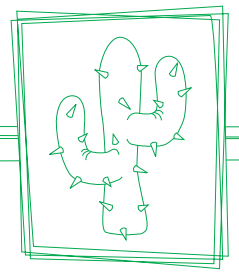

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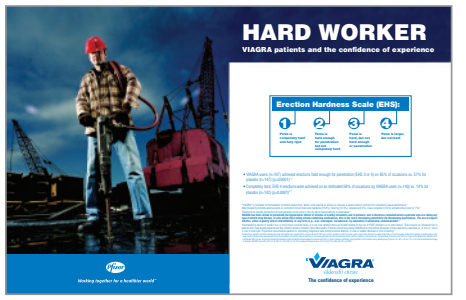


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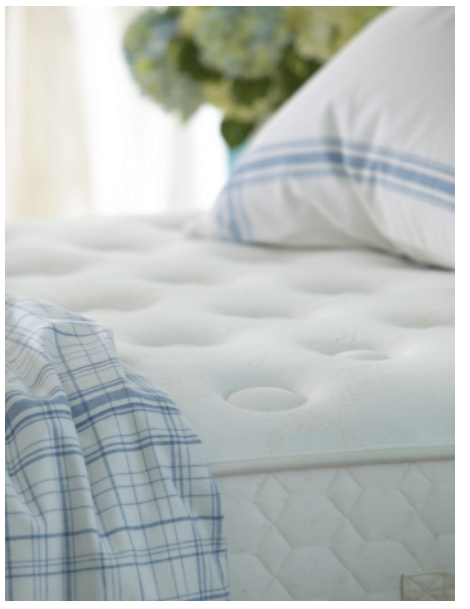

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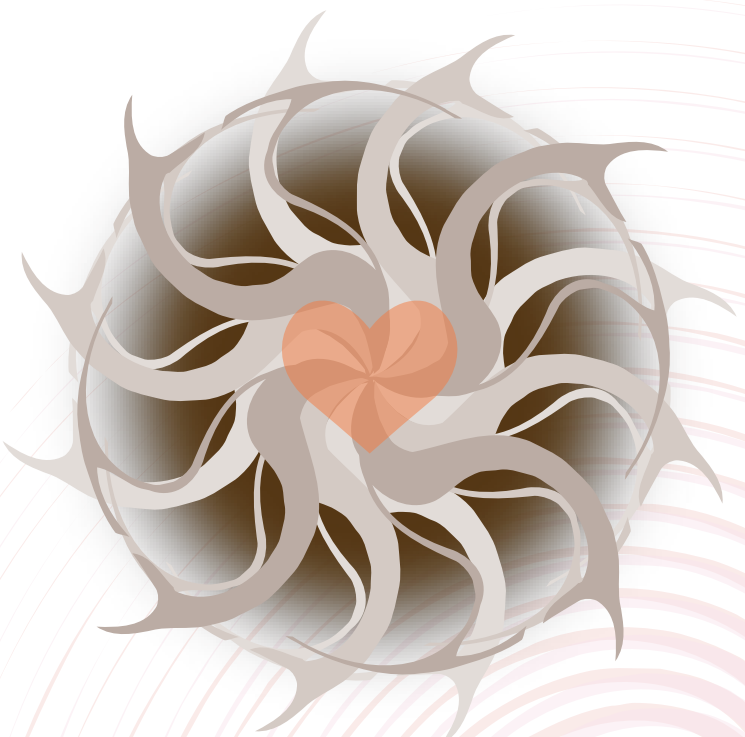

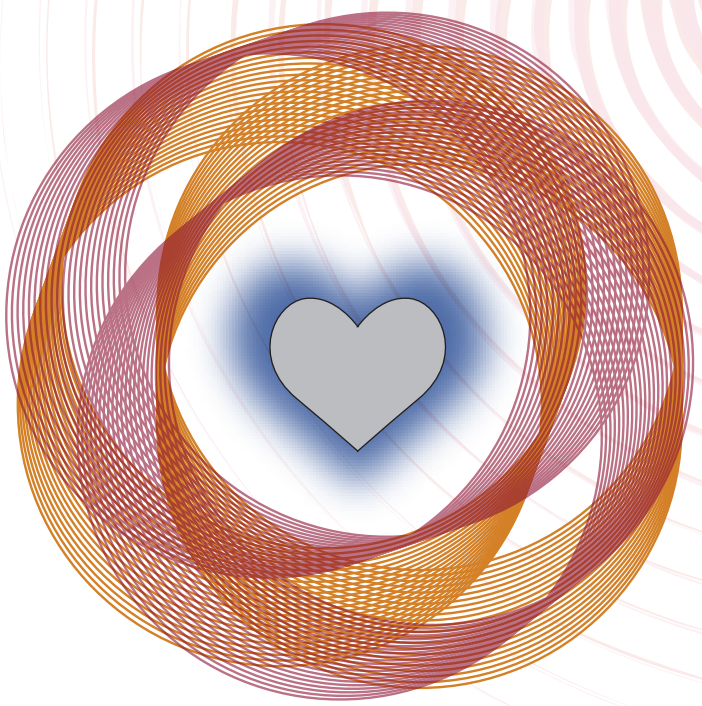

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BECAUSE THE LARGEST HUMAN ORGAN
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INTRODUCING **ELIDEL**

A NEW EFFECTIVE NON-STEROID CREAM FOR THE MANAGEMENT OF MILD TO MODERATE ECZEMA.†

FOR BOTH OF THEM

DEMONSTRATED EFFICACY

- Rapidly controlled the acute signs and symptoms (itch, redness and swelling) of eczema[1,2,3,5‡§]
- Demonstrated to help prevent progression to flares[1,3,4,5§¶]

NO OBSERVED SKIN ATROPHY

- Did not elicit skin atrophy compared to topical corticosteroid use[1]

CAN BE USED ON ALL SKIN SURFACES

- ELIDEL Cream 1% is available in 15, 30 and 60g tubes, and should be applied twice daily to affected areas until symptoms disappear[**]

† ELIDEL Cream 1% is indicated for the short-term and intermittent long-term therapy of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older, in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or intolerant of alternative, conventional therapies.

Most common adverse event was burning or a sensation of warmth at the site of application. Application site reactions were mostly mild and transient (application site burning was 1.5% - 10.4% in pediatric patients versus 6.7% - 12% for vehicle and in adults application site burning was 25.9% with ELIDEL Cream). Other common adverse events which may or may not be drug-related included headache (7-25% versus 9-16% for vehicle), nasopharyngitis (8-26% versus 7-21% for vehicle), fever (1-12% versus 5-9% for vehicle), cough (2-16% versus 8-11% for vehicle) and upper respiratory tract infection (4-19% versus 8-13% for vehicle).

ELIDEL Cream 1% should not be applied to areas of active cutaneous viral infections, and may be associated with increased risk of viral skin infections. Reported cases of lymphadenopathy generally resolved with antibiotic therapy; patients should be monitored to ensure that lymphadenopathy resolves. ELIDEL Cream 1% is not for ophthalmic use. Use only if clearly needed during pregnancy. Use during nursing should take into consideration the potential for serious adverse reactions in nursing infants. Patients should minimize or avoid exposure to natural or artificial sunlight.

** If no improvement occurs after 3 weeks of treatment, or in the case of disease exacerbation, ELIDEL therapy should be discontinued.

‡ Pooled data from 2 identical studies; n=403 patients aged 2-17 years with mild to moderate disease; patients were randomised to receive ELIDEL cream 1% (n=267) or vehicle (n=136), applied twice daily; study duration was 6 weeks. Redness and swelling were reduced by the first treatment visit (day 8).

§ n=192 adults, of whom 130 had moderate eczema, randomised to receive ELIDEL cream 1% (n=96) or vehicle (n=96), applied twice daily at the first signs and symptoms of eczema; study duration was 24 weeks; itching was relieved at 2 days of treatment ($p<0.001$); at study end 64.3% were flare-free (n=36/56) versus 35.7% for vehicle control (n=15/42); ($p=0.002$).

¶ n=713 patients aged 2-17 years randomised to receive ELIDEL cream 1% (n=476) or control (n=237), applied twice daily at the first signs and symptoms of eczema; study duration was 12 months; at 6 months 61.0% (n=220/360) of patients were flare-free versus 34.2% (n=42/123) for vehicle control ($p<0.001$).

References:
1. Novartis Pharmaceuticals Canada Inc. ELIDEL Product Monograph, March 2003.
2. Eichenfield LF, **et al.** Safety and efficacy of pimecrolimus (ASM 981) cream 1% in the treatment of mild and moderate atopic dermatitis in children and adolescents. **J Am Acad Dermatol** 2002; 46:495-504.
3. Data on file. Novartis Pharmaceuticals Canada Inc. Clinical Study Report CASM981-DE-01.
4. Wahn U, **et al.** Efficacy and safety of pimecrolimus cream in the long-term management of atopic dermatitis in children. **Pediatrics** 2002; 110(1 Pt 1):e2.
5. Meurer M, **et al.** Pimecrolimus cream in the long-term management of atopic dermatitis in adults: a six-month study. **Dermatology** 2002; 205: 271-277.

NOVARTIS

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A new combined oral contraceptive (COC) now available in Canada
NEXTSTELLIS (estetrol monohydrate [E4] and drospirenone [DRSP]) is indicated for the prevention of pregnancy in women.1
* Comparative clinical significance has not been established.
The first and only E4-containing COC in Canada (15 mg E4/3 mg DRSP).1,2*
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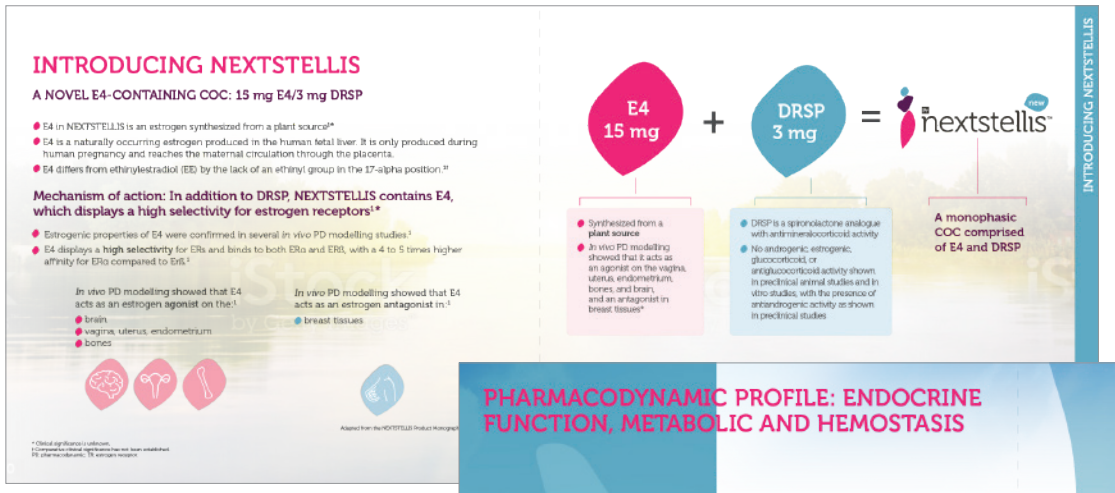
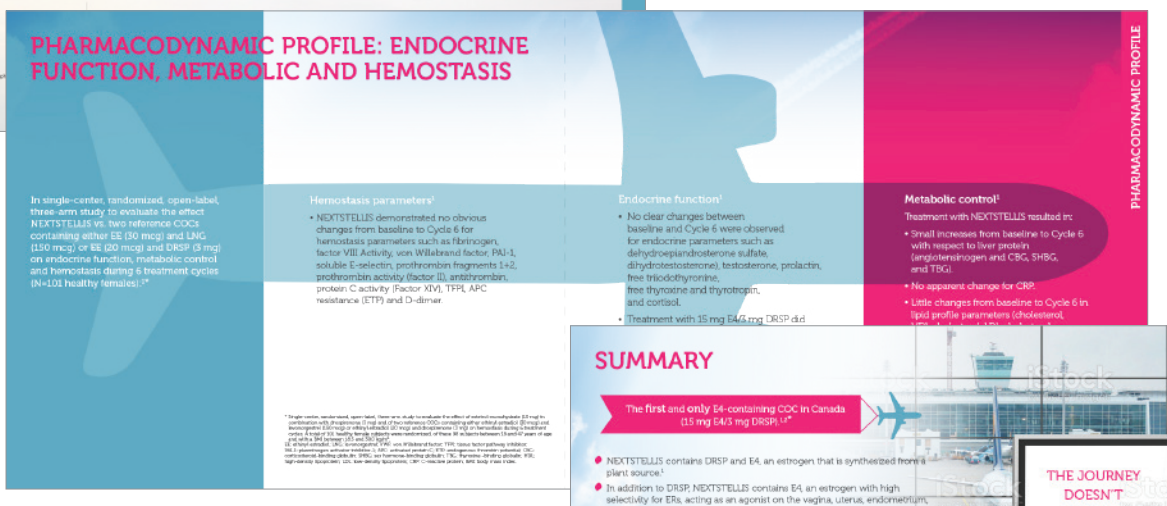
PHARMACODYNAMIC PROFILE
EFFICACY DATA
SAFETY PROFILE


INTRODUCING NEXTSTELLIS
A NOVEL E4-CONTAINING COC: 15 mg E4/3 mg DRSP
E4 in NEXTSTELLIS is an estrogen synthesized from a plant source1*
E4 is a naturally occurring estrogen produced in the human fetal liver. It is only produced during human pregnancy and reaches the maternal circulation through the placenta.
E4 differs from ethinylestradiol (EE) by the lack of an ethinyl group in the 17-alpha position.2†
Mechanism of action: In addition to DRSP, NEXTSTELLIS contains E4, which displays a high selectivity for estrogen receptors1,*
Estrogenic properties of E4 were confirmed in several in vivo PD modelling studies.1
E4 displays a high selectivity for ERs and binds to both ERα and ERβ, with a 4 to 5 times higher affinity for ERα compared to ERβ.1
In vivo PD modelling showed that E4 acts as an estrogen agonist on the:1
brain
vagina, uterus, endometrium
bones
In vivo PD modelling showed that E4 acts as an estrogen antagonist in:1
breast tissues
E4 15 mg
+
DRSP 3 mg
=
nextstellis
Synthesized from a plant source
In vivo PD modelling showed that it acts as an agonist on the vagina, uterus, endometrium, bones, and brain, and an antagonist in breast tissues*
DRSP is a spironolactone analogue with antimineralocorticoid activity
No androgenic, estrogenic, glucocorticoid, or antiglucocorticoid activity shown in preclinical animal studies and in vitro studies, with the presence of antiandrogenic activity as shown in preclinical studies
A monophasic COC comprised of E4 and DRSP
INTRODUCING NEXTSTELLIS


PHARMACODYNAMIC PROFILE: ENDOCRINE FUNCTION, METABOLIC AND HEMOSTASIS
In single-center, randomized, open-label, three-arm study to evaluate the effect NEXTSTELLIS vs. two reference COCs containing either E3 (30 mcg) and LNG (150 mcg), or E2 (20 mcg) and DRSP (3 mg) on endocrine function, metabolic control and hemostasis during 6 treatment cycles (N=101 healthy females):1*
Hemostasis parameters1
NEXTSTELLIS demonstrated no obvious changes from baseline to Cycle 6 for hemostasis parameters such as fibrinogen, factor VIII Activity, von Willebrand factor, PAI-1, soluble E-selectin, prothrombin fragments 1+2, prothrombin activity (factor II), antithrombin, protein C activity (Factor XIV), TFPI, APC resistance (ETP) and D-dimer.
Endocrine function1
No clear changes between baseline and Cycle 6 were observed for endocrine parameters such as dehydroepiandrosterone sulfate, dihydrotestosterone), testosterone, prolactin, free triiodothyronine, free thyroxine and thyrotropin, and cortisol.
Treatment with 15 mg E4/3 mg DRSP did
Metabolic control1
Treatment with NEXTSTELLIS resulted in:
Small increases from baseline to Cycle 6 with respect to liver protein (angiotensinogen and CBG, SHBG, and TBG).
No apparent change for CRP.
Little changes from baseline to Cycle 6 in lipid profile parameters (cholesterol,
PHARMACODYNAMIC PROFILE


SUMMARY
The first and only E4-containing COC in Canada (15 mg E4/3 mg DRSP).1,2*
NEXTSTELLIS contains DRSP and E4, an estrogen that is synthesized from a plant source.1
In addition to DRSP, NEXTSTELLIS contains E4, an estrogen with high selectivity for ERs, acting as an agonist on the vagina, uterus, endometrium, bones, and brain, and an antagonist in breast tissues.2†
In an open-label study, NEXTSTELLIS demonstrated a favourable endocrine function, metabolic and hemostasis pharmacodynamic profile.1
In pooled data from two open-label pivotal studies, NEXTSTELLIS demonstrated contraceptive efficacy (Pearl Index 1.52, 95% CI 1.04, 2.16).
In the pivotal studies for NEXTSTELLIS, trial discontinuation related to vaginal bleeding was 2.8%.1
THE JOURNEY DOESN'T END HERE, TO LEARN MORE VISIT NEXTSTELLIS.CA
nextstellis
REFERENCES 1. NEXTSTELLIS Product Monograph, Searchlight Pharma Inc. March 5, 2021. 2. Searchlight Pharma Inc. Data on file. April 23, 2021.
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product catalogue

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DISCOVER THE POWER OF VENCLEXTA

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VENCLEXTA (venetoclax), in combination with obinutuzumab, is indicated for the treatment of patients with previously untreated CLL.[1]

VENCLEXTA (venetoclax), in combination with rituximab, is indicated for the treatment of adult patients with CLL who have received at least one prior therapy.[1]

DEMONSTRATED PFS

In an open-label study (CLL14), VENCLEXTA + obinutuzumab demonstrated superior PFS compared with obinutuzumab + chlorambucil in previously untreated CLL patients [1†]

- 65% reduction in the risk of disease progression or death vs. obinutuzumab + chlorambucil (HR: 0.35 [95% CI: 0.23–0.53]; $p<0.0001$)[1‡]
  - Number of events was 30/216 for VENCLEXTA + obinutuzumab vs. 77/216 for obinutuzumab + chlorambucil

In an open-label study (MURANO), VENCLEXTA + rituximab demonstrated superior PFS compared with bendamustine + rituximab in patients with R/R CLL [1§]

- 81% reduction in instantaneous risk of progression or death vs. bendamustine + rituximab (HR: 0.19 [95% CI: 0.13–0.28]; $p<0.0001$)[1¶]
  - The 2-year rates of PFS for the VENCLEXTA + rituximab and bendamustine + rituximab arms were 82.76% (95% CI: 76.62–88.90) and 39.42% (95% CI: 31.03–47.82), respectively (IRC-assessed in the ITT population)[1,2]

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Clinical use:
No safety and efficacy data for VENCLEXTA in children and adolescents below 18 years of age are available.

Contraindication:
In patients with CLL, concomitant use with strong CYP3A inhibitors at initiation and during ramp-up phase.

Most serious warnings and precautions:

- **VENCLEXTA should only be prescribed by a qualified physician who is experienced in the use of anti-cancer agents.**
- **VENCLEXTA is only available through specialty pharmacies and/or retail oncology pharmacies that are part of AbbVie's managed distribution program.**
- **Tumour lysis syndrome (TLS)**
  - Weekly dosage ramp-up over a period of 5 weeks with CLL, with blood chemistry monitoring on each dose ramp-up is required.
  - Patients must receive prophylaxis for TLS, including hydration and anti-hyperuricemics prior to initiating treatment.
  - In patients with CLL, concomitant use of strong CYP3A inhibitors at initiation and during ramp-up phase is contraindicated.
- **Serious infections that may lead to hospitalization or death.**

Other relevant warnings and precautions:

- Second primary malignancies: monitor patients for the appearance of non-melanoma skin cancers.
- Monitor patients more frequently for signs of VENCLEXTA toxicities.
- Neutropenia; dose interruption/reduction recommended for severe neutropenia; prophylactic use of growth factors (e.g. G-CSF) may be considered.
- Immunization using live vaccines should be avoided during treatment and thereafter until B-cell recovery.
- Monitor for signs of infection and have their complete blood counts monitored throughout treatment.
- Recommended dose not determined for patients with severe renal impairment (CrCl <30 mL/min) or on dialysis.
- Females of reproductive potential: test to exclude pregnancy before treatment; use of effective contraceptives during treatment and for at least 30 days after last dose.
- Male fertility may be compromised.
- Avoid use during pregnancy.
- Breastfeeding should be discontinued.
- No overall difference in effectiveness and safety observed in patients ≥65 years of age compared to younger patients. In the combination study (MURANO), patients ≥65 years of age experienced higher incidences of diarrhea, peripheral oedema, dizziness, blood creatinine increased, constipation, pyrexia and fall than those <65 years of age.
- Patients with hepatic impairment should be monitored more closely for signs of toxicity.
  - Severe hepatic impairment: A 50% reduction in VENCLEXTA dose is recommended throughout the initiation, ramp-up phase and steady state once daily dose.
- Monitoring and laboratory tests: tumour burden assessment; blood chemistry monitoring; signs of infection; complete blood counts; baseline renal function and hepatic status; bleeding events. Treatment should be interrupted as appropriate.

For more information:
Please consult the Product Monograph at abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/VENCLEXTA_PM_EN.pdf for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-888-704-8271 or 514-906-9771.

Please refer to the study parameters[1§] and reference list at: meddocs.ca/CA-VENC-210030.html

* V: VENCLEXTA.
‡ The median follow-up at the time of analysis was 28 months (range: 0 to 36 months).
¶ The median follow-up at the time of primary analysis was 24.8 months (range: 0.3 to 37.4 months) in the VENCLEXTA + rituximab arm and 22.1 months (range: 0 to 33.8 months) in the bendamustine + rituximab arm (data cut-off date May 8, 2017).

CLL: chronic lymphocytic leukemia; PFS: progression-free survival; HR: hazard ratio; CI: confidence interval; IRC: independent review committee; ITT: intention-to-treat; G-CSF: granulocyte-colony stimulating factor; CrCL: creatinine clearance.

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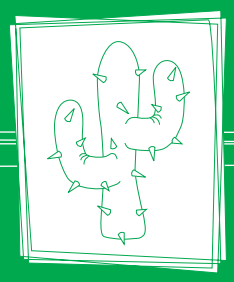

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