

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209353Orig1s000

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ALTRENO safely and effectively. See full prescribing information for ALTRENO.

ALTRENO™ (tretinoin) lotion, for topical use

Initial U.S. Approval: 1973

INDICATIONS AND USAGE

ALTRENO is a retinoid indicated for

The topical treatment of acne vulgaris in patients 9 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Apply a thin layer of ALTRENO to affected areas once daily. Avoid eyes, mouth, paranasal creases, and mucous membranes. (2)
- Not for ophthalmic, oral, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Lotion, 0.05% (3)

Each gram of ALTRENO contains 0.5 mg (0.05%) tretinoin. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Skin Irritation: Dryness, pain, erythema, irritation and exfoliation may occur with use of ALTRENO. (5.1)
- Ultraviolet Light and Environmental Exposure: Minimize exposure to sunlight and sunlamps. Use sunscreen and protective clothing when sun exposure cannot be avoided. (5.2)
- Fish Allergies: Use ALTRENO with caution if allergic to fish due to potential for allergenicity to fish protein. Advise patients to contact their healthcare provider if they develop pruritus or urticaria. (5.3)

ADVERSE REACTIONS

- The most common adverse reactions occurring in $\geq 1\%$ of subjects and greater than vehicle were dryness, pain, erythema, irritation and exfoliation (all at the application site). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 08/2018

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

2 DOSAGE AND ADMINISTRATION

Apply a thin layer of ALTRENO to the affected areas once daily. Avoid the eyes, mouth, paranasal creases, and mucous membranes.

ALTRENO is for topical use only. Not for ophthalmic, oral, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Lotion, 0.05%

Each gram of ALTRENO contains 0.5 mg (0.05%) tretinoin in an opaque, pale yellow topical lotion.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Skin Irritation

Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

5.2 Ultraviolet Light and Environmental Exposure

Minimize unprotected exposure to ultraviolet light including sunlight and sunlamps during the use of ALTRENO. Warn patients who normally experience high levels of sun exposure and those with inherent sensitivity to sun to exercise caution. Use sunscreen products and protective clothing over treated areas when sun exposure cannot be avoided.

5.3 Fish Allergies

ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In 2 randomized, double-blind, vehicle-controlled trials, subjects age 9 years and older applied ALTRENO or vehicle once daily for 12 weeks. The majority of subjects were White (74%) and female (55%). Approximately 47% were Hispanic/Latino and 45% were younger than 18 years of age. Adverse reactions reported by $\geq 1\%$ of subjects treated with ALTRENO and more frequently than vehicle are summarized in Table 1.

Table 1: Adverse Reactions Reported by $\geq 1\%$ of Subjects Treated with ALTRENO and More Frequently than Vehicle

Adverse Reactions n (%)		
	ALTRENO N=767	Vehicle N=783
Application site dryness	29 (4)	1 (<1)
Application site pain ¹	25 (3)	3 (<1)
Application site erythema	12 (2)	1 (<1)
Application site irritation	7 (1)	1 (<1)
Application site exfoliation	6 (1)	3 (<1)

¹Application site pain defined as application site stinging, burning or pain.

Skin irritation was evaluated by active assessment of erythema, scaling, hypopigmentation, hyperpigmentation, itching, burning and stinging. The percentage of subjects who were assessed to have these signs and symptoms at any post baseline visit are summarized in Table 2.

Table 2: Application Site Tolerability Reactions at Any Post Baseline Visit

	ALTRENO N=760 Mild/Mod/Severe	Vehicle N=782 Mild/Mod/Severe
Erythema	51%	44%
Scaling	49%	30%
Hypopigmentation	12%	10%
Hyperpigmentation	35%	35%
Itching	35%	28%
Burning	30%	14%
Stinging	21%	8%

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from published observational studies of topical tretinoin in pregnant women have not established a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are no data on ALTRENO use in pregnant women. The systemic levels following topical administration are lower than with administration of oral tretinoin; however, absorption of this product may result in fetal exposure. There are reports of major birth defects similar to those seen in infants exposed to oral retinoids, but these case reports do not establish a pattern or association with tretinoin-related embryopathy (*see Data*).

Animal reproduction studies have not been conducted with ALTRENO. Topical administration of tretinoin in a different formulation to pregnant rats during organogenesis was associated with malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) at doses up to 0.5 mg tretinoin/kg/day, approximately 2 times the maximum recommended human dose (MRHD) based on body surface area (BSA) comparison and assuming 100% absorption. Oral administration of tretinoin to pregnant cynomolgus monkeys during organogenesis was associated with malformations at 10 mg/kg/day (approximately 100 times the MRHD based on BSA comparison and assuming 100% absorption) (*see Data*).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, and other adverse outcomes. The background risk in the U.S. general population of major birth defects is 2 to 4% and of miscarriage is 15 to 20% of clinically recognized pregnancies.

Data

Human Data

While available studies cannot definitively establish the absence of risk, published data from multiple prospective controlled observational studies on the use of topical tretinoin products during pregnancy have not identified an association with topical tretinoin and major birth defects or miscarriage. The available studies have methodologic limitations, including small sample size and in some cases, lack of physical exam by an expert in birth defects. There are published case reports of infants exposed to topical tretinoin during the first trimester that describe major birth defects similar to those seen in infants exposed to oral retinoids; however, no pattern of malformations has been identified and no causal association has been established in these cases. The significance of these spontaneous reports in terms of risk to the fetus is not known.

Animal Data

Tretinoin in a 0.05% gel formulation was topically administered to pregnant rats during organogenesis at doses of 0.1, 0.3 and 1 g/kg/day (0.05, 0.15, 0.5 mg tretinoin/kg/day). Possible tretinoin malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) were observed at maternal doses of 0.5 mg tretinoin/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption). These findings were not observed in control animals. Other maternal and reproductive parameters in tretinoin-treated animals were not different from control. For purposes of comparison of the animal exposure to human exposure, the MRHD is defined as 4 g of ALTRENO applied daily to a 60-kg person.

Other topical tretinoin embryofetal development studies have generated equivocal results. There is evidence for malformations (shortened or kinked tail) after topical administration of tretinoin to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison and assuming 100% absorption). Anomalies (humerus: short 13%, bent 6%, os parietal incompletely ossified 14%) have also been reported when 10 mg/kg/day (approximately 50 times the MRHD based on BSA comparison and assuming 100% absorption) was topically applied to pregnant rats during organogenesis. Supernumerary ribs have been a consistent finding in rat fetuses when pregnant rats were treated topically or orally with retinoids.

Oral administration of tretinoin during organogenesis has been shown to induce malformations in rats, mice, rabbits, hamsters, and nonhuman primates. Fetal malformations were observed when tretinoin was orally administered to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison). In the cynomolgus monkey, fetal malformations were reported when an oral dose of 10 mg/kg/day was administered to pregnant monkeys during organogenesis (approximately 100 times the MRHD based on BSA comparison). No fetal malformations were observed at an oral dose of 5 mg/kg/day (approximately 50 times the MRHD based on BSA comparison). Increased skeletal variations were observed at all doses in this study and dose-related increases in embryo lethality and abortion were reported in this study. Similar results have also been reported in pigtail macaques.

Oral tretinoin has been shown to be fetotoxic in rats when administered at doses 10 times the MRHD based on BSA comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered at doses 4 times the MRHD based on BSA comparison.

8.2 Lactation

Risk Summary

There are no data on the presence of tretinoin or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

8.4 Pediatric Use

Safety and effectiveness of ALTRENO for the topical treatment of acne vulgaris have been established in pediatric patients age 9 years to less than 17 years based on evidence from two multicenter, randomized, double-blind, parallel-group, vehicle-controlled, 12-week trials and an open-label pharmacokinetic study. A total of 318 pediatric subjects aged 9 to less than 17 years received ALTRENO in the clinical studies [see *Clinical Pharmacology* (12.3) and *Clinical Studies* (14)].

The safety and effectiveness of ALTRENO in pediatric patients below the age of 9 years have not been established.

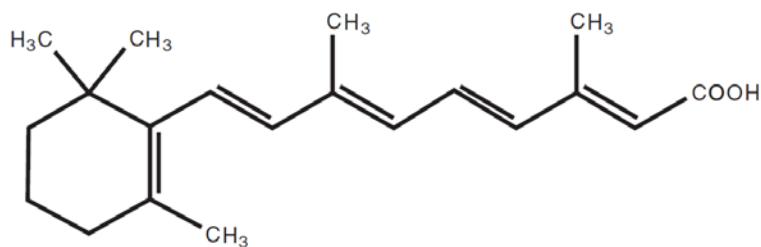
8.5 Geriatric Use

Clinical trials of ALTRENO did not include any subjects age 65 years and older to determine whether they respond differently from younger subjects.

11 DESCRIPTION

ALTRENO (tretinoin) lotion is an opaque, pale yellow lotion containing 0.05% tretinoin by weight for topical administration.

Chemically, tretinoin is all-trans-retinoic acid, also known as (all-E)-3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraenoic acid. It is a member of the retinoid class of compounds and a metabolite of vitamin A. Tretinoin has the following chemical structure:



Molecular Formula: $C_{20}H_{28}O_2$

Molecular Weight: 300.44

Each gram of ALTRENO contains 0.5 mg (0.05%) of tretinoin in an opaque, pale yellow lotion base consisting of benzyl alcohol, butylated hydroxytoluene, carbomer copolymer type B (Pemulen TR-1), carbomer homopolymer type A (Carbopol 981), glycerin, methylparaben, mineral oil, octoxynol-9, purified water, sodium hyaluronate, soluble collagen and trolamine.

12 CLINICAL PHARMACOLOGY

12.1 MECHANISM OF ACTION

Tretinoin is a metabolite of vitamin A that binds with high affinity to specific retinoic acid receptors located in both the cytosol and nucleus.

Tretinoin activates three members of the retinoic acid (RAR) nuclear receptors (RAR α , RAR β , and RAR γ) which act to modify gene expression, subsequent protein synthesis, and epithelial cell growth and differentiation. It has not been established whether the clinical effects of tretinoin are mediated through activation of retinoic acid receptors, other mechanisms, or both.

Although the exact mode of action of tretinoin in acne treatment is unknown, current evidence suggests that topical tretinoin decreases cohesiveness of follicular epithelial cells with decreased microcomedo formation. Additionally, tretinoin stimulates mitotic activity and increased turnover of follicular epithelial cells causing extrusion of the comedones.

12.2 Pharmacodynamics

The pharmacodynamics of ALTRENO in the treatment of acne vulgaris are unknown.

12.3 Pharmacokinetics

Plasma concentrations of tretinoin and its major metabolites (isotretinoin and 4-oxo-isotretinoin) were evaluated in 20 subjects in an open-label, randomized, pharmacokinetic study. Subjects aged 10 years to less than 17 years old with acne vulgaris applied approximately 3.5 g of ALTRENO to the skin of the entire face (excluding eyes and lips), neck, upper chest, upper back and shoulders once daily for 14 days. Single-dose pharmacokinetic (PK) characteristics were determined from samples drawn on Days 1 and 2 of dosing and steady-state PK characteristics were determined from samples drawn on Days 14 and 15 under maximal use conditions. The mean baseline corrected C_{max} and AUC_{0-t} of tretinoin and its metabolites after once daily application of ALTRENO for 14 days are shown below:

Compound	Mean ($\pm$ SD) C _{max} (ng/mL)	Mean ($\pm$ SD) AUC _{0-t} (ng*h/mL)
Tretinoin	0.33 (0.33)	6.46 (5.15)
Isotretinoin	0.49 (0.66)	9.30 (9.95)
4-oxo-isotretinoin	0.57 (0.82)	14.51 (18.28)

The mean concentrations of tretinoin and its metabolites (isotretinoin and 4-oxo-isotretinoin) remain relatively stable and unchanged over the 24-hour period after both the Day 1 dose and the Day 14 dose. Systemic concentrations of tretinoin appear to be at or near steady state by Day 14. Mean accumulation ratios of the baseline corrected AUC between Day 14 and Day 1 were 1.5, 4.5 and 7.3 for tretinoin, isotretinoin, and 4-oxo-isotretinoin, respectively.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year dermal mouse carcinogenicity study was conducted with topical administration of 0.005%, 0.025% and 0.05% of a tretinoin gel formulation. Although no drug-related tumors were observed in surviving animals, the irritating nature of the drug product precluded daily dosing, confounding data interpretation and reducing the biological significance of these results.

Studies in hairless albino mice with a different formulation suggest that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect was confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

The genotoxic potential of tretinoin was evaluated in an in vitro bacterial reversion test, an in vitro chromosomal aberration assay in human lymphocytes and an in vivo rat micronucleus assay. All tests were negative.

In dermal fertility studies of another tretinoin formulation in rats, slight (not statistically significant) decreases in sperm count and motility were seen at 0.5 mg/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption), and slight (not statistically significant) increases in the number and percent of nonviable embryos in females treated with 0.25 mg/kg/day and above (approximately the MRHD based on BSA comparison and assuming 100% absorption) were observed.

14 CLINICAL STUDIES

The safety and efficacy of once daily use of ALTRENO for the treatment of acne vulgaris were assessed in two multicenter, randomized, double-blind clinical trials enrolling 1640 subjects age 9 years and older with acne vulgaris. Enrolled subjects had a score of moderate (3) or severe (4) on the Evaluator's Global Severity Score (EGSS), 20 to 40 inflammatory lesions (papules, pustules, and nodules), 20 to 100 non-inflammatory lesions (open and closed comedones) and two or fewer facial nodules. The coprimary efficacy endpoints of success on the EGSS, absolute change in noninflammatory lesion count, and absolute change in inflammatory lesion count were assessed at Week 12. Success on the EGSS was defined as at least a 2-grade improvement from Baseline and an EGSS score of clear (0) or almost clear (1). Table 3 lists the efficacy results for trials 1 (NCT02491060) and 2 (NCT02535871).

Table 3: Efficacy Results at Week 12

Trial 1	ALTRENO N=406	Vehicle N=414
EGSS		
Clear or Almost Clear and 2-Grade Reduction from Baseline	16.5%	6.9%
Non-Inflammatory Facial Lesions		
Mean Absolute Reduction	17.8	10.6
Mean Percent Reduction	47.5%	27.3%
Inflammatory Facial Lesions		
Mean Absolute Reduction	13.1	10.2
Mean Percent Reduction	50.9%	40.4%
Trial 2	ALTRENO N=413	Vehicle N=407

EGSS		
Clear or Almost Clear and 2-Grade Reduction from Baseline	19.8%	12.5%
Non-Inflammatory Facial Lesions		
Mean Absolute Reduction	21.9	13.9
Mean Percent Reduction	45.6%	31.9%
Inflammatory Facial Lesions		
Mean Absolute Reduction	13.9	10.7
Mean Percent Reduction	53.4%	41.5%

16 HOW SUPPLIED/STORAGE AND HANDLING

ALTRENO (tretinoin) lotion, 0.05% is an opaque, pale yellow topical lotion and available as:

- 45 g tube (NDC 0187-0005-45)

Storage and Handling Conditions

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from freezing.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

- Warn patients of the potential for skin irritation during treatment.
- Advise patients to minimize exposure to sunlight and sunlamps; recommend the use of sunscreen products and protective apparel (e.g., hat) when sun exposure cannot be avoided.

Manufactured for:

Dow Pharmaceutical Sciences, a division of Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

By:

Valeant Pharmaceuticals International, Inc.
Laval, Quebec H7L 4A8, Canada

U.S. Patent Number: 6,517,847

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08/2018

PATIENT INFORMATION
ALTRENO™ (al-TREN-oh)
(tretinoin) lotion, 0.05%
for topical use

Important information: ALTRENO is for use on skin only. Do not use ALTRENO in your eyes, mouth, the corners of your nose, or vagina.

What is ALTRENO?

ALTRENO is a prescription medicine used on the skin (topical) to treat people with acne. Acne is a condition in which the skin has blackheads, whiteheads, and other pimples.

It is not known if ALTRENO is safe and effective in children under 9 years of age.

Before using ALTRENO, tell your healthcare provider about all your medical conditions, including if you:

- are allergic to fish. ALTRENO contains fish proteins. Tell your healthcare provider if you get hives or itching while using with ALTRENO.
- have eczema or any other skin problems.
- have a sunburn.
- are pregnant or plan to become pregnant. It is not known if ALTRENO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ALTRENO passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use ALTRENO?

- Use ALTRENO exactly as your healthcare provider tells you to use it.
- Apply a thin layer of ALTRENO to cover the affected areas 1 time each day.

What should I avoid while using ALTRENO?

- You should avoid sunlamps, tanning beds, and ultraviolet light during treatment with ALTRENO.
- Minimize exposure to sunlight.
- If you have to be in the sunlight or are sensitive to sunlight, use a sunscreen with a SPF (sun protection factor) of 15 or more and wear protective clothing and a wide-brimmed hat to cover the treated areas.

What are the possible side effects of ALTRENO?

ALTRENO may cause serious side effects, including:

Skin irritation. ALTRENO may cause irritation including skin dryness, pain, redness, excessive flaking or peeling. If you develop these symptoms, your healthcare provider may tell you to use a moisturizer, decrease the number of times you apply ALTRENO, or completely stop treatment with ALTRENO. Avoid applying ALTRENO to skin that is affected by eczema or sunburned skin.

These are not all the possible side effects of ALTRENO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ALTRENO?

- Store ALTRENO at room temperature between 68 to 77°F (20 to 25°C).
- Do not freeze.

Keep ALTRENO and all medicines out of the reach of children.

General information about the safe and effective use of ALTRENO

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ALTRENO for a condition for which it was not prescribed. Do not give ALTRENO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ALTRENO that is written for health professionals.

What are the ingredients in ALTRENO?

Active ingredient: tretinoin

Inactive ingredients: benzyl alcohol, butylated hydroxytoluene, carbomer copolymer type B (Pemulen TR-1), carbomer homopolymer type A (Carbopol 981), glycerin, methylparaben, mineral oil, octoxynol-9, purified water, sodium hyaluronate, soluble collagen and trolamine.

Manufactured for: Dow Pharmaceutical Sciences, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA

By: Valeant Pharmaceuticals International, Inc., Laval, Quebec H7L 4A8, Canada.

For more information, call 1-800-321-4576.

U.S. Patent Number: 6,517,847

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This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 08/2018

NDC 0187-0005-45

**For Topical Use Only
Not for Eye Use**


Altreno[™]
(tretinoin) Lotion, 0.05%

Rx only

Net Wt. 45 g

Ortho | Dermatologics

Usual Dosage: Apply a thin layer to the affected areas once daily. See package insert for complete prescribing information.

Keep out of reach of children.

Each gram contains: 0.5 mg (0.05%) of tretinoin in an opaque, pale yellow lotion base consisting of benzyl alcohol, butylated hydroxytoluene, carbomer copolymer type B (Pemulen TR-1), carbomer homopolymer type A (Carbopol 981), glycerin, methylparaben, mineral oil, octoxynol-9, purified water, sodium hyaluronate, soluble collagen and triamine.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from freezing.

NDC 0187-0005-45

**For Topical Use Only
Not for Eye Use**


Altreno[™]
(tretinoin) Lotion, 0.05%

Rx only

Net Wt. 45 g

Ortho | Dermatologics

Manufactured for:
Dow Pharmaceutical Sciences, a division of
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By:
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Laval, Quebec H7L 4A8, Canada
Product of Canada

U.S. Patent Number: 6,517,847

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Lot, exp, and
serialization area



Area for
SERIALIZATION
laser burned
on dark color

Lot, exp, and
serialization area





This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JILL A LINDSTROM
08/23/2018

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