PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

XIIDRA®

Lifitegrast Ophthalmic Solution

Solution, 5% w/v Ophthalmic

Lymphocyte function associated antigen-1 (LFA-1) antagonist

Bausch & Lomb Inc.
1400 N Goodman Street
Rochester, NY 14609
USA

Imported and Distributed by:
Bausch + Lomb Corporation
Vaughan, Ontario
L4K 4B4

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XIIDRA is a registered trademark.

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XIIDRA®

Lifitegrast Ophthalmic Solution

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Ophthalmic	Solution containing lifitegrast 5% (w/v).	*For a complete listing see Dosage Forms Composition and Packaging Section*

INDICATIONS AND CLINICAL USE

XIIDRA® (Lifitegrast) is indicated for the treatment of the signs and symptoms of dry eye disease.

Geriatrics (> 65 years of age)
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Pediatrics (< 18 years of age)
The safety and efficacy of XIIDRA have not been established in pediatric patients.

CONTRAINDICATIONS

Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the **Dosage Forms, Composition and Packaging** section of the Product Monograph.

WARNINGS AND PRECAUTIONS

Immune

Hypersensitivity reactions are possible with XIIDRA. Rarely, allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with post marketing reports for XIIDRA. Immediately discontinue administration and initiate appropriate treatment if hypersensitivity reactions occur.

Driving and Operating Machinery

XIIDRA may cause transient blurred vision at instillation. If patients experience blurred vision, they should be advised not to drive or operate machinery until their vision has cleared.

Special Populations

Pregnant Women
There are no adequate and well-controlled studies of XIIDRA use in pregnant women. In a reproductive toxicology study in rats, intravenous administration of lifitegrast from pre-mating through gestation day 17 resulted in an increase in incidence of pre-implantation loss and incidences of skeletal malformations. In a reproductive toxicity study in rabbits, intravenous administration of lifitegrast during organogenesis resulted in incidences of omphalocele. Since human systemic exposure to lifitegrast following ocular administration at the recommended human ophthalmic dose (RHOD) is low, the applicability of animal findings to the risk of lifitegrast use in humans during pregnancy is unclear.

XIIDRA should be used with caution during pregnancy (see **TOXICOLOGY, Reproductive and Developmental Toxicity**).

Nursing Women
It is not known whether XIIDRA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when XIIDRA is administered to a nursing woman.

Pediatrics
The safety and efficacy of XIIDRA have not been established in pediatric patients.

Geriatrics
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

The most common ocular adverse reactions were eye irritation (18%), eye pain (13%) and instillation site reactions (12%); the majority of ocular adverse reactions were mild and transient in nature. The most common non-ocular adverse reaction was dysgeusia (14%).

Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

In 5 clinical studies of dry eye disease, 1401 subjects received at least 1 dose of lifitegrast (1287 of which received lifitegrast ophthalmic solution 5%). The majority of subjects (84%) had ≤3 months of treatment exposure. 177 subjects were exposed to lifitegrast for >6 months and 170 subjects were exposed to lifitegrast for approximately 12 months. The lifitegrast population was predominantly female (77%) and white (84%).

The incidence rates of adverse reactions listed in the following table were derived from placebo-controlled trials of up to 12 weeks duration in patients receiving XIIDRA:

Table 1: Treatment Emergent Adverse Events in ≥ 1 % Dry Eye Disease Patients Treated with XIIDRA and Greater than Placebo in 12-week Dry Eye Disease studies – Safety Population[1]

System Organ Class (Preferred Term)	XIIDRA N=1067 (%)	Placebo N=1066 (%)
Eye Disorders		
Visual Acuity Reduced	35 (3.3)	42 (3.9)
Vision Blurred	29 (2.7)	8 (0.8)
Lacrimation Increased	28 (2.6)	4 (0.4)
Eye Irritation	25 (2.3)	9 (0.8)
Eye Pain	18 (1.7)	8 (0.8)
Ocular Hyperemia	16 (1.5)	6 (0.6)
Eye Pruritus	14 (1.3)	11 (1.0)
Conjunctival Hemorrhage	11 (1.0)	5 (0.5)

Table 1: Treatment Emergent Adverse Events in ≥ 1 % Dry Eye Disease Patients Treated with XIIDRA and Greater than Placebo in 12-week Dry Eye Disease studies – Safety Population[1]		
System Organ Class (Preferred Term)	**XIIDRA N=1067 (%)**	**Placebo N=1066 (%)**
Photophobia	11 (1.0)	1 (<0.1)
Gastrointestinal Disorders		
Dysgeusia	150 (14.1)	2 (0.2)
General Disorders and Administration Site Conditions		
Instillation Site Irritation	162 (15.2)	28 (2.6)
Instillation Site Reaction	129 (12.1)	25 (2.3)
Instillation Site Pain	119 (11.2)	23 (2.2)
Instillation Site Pruritus	37 (3.5)	8 (0.8)
Nervous System Disorders		
Headache	20 (1.9)	8 (0.8)

[1] Patients from safety population received at least one dose of study treatment during the study trial.

Long-Term Study

A long-term randomized, double-masked and placebo-controlled safety study was conducted over the course of 12 months in 332 patients (262 subjects completed) with dry eye disease. Patients were allowed to use artificial tears concomitantly. The safety profile observed in this long-term study was similar to that seen in the short-term 12-week studies.

Post-Market Adverse Reactions

The following adverse reactions have been identified during post-approval use of XIIDRA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Serious adverse reactions identified in post-marketing hypersensitivity reports included anaphylactic reaction, swollen tongue, hypersensitivity, Type IV hypersensitivity reaction, asthma, dyspnoea, pharyngeal edema, respiratory distress, angioedema, conjunctivitis allergic, and dermatitis allergic.

DRUG INTERACTIONS

Drug-Drug Interactions

No formal drug-drug interaction studies have been conducted.

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Interactions with herbal products have not been established.

Drug-Laboratory Interactions

Interactions with laboratory tests have not been established.

Drug-Lifestyle Interactions

Interactions with lifestyle have not been established

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

One drop of XIIDRA twice a day (i.e., AM and PM approximately 12 hours apart) into each eye.

Missed Dose

Advise the patient that a missed dose should be taken as soon as they remember unless it is almost time for their next dose. If that is the case, advise the patient to continue with their next scheduled dose. Patients should not take two doses at the same time.

Administration

Contact lenses should be removed prior to the administration of XIIDRA and may be reinserted 15 minutes following administration.

Instill one drop of XIIDRA into each eye using a single-use container. The single-use container should be discarded immediately after use.

Advise patients to wash their hands before each use and not to touch the tip of the single-use

container to their eye or any other surface, in order to avoid eye injury or contamination of the solution.

Advise patients that the solution for one single-use container is to be used immediately after opening. It can be used to dose both eyes. The single-use container, including any remaining contents, should be discarded immediately after administration.

Instruct patients to store single-use containers in the original foil pouch until ready to use.

OVERDOSAGE

There is no information regarding overdose in patients taking XIIDRA.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Lifitegrast binds to the integrin lymphocyte function-associated antigen-1 (LFA-1), a cell surface protein found on leukocytes and blocks the interaction of LFA-1 with its cognate ligand intercellular adhesion molecule-1 (ICAM-1).[1] ICAM-1 may be over expressed in corneal and conjunctival tissues in dry eye disease.[2] LFA-1/ICAM-1 interactions supports T-cell migration and activation, which promotes the release of cytokines that sustain inflammation. *In vitro* studies demonstrated that lifitegrast may inhibit T-cell adhesion to ICAM-1 and may inhibit the secretion of key inflammatory cytokines in human peripheral blood mononuclear cells. The exact mechanism of action of lifitegrast in dry eye disease is not known.

Pharmacodynamics

No studies of pharmacodynamic effects have been performed in humans.

Pharmacokinetics

Absorption

Tear: When administered clinically twice daily for 10 days, tear pharmacokinetic parameters for

[1] Module 2.6.2 Pharmacology Written Summary, section 2.6.2.2.1 In Vitro Pharmacodynamics

[2] Relocation of sentence from deleted paragraph

lifitegrast 5% were: C_{max} = 91,413 ± 43,308 ng/mL, $AUC_{0\text{-}8hours}$ = 127,697 ± 66,418 ng·h/mL and T_{max} 0.44 ± 0.22 hours. There was no accumulation of lifitegrast in tears during twice daily and 3 times daily administration of lifitegrast.

Plasma: In clinical studies, lifitegrast 5% solution is rapidly absorbed into the plasma with a mean T_{max} of 0.09 ± 0.01 hours (approximately 5.4 minutes) when administered twice daily for 10 days. Lifitegrast is also rapidly eliminated from plasma with lifitegrast concentrations typically being measureable for only up to 30 minutes after administration. Systemic exposure to lifitegrast is low with C_{max}=1.70 ± 1.36 ng/mL and $AUC_{0\text{-}8hours}$ = 0.69 ± 0.47 ng·h/mL when administered twice daily for 10 days; therefore lifitegrast disposition half-life ($t_{½}$) cannot be determined accurately. The overall plasma pharmacokinetic profile demonstrated no systemic accumulation of lifitegrast when administered twice daily over 10 days.

Distribution
Following topical ocular administration to rats, dogs, or rabbits, lifitegrast was absorbed into the eye with a high level of exposure in anterior ocular tissues, the site of action, and limited distribution to the posterior segment. Systemic exposure following topical administration was found to be limited.

Lifitegrast is highly bound to human serum albumin (mean of 94.8 to 97.6%). Binding to melanin was moderate *in vitro* (mean of 35.2-60.4% bound); however tissue distribution of [^{14}C]-lifitegrast in pigmented and albino rats was comparable indicating that lifitegrast did not preferentially bind to melanin.

Metabolism
An *in vitro* ^{14}C-lifitegrast metabolic study in rat, dog, monkey and human hepatocytes showed that lifitegrast is metabolically stable with minimal CYP-mediated conversion to metabolites across species. No metabolites were characterized from pooled plasma, urine and fecal homogenate samples, following either IV or ocular administration of [^{14}C]-lifitegrast in rats and dogs.

Excretion
In nonclinical studies, the majority of the drug is excreted unchanged via the fecal route. The main route of excretion following ocular administration was via feces, accounting for approximately 60% of the administered radioactivity up to 168 hours post-dose. Urinary excretion accounted for up to 2% of the administered radioactivity.

STORAGE AND STABILITY

Store between 15-30°C. After opening of the aluminum pouch, the single-use containers should be kept in the original foil pouch to protect from light. Any opened single-use container should be discarded immediately after use.

DOSAGE FORMS, COMPOSITION AND PACKAGING

XIIDRA (lifitegrast ophthalmic solution 5%) is supplied as a sterile solution with a pH range of 7.0 – 8.0 and an osmolality range of 200 – 330 mOsmol/kg.

XIIDRA contains Active: lifitegrast 50 mg/mL; Inactives: sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH), sodium phosphate dibasic anhydrous, sodium thiosulfate pentahydrate, and water for injection.

XIIDRA is a sterile, preservative-free, clear, colourless to slightly yellowish solution supplied in low density polyethylene single-use containers, packaged in foil pouches. Each single-use container contains 0.2 mL solution corresponding to 10 mg lifitegrast.

XIIDRA is available in cartons of 12 pouches. Each pouch contains 5 single-use containers.

XIIDRA is also available in cartons of 4 pouches. Each pouch contains 5 single-use containers.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

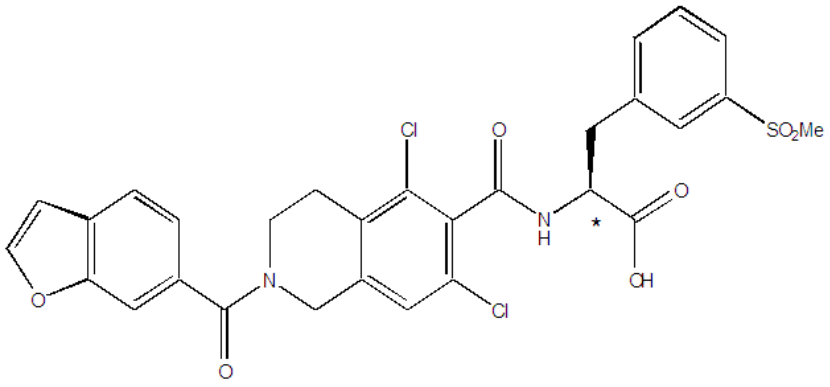
Drug Substance

Common name: Lifitegrast

Chemical name: (S)-2-(2-(benzofuran-6-carbonyl)-5,7-dichloro-1,2,3,4-tetrahydroisoquinoline-6 -carboxamido)- 3-(3-(methylsulfonyl) phenyl)propanoic acid

Molecular formula and molecular mass: $C_{29}H_{24}Cl_2N_2O_7S$ and its molecular weight is 615.48.

Structural formula:



* Chiral center

Physicochemical properties: Lifitegrast is a white to off-white powder which is soluble in water, its aqueous solubility is pH dependent.

pH	Solubility (µg/mL)
1.2	0.5
3.0	2.0
4.0	20
5.0	166
6.0	>1000
7.0	>1000
8.0	>1000

CLINICAL TRIALS

Study demographics and trial design

Table 2: Summary of patient demographics for 12-week efficacy studies in Dry Eye Disease Patients

Study #	Trial design	Dosage, route of administration and duration	Study subjects (n = number)	Mean age (Range)	Gender
Study 1	Multicenter, randomized, prospective, double-masked, placebo controlled, parallel arm study; CAE used at screening	0.1, 1.0, or 5.0% lifitegrast or placebo; single drop BID; 84 days (12 weeks)	n=230	62.3 years (26-91)	Male: 22.2% Female:77.8%
Study 2	Multicenter, randomized, prospective, double-masked, placebo controlled, parallel arm study: CAE used at screening	5.0% lifitegrast or placebo; single eye drop BID; 12 weeks	n=588	60.6 years (20-91)	Male: 24.1% Female:75.9%
Study 3	Multicenter, randomized, prospective, double-masked, placebo controlled, parallel arm study; stratified by ICSS (≤1.5 or >1.5) and EDS (<60 or ≥60) in trial design; recent artificial tear use required	5.0% lifitegrast or placebo; single eye drop BID; 12 weeks	n=718	58.8 years (19-97)	Male: 23.4% Female:76.6%
Study 4	Multicenter, randomized, prospective, double-masked, placebo controlled, parallel arm study; stratified by ICSS (≤1.5 or >1.5) and EDS (<60 or ≥60) in trial design; recent artificial tear use required	5.0% lifitegrast or placebo; single eye drop BID; 12 weeks	n=711	58.7 years (18-93)	Male: 24.5% Female:75.5%

The effects of lifitegrast treatment on the signs and symptoms of dry eye disease were assessed in a total of 2247 subjects in four 12-week, randomized, multi-centre, double-masked, placebo-controlled studies. In all studies, subjects were randomized to XIIDRA 5% or placebo in 1:1 ratio. The majority of subjects were 55 years of age and older (68%), white (85%) and female (76%). In all studies, subjects reported a history of dry eye disease in both eyes at study entry. In studies 1 and 2, a controlled adverse environment (CAE) model was used during the screening period to identify subjects who were more susceptible to environmental stressors. In studies 3 and 4, subjects were required to have a history of recent artificial tear use. In all four studies, use of artificial tears was prohibited during the 12-week study period.

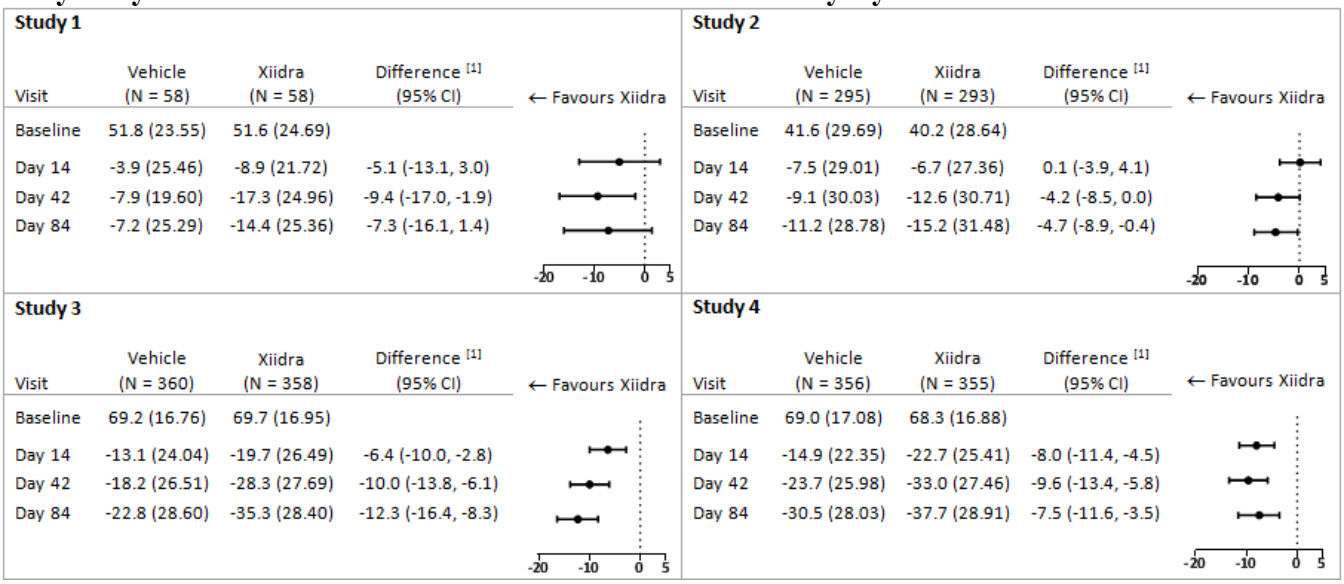
Enrolment criteria included minimal signs (i.e., Corneal Fluorescein Staining [CFS] and non-anesthetized Schirmer Tear Test (STT) and symptoms (i.e., Eye Dryness Score [EDS] and Ocular Discomfort Score [ODS]) severity scores at baseline.

Study results

Effects on Symptoms of Dry Eye Disease

Eye dryness Score (EDS) was rated by patients using a visual analogue scale (VAS) (0 = no discomfort, 100 = maximal discomfort) at each study visit. The average baseline EDS was between 40 and 70. A larger reduction in EDS favoring XIIDRA was observed in all studies at Day 42 and Day 84 (see Figure 1).

Figure 1: Mean Change (SD) from Baseline and Treatment Difference (XIIDRA – Vehicle) in Eye Dryness Score in 12-Week Studies in Patients with Dry Eye Disease

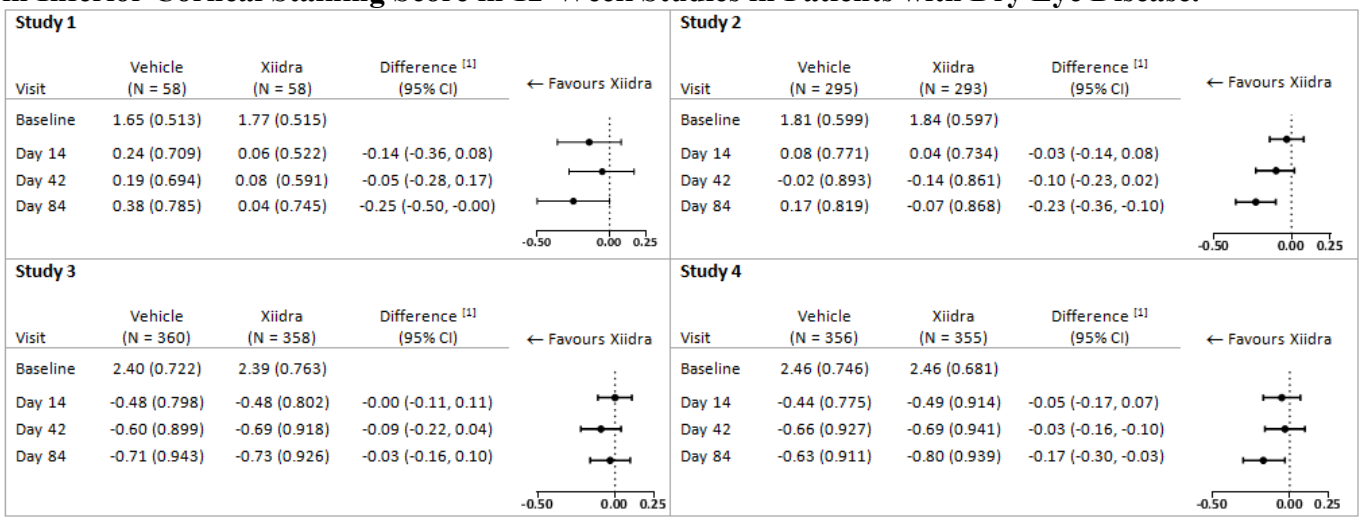


[1] Based on ANCOVA model adjusted for baseline value in Study 1, and ANCOVA model adjusted for baseline value and randomization stratification factors in Studies 2-4. All randomized and treated patients were included in the analysis and missing data were imputed using last-available data. In Study 1, one XIIDRA treated subject who did not have a baseline value was excluded from analysis.

Effects on Signs of Dry Eye Disease

Inferior fluorescein corneal staining score (ICSS) (0 = no staining, 1 = few/rare punctate lesions, 2 = discrete and countable lesions, 3 = lesions too numerous to count but not coalescent, 4 = coalescent) was recorded at each study visit. The average baseline ICSS was approximately 1.8 in Studies 1 and 2, and 2.4 in Studies 3 and 4. At Day 84, a larger reduction in ICSS favoring XIIDRA was observed in three of the four studies (see Figure 2).

Figure 2: Mean Change (SD) from Baseline and Treatment Difference (XIIDRA – Vehicle) in Inferior Corneal Staining Score in 12-Week Studies in Patients with Dry Eye Disease.



[1] Based on ANCOVA model adjusted for baseline value in Study 1, and ANCOVA model adjusted for baseline value and randomization stratification factors in Studies 2-4. All randomized and treated patients were included in the analysis and missing data were imputed using last-available data. In Study 2, one Vehicle treated subject who did not have a study eye designated was excluded from analysis.

DETAILED PHARMACOLOGY

Lifitegrast binds to the integrin lymphocyte function-associated antigen-1 (LFA-1), a cell surface protein found on leukocytes and blocks the interaction of LFA-1 with its cognate ligand intercellular adhesion molecule-1 (ICAM-1). ICAM-1 may be overexpressed in corneal and conjunctival tissues in dry eye disease. LFA-1/ICAM-1 interactions support T-cell migration and activation, which promotes the release of cytokines that sustain inflammation. *In vitro* studies demonstrated that lifitegrast may inhibit T-cell adhesion to ICAM-1 and may inhibit the secretion of key inflammatory cytokines in human peripheral blood mononuclear cells. The therapeutic effects of lifitegrast were demonstrated in several *in vivo* pharmacology studies, including a veterinary clinical study in dogs with spontaneously occurring keratoconjunctivitis sicca, in which a 1.0% dose of lifitegrast ophthalmic solution administered TID for 12 weeks resulted in improved Schirmer Tear Test scores, indicative of increased tear production. A pharmacological response in attenuating conjunctival inflammation was also observed histopathologically. In a murine model of corneal abrasion and inflammation associated with contact lens usage, topical ocular administration of lifitegrast (0.1%, 1.0% and 5.0%) prior to corneal abrasion and/or bacterial challenge, correlated with significant reduction in neutrophil infiltration at all 3 dose levels. Additional testing confirmed that lifitegrast was presence in the corneal tissue at all 3 dose levels.

In safety pharmacology studies, the IV administration of lifitegrast was shown to have no adverse effects on CNS, CV, or pulmonary functions.

TOXICOLOGY

Thirteen-week and 39-week repeat-dose ocular toxicity studies were conducted in New Zealand White rabbits and beagle dogs using the topical ocular route of administration with three times daily dosing (TID). Squinting or blinking immediately following dosing with lifitegrast was observed in both species, but was non-adverse. Other non-adverse findings in the 39-week studies included a slight increase in the severity of muscle fiber regeneration in the tongue of rabbits dosed ≥ 1.05 mg/eye/day, and minimal granulomatous inflammation of the tongue in a few dogs at the highest dose of 5.25 mg/eye/day. In both species, the no-observed-adverse-effect level (NOAEL) for ocular toxicity was 5.25 mg/eye/day (35 µL/eye of 5% formulation; TID), the highest dose tested. This NOAEL provides a 1.05-fold margin of safety in terms of total mg/day, and a 138-fold and 16-fold margin of safety when comparing systemic exposure (AUC) in rabbits and dogs, respectively, to the highest exposure reported in human clinical trials.

The NOAEL for the systemic toxicity of lifitegrast in beagle dogs following intravenous administration is 30 mg/kg/day, the highest dose tested in a 4-week study, providing a margin of safety of approximately 20,000-fold based on plasma AUC values. In rats, the NOAEL for systemic toxicity is 10 mg/kg/day, based on the following findings at 30 mg/kg/day in a 13-week intravenous study: an increase in incidence of thymic epithelial hyperplasia in females, renal/bladder/ureter and prostatic effects in one male, and testicular/epididymal effects in a second male. The NOAEL in rats provides a margin of safety of approximately 660-fold.

Since human systemic exposure to lifitegrast following ocular administration at the RHOD is low, the applicability of animal findings to the risk of XIIDRA use is unclear.

Carcinogenicity

Long-term studies in animals to evaluate carcinogenic potential of lifitegrast have not been performed on the basis that systemic exposure following topical ocular administration of lifitegrast is very low.

Genotoxicity

Lifitegrast was not mutagenic in the *in vitro* Ames assay. Lifitegrast also showed no evidence of clastogenicity in the *in vitro* chromosomal aberration assay in mammalian cells (Chinese hamster ovary cells), except at a cytotoxic concentration in the absence of metabolic activation. Lifitegrast was not clastogenic in an *in vivo* mouse micronucleus, indicating lack of genotoxic potential.

Reproductive and Developmental Toxicity

In a combined, reproductive and developmental toxicity study, lifitegrast at intravenous doses of up to 30 mg/kg/day, from pre-mating through gestation day 17, had no effect on fertility and reproductive performance in male and female rats. The NOAEL of 30 mg/kg/day provides for a margin of safety of approximately 5400-fold based on plasma AUC values.

In the reproductive and developmental study in rats, the NOAEL for developmental toxicity was 10 mg/kg/day based on an increase in incidence of pre-implantation loss and incidences of skeletal malformations observed at 30 mg/kg/day. The NOAEL of 10 mg/kg/day provides for a margin of safety of approximately 460-fold based on plasma AUC values.

In a developmental toxicity study in rabbits, intravenous administration of lifitegrast to pregnant rabbits during organogenesis (gestation days 7 through 19) resulted in incidences of omphalocele (an external malformation) at the lowest (3 mg/kg/day) and highest (30 mg/kg/day) doses tested. A NOAEL for developmental toxicity in the rabbit was therefore not identified. The systemic exposure (AUC) at the lowest dose was approximately 460-fold the highest exposure reported in human clinical trials.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

XIIDRA®

Lifitegrast Ophthalmic Solution

Read this carefully before you start taking XIIDRA® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about XIIDRA.

What is XIIDRA used for?
XIIDRA is an eye drop used to treat the signs and symptoms of dry eyes. Dry eyes occur when your eyes are not making enough tears or your tears are not normal.

How does XIIDRA work?
XIIDRA works by blocking the interaction between two types of proteins that can cause inflammation in dry eye disease.

It is important that you continue to use XIIDRA drops every day. Some patients may experience improvements in eye dryness symptoms in as early as 2 weeks.

What are the ingredients in XIIDRA?
Medicinal ingredient: Lifitegrast, 5% w/v

Non-medicinal ingredients: sodium chloride, sodium phosphate dibasic anhydrous, sodium hydroxide and/or hydrochloric acid (to adjust pH), sodium thiosulfate pentahydrate and water for injection.

XIIDRA comes in the following dosage forms:
XIIDRA is a sterile, preservative-free, clear and colourless to slightly yellowish solution supplied in low density polyethylene single-use containers, packaged in foil pouches (5 single-use containers per pouch). Each single-use container contains 0.2 mL solution corresponding to 10 mg lifitegrast.

Each carton contains 12 pouches.

Do not use XIIDRA if:
You have an allergy to lifitegrast or any of the ingredients in XIIDRA. See **What are the ingredients in XIIDRA?**

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use XIIDRA. Talk about any health conditions or problems you may have, including if you:

- Are pregnant or plan to become pregnant. It is not known if XIIDRA will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known whether or not XIIDRA is passed into breast milk.

Other warnings you should know about:
XIIDRA may cause your vision to blur temporarily when you put the drops in. If you experience blurred vision, wait until your vision clears before you try to drive or operate a machine.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XIIDRA:
There are no known drug interactions with lifitegrast.

How to use XIIDRA:
XIIDRA is for use in the eye only.

- The recommended dose is one drop into each eye – do this twice a day.

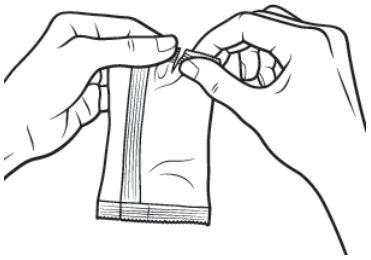
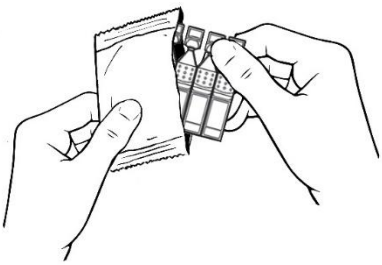
Before you use XIIDRA:

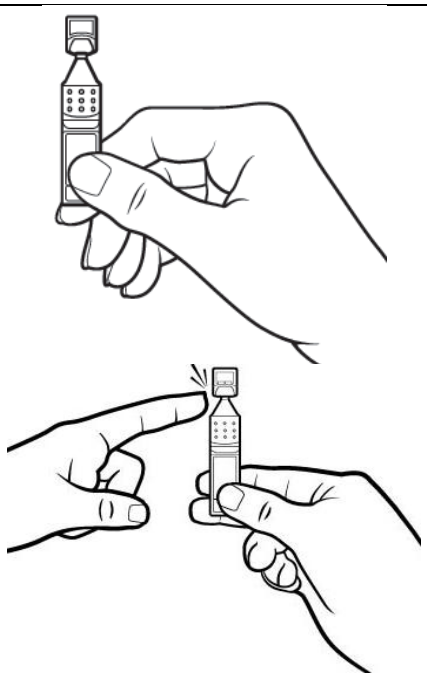
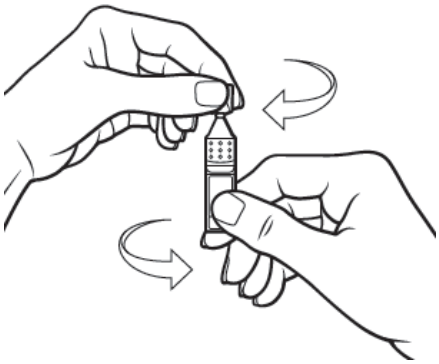
- Wash your hands before each use – this is to make sure you do not infect your eyes.
- If you wear contact lenses, remove them before using XIIDRA. You can put your lenses back in 15 minutes after you use XIIDRA.
- XIIDRA comes in single-use containers in a foil pouch. Do not remove the containers from the foil pouch until you are ready to use XIIDRA.
- Do not let the tip of the container touch your eye or any other surfaces - this is to prevent eye injuries and to help stop contamination.

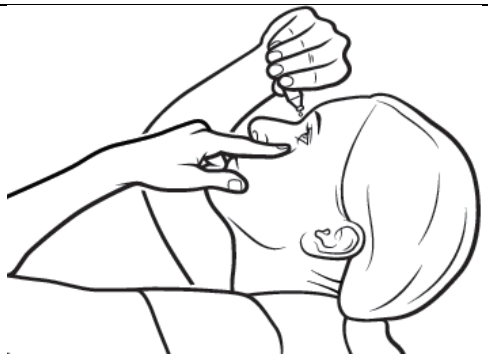
About the single-use containers:
Each single-use container of XIIDRA contains enough for one dose in both of your eyes.

- There is some extra solution in each single-use container – this is in case you miss getting a drop into your eye.
- After you have used the drops, throw away the single-use container and any unused solution.
- Do not save any unused XIIDRA.

How to use:

Step 1. • Take a foil pouch out of the XIIDRA box. • Open the pouch and remove the strip of single-use containers. • Pull off 1 container from the strip.	 
Step 2. • Put the remaining strip of containers back in the pouch. • Then fold the edge to close the pouch.	 

Step 3. • Hold the container upright. • Tap the top of the container until all of the solution is in the bottom part of the container.	
Step 4. • Twist off the tab to open the container. • Make sure that the tip of the single-use container does not touch anything - this is to help stop contamination.	
Step 5. • Tilt your head backwards. • If you are not able to tilt your head, lie down.	

Step 6. • Gently pull your lower eyelid downwards - then look up. **Step 7**. • Place the tip of the container close to your eye - but be careful not to touch your eye with it. **Step 8.** • Gently squeeze the container • Let 1 drop fall into the space between your lower eyelid and your eye. • If a drop misses your eye, try again.	
Step 9. • Repeat steps 5-8 for your other eye. • There is enough XIIDRA in one container for both eyes. **After use** After you have applied a drop to both eyes, throw away the opened container - including any remaining solution. If you use contact lenses - wait for at least 15 minutes before placing them back in your eyes.	

Usual dose:
Use 1 drop of XIIDRA in each eye, twice a day, about 12 hours apart.

Overdose:

If you think you have used too much XIIDRA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you missed a dose of this medication, use it as soon as you remember. But if it is almost time

for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time.

What are possible side effects from using XIIDRA?
These are not all the possible side effects you may feel when using XIIDRA. If you experience any side effects not listed here, contact your healthcare professional.

The very common side effects were:
- eye irritation, eye pain, eye reaction when drops are applied to the eyes
- unpleasant taste in the mouth

These effects occur when the drops are applied to the eyes.

Other common side effects are:
- blurred vision
- itchy eyes
- eye redness
- increase in tears
- headache
- sensitivity to light

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reactions: difficulty breathing or swallowing, swelling of tongue, lips and face, skin rash, itching and hives			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:
- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store XIIDRA between 15-30°C
- Store XIIDRA in the original foil pouch to protect it from light
- Do not open the XIIDRA foil pouch until you are ready to use the eye drops
- Return unused single-use container to their original foil pouch to protect from excessive light exposure
- Discard opened single-use container immediately after use

Keep out of reach and sight of children.

If you want more information about XIIDRA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website https://www.canada.ca/en/health-canada.html, the manufacturer's website www.bausch.ca, or by calling 1-888-459-5000.

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