryptophan, 5-HT). The performance of Cipralex MELTZ 10 and 20 mg and Cipralex tablets can be considered equivalent with respect to the delivery of escitalopram. Approval for this new formulation was based on equivalent escitalopram serum levels to the existing oral tablet formulation. There is no reported independent efficacy data for the Meltz formulation.

**Place in Therapy**
Place in therapy mirrors that for Cipralex oral tablets. This formulation offers an alternative drug delivery mechanism which delivers equivalent escitalopram levels.

**Comparative Pricing**

| | Cipralex Meltz | Cipralex |
|---|---|---|
| **Unit cost** | Price not available | $1.78 to $1.89 |
| **Annual cost** | Price not available | $650 to $670 |

**Impact/Plan Management Suggestions**
Minimal impact anticipated (cost shift from tablet formulation).

**NEW BRAND/INDICATION**

## Dysport (botulinum toxin type A [abobotulinumtoxinA])

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Intramuscular injection | 02387735 – 300 Units/vial | Ipsen Biopharm Limited | 92:92.00 – Other miscellaneous therapeutic agents |

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**Indication(s)**
Dysport (botulinum toxin type A) is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines in adult patients < 65 years of age.

**Dose**
50 Units per dose by intramuscular injection – 10 Units in each of five injection sites. Clinical effect expected to last for up to four months. Minimum dosing interval is three months.

**Therapeutic Alternatives**
Botox Cosmetic, Xeomin Cosmetic

**Clinical Notes**
Botulinum toxin type A, the active ingredient in Dysport (abobotulinumtoxinA), is a purified neurotoxin type A complex produced by fermentation of the bacterium *Clostridium botulinum* type A, Hall Strain. DYSPORT™ inhibits release of the neurotransmitter, acetylcholine, from peripheral cholinergic nerve endings. The primary pharmacodynamic effect of Dysport is due to chemical denervation of the treated muscle resulting in a measurable decrease of the compound muscle action potential, causing a localized reduction of muscle activity.

The term "Unit" upon which dosing is based, is a specific measurement of toxin activity that is unique to Ipsen's formulation of botulinum toxin type A. Therefore, the units used to describe Dysport activity are different from those used to describe that of other botulinum toxin preparations and the units representing Dysport activity are not interchangeable with other products.

Postmarketing reports indicate that the effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death.

**Place in Therapy**
Dysport is a botulinum toxin type A product indicated only for the treatment of glabellar lines (wrinkles on forehead) and thus has only cosmetic uses in Canada. It offers an alternative to other botulinum toxin products (e.g., Botox Cosmetic, Xeomin Cosmetic).

**Comparative Pricing**

| | Dysport |
|---|---|
| **Unit cost** | Price not available |
| **Estimated cost per Course of Treatment** | Price not available |

**Impact/Plan Management Suggestions**
Minimal impact. Due to cosmetic nature of treatment, most plans will not cover depending on plan design (similar to Botox Cosmetic or Xeomin Costmetic).


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### Cialis (tadalafil)

| Dosage Form | DIN & Strength | Manufacturer | AHFS Class |
|---|---|---|---|
| Tablet | 02296888 – 2.5mg<br>02296896 – 5mg | Eli Lilly Canada Inc | 24:12.12 – Phosphodiesterase Type 5 Inhibitors |

**Indication(s)**

New indications Applies only to Cialis *Once-a-Day* (2.5mg, 5mg)

1) Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).
2) Treatment of erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (ED/BPH).

**Dose**

The recommended dose for BPH and ED/BPH is 2.5 to 5mg per day.

**Therapeutic Alternatives**

5-Alpha-reductase inhibitors: Avodart (dutasteride), Proscar (finasteride)*
Alpha$_1$-adrenergic antagonists: Cardura (doxazosin)*, Hytrin (terazosin)*, Xatral (alfuzosin)*, Rapaflo (silodosin), Flomax CR (tamsulosin)*
*generics available

**Clinical Notes**

Cialis (tadalafil) is a potent, selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP) -specific phosphodiesterase type 5 (PDE5). The mechanism for reducing BPH symptoms has not been fully established. The effect of PDE5 inhibition on cGMP concentration seen in the corpus cavernosum and pulmonary arteries is also observed in the smooth muscle of prostate, bladder and their vascular supply. The vascular relaxation results in increased blood perfusion and may reduce BPH symptoms. Relaxation of stromal smooth muscle of the prostate and bladder may complement these vascular effects without compromising bladder emptying.

The efficacy and safety of Cialis for once daily use for the treatment of the signs and symptoms of BPH was evaluated in 3 randomized, multinational, double-blinded, placebo-controlled, parallel-design, efficacy and safety studies of 12 weeks duration.

Current Canadian Urological Association BPH guidelines (2010) recommend alpha-blockers as first line treatment for symptomatic treatment. They also advocate the use of 5-alpha-reductase inhibitors as appropriate and effective treatments for BPH that may also slow the progression of BPH. The use of PDE-5 inhibitors is not recommended in these guidelines.

**Place in Therapy**

Cialis (tadalafil) offers another treatment option in men who require symptomatic treatment for benign prostatic hyperplasia or who require symptomatic treatment for both benign prostatic hyperplasia and erectile dysfunction. A more precise place in therapy (i.e., in relation to alpha-blockers and 5-alpha reductase inhibitors) is not available at this time.



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**Comparative Pricing**

| | Cialis | Apo-Finasteride | Apo-Tamsulosin |
|---|---|---|---|
| **Unit Price** | $4.20 (2.5mg or 5mg) | 5mg - $0.50 | 0.4mg - $0.15 |
| **Annual Cost** | $1,520 | $170 | $55 |

**Impact/Plan Management Suggestions**

Since Cialis' place in therapy for BPH is not fully defined, it is recommended to maintain the status quo with respect to the management of this drug.

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## FIRST TIME GENERICS

**First-Time Generic Drugs (Notices of Compliance from June 7, 2012 to Aug 30, 2012)**

| Generic Name | Reference Drug (Brand) | Rank by ingredient cost in 2011 | Manufacturer | Route of Administration | Approved Indications |
|---|---|---|---|---|---|
| Donepezil/Donepezil RDT | Aricept/Aricept RDT | 203 | GenMed a division of Pfizer Canada Inc | Oral | Alzheimer's disease |
| Clopidogrel 300mg | Plavix 300mg | - | Teva Canada Limited | Oral | Platelet aggregation inhibitor |
| Temozolomide | Temodal | 195 | Accord Healthcare Inc | Oral | Cancer |
| Anastrozole | Arimidex | 196 | Sandoz Canada Incorporated | Oral | Breast cancer |
| Fenofibrate [nanocrystal formulation] | Lipidil EZ | 101 | Sandoz Canada Incorporated | Oral | High cholesterol |


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PRODUCT LINE-EXTENSION

**Product Line-Extension (Notices of Compliance from June 7, 2012 to Aug 30, 2012)**

| Brand name | Chemical name | Manufacturer | Dosage form | Type of Line Extension | Specifics/Comments |
|---|---|---|---|---|---|
| Yaz Plus | ethinyl estradiol/ drospirenone/ levomefolate calcium | Bayer Inc | Tablet | New drug combination | Addition of folic acid to Yaz |
| Targin | oxycodone/naloxone | Purdue Pharma | Controlled release tablet | New strength | 5mg/2.5mg strength |
| Onglyza | saxagliptin hydrochloride | Bristol Myers Squibb Canada | Tablet | New indication | Indicated for use in combination with insulin |
| Banzel | rufinamide | Eisai Limited | Oral suspension | New dosage form | Oral liquid introduced |
| Komboglyze | saxagliptin/ metformin | Bristol Myers Squibb Canada | Tablet | New drug combination | Fixed dose combination of DPP-4 inhibitor, saxagliptin, with metformin |
| Votrient | pazopanib hydrochloride | GlaxoSmith Kline | Tablet | New indication | Soft tissue sarcoma (selected tumour types) |
| Tarceva | erlotinib hydrochloride | Hoffmann La Roche Limited | Tablet | New indication | First line treatment for locally advanced or metastatic non-small cell lung cancer in patients with EGFR mutations |
| Cymbalta | duloxetine hydrochloride | Eli Lilly Canada Inc | Delayed release capsule | New indication | Chronic pain associated with osteoarthritis of the knee |
| Olmetec | omesartan medoxomil | Merck Canada Inc | Tablet | New indication | Pediatric hypertension in children 6-16 years of age |
| Byetta | exenatide | Eli Lilly Canada Inc | Subcutaneous injection | New indication | Add-on to insulin glargine |
| Januvia | sitagliptin phosphate monohydrate | Merck Canada Inc | Tablet | New indication New strengths | Use in combination with insulin; 25mg and 50mg strengths |
| Janumet | sitagliptin phosphate monohydrate/ metformin hydrochloride | Merck Canada Inc | Tablet | New indication | Use in combination with insulin |



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| | | | | | |
|---|---|---|---|---|---|
| Zyclara | imiquimod | Medicis Pharmaceutical Corp | Cream | New strength | 2.5% |
| Sublinox | zolpidem hydrochloride | Meda AB | Orally disintegrating tablet | New strength | 5mg |
| Exjade | deferasirox | Novartis Pharmaceuticals Canada Inc. | Tablet for suspension | New indication | Treatment of iron overload in patients > 10 years with non-transfusion-dependent thalassemia syndromes |
| Cervarix | Human papillomavirus types 16 & 18 vaccine | GlaxoSmithKline | Intramuscular injection | New indication | Use approved for age 9 years to 25 years |

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