offspring. Maternal toxicity, possible occurrence of abnormalities and growth retardation started at 4 times the Lotemax™ clinical dose.

Neurologic

Disturbances and suppression of the Hypothalamic-Pituitary-Adrenal (HPA) axis can occur with systemic exposure to corticosteroids. However, given the very low systemic exposure to loteprednol etabonate when using Lotemax™ as directed, these possible effects are not likely.

Endocrine and Metabolism

Glucocorticoids, mostly when systemic exposure occurs, decrease the hypoglycemic activity of insulin and oral hypoglycemics, so that a change in dose of the antidiabetic drugs may be necessitated. In high doses, glucocorticoids also decrease the response to somatotropin. The usual doses of mineralocorticoids and large doses of some glucocorticoids cause hypokalemia and may exaggerate the hypokalemic effects of thiazides and high-ceiling diuretics. In combination with amphotericin-B, they also may cause hypokalemia. Glucocorticoids appear to enhance the ulcerogenic effects of non-steroidal anti-inflammatory drugs. They decrease the plasma levels of salicylates, and salicylism may occur on discontinuing steroids. Glucocorticoids may increase or decrease the effects of prothrombopenic anticoagulants. Estrogens, phenobarbital, phenytoin and rifampin increase the metabolic clearance of adrenal steroids and hence necessitate dose adjustments.

However, given the very low systemic exposure to loteprednol etabonate when using Lotemax™ as directed, these possible effects are not likely.

Immune

Cortisol and the synthetic analogs of cortisol have the capacity to prevent or suppress the development of the local heat, redness, swelling, and tenderness by which inflammation is recognized. At the microscopic level, they inhibit not only the early phenomena of the inflammatory process (edema, fibrin deposition, capillary dilation, migration of leukocytes into the inflamed area, and phagocytic activity) but also the later manifestations, such as capillary proliferation, fibroblast proliferation, deposition of collagen, and, still later, cicatrisation.

Clinical Trial Adverse Drug Reactions

Incidence of Medical Events from two Phase III studies:

	Lotemax™ N=212		Placebo N=218	
	N	%	N	%
No signs or symptoms	93	44	48	22
Discomfort eye	28	13	49	22
Epiphora (eye/app)	25	12	49	22
Itching eye	24	11	33	15
Photophobia	23	11	72	33
Eye pain	18	8	53	24
Dry eyes	13	6	18	8
Injection	11	5	50	23
Cell, anterior chamber	8	4	20	9
Ciliary flush	6	3	17	8
Erythema, eyelids	6	3	17	8
Discharge, eye	5	2	14	6
Edema, corneal	5	2	17	8
Chemosis	2	1	9	4
Flare, anterior chamber	2	1	23	11
Hyphema	1	<1	1	<1

Intraocular Pressure

Elevated IOP is associated with the application of topical corticosteroids. IOP was closely monitored in the phase III studies. In the phase III studies, IOP increases of 6 to 9 mm Hg were seen in 11 subjects in the Lotemax™ group and in the placebo group (see table below). Four patients, 3 Lotemax™ and 1 placebo, reached an IOP of 22 to 24 mm Hg. One placebo patient reached an IOP of 29 mm Hg.

Incidence of IOP increases from baseline

(number of patients and percentages)

	Visit 2 Day 2-6	Visit 3 Day 7-12	Visit 4 Day 13+	Any Visit
Pivotal Study A				
≥10 mm Hg				
Placebo	0 (0%)	0 (0%)	0 (0%)	0 (0%)
LE	2 (2%)	1 (1%)	0 (0%)	3 (3%)*
6 to 9 mm Hg				
Placebo	3 (3%)	1 (1%)	1 (1%)	5 (4%)
LE	1 (1%)	5 (5%)	2 (2%)	7 (6%)
Pivotal Study B				
≥10 mm Hg				
Placebo	0 (0%)	1 (1%)	0 (0%)	1 (1%)**
LE	0 (0%)	0 (0%)	0 (0%)	0 (0%)
6 to 9 mm Hg				
Placebo	4 (4%)	2 (2%)	2 (3%)	6 (6%)
LE	0 (0%)	3 (3%)	2 (2%)	4 (4%)

One eye developed severe uveitis and increased from 18mm Hg pre-op to 50mm Hg at Visit 3
One eye increased from 7mm Hg pre-op to 26mm Hg post-op and to 30mm Hg by Visit 2
One eye increased from 8mm Hg pre-op to 23mm Hg post-op and to 25mm Hg by Visit 2
**One eye increased from 19mm Hg pre-op and 18mm Hg post-op to 48mm Hg by Visit 3

SYMPTOMS AND TREATMENT OF OVERDOSAGE

For management of suspected accidental oral ingestion or drug overdose, consult your regional poison control centre. No cases of overdose have been reported.

Full Product Monograph available for health professionals at: http://www.bausch.ca

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CALENDAR OF EVENTS

June 26–29, 2010
Canadian Ophthalmological Society Annual Meeting & Exhibition
Québec, QC
http://eyesite.ca/quebec2010

July 13–17, 2010
XIVth International Symposium on Retinal Degeneration
Mont-Tremblant, QC
http://rd2010.ouhsc.edu/

July 18–23, 2010
XIX Biennial Meeting of the International Society for Eye Research
Montréal, QC
http://www.iser.org

July 29–August 1, 2010
34th Annual Meeting of the Christian Ophthalmology Society
Cincinnati, Ohio
http://www.cosw.org

September 9–11, 2010
28th Annual Meeting of the European Society of Ophthalmic Plastic and Reconstructive Surgery
Munich, Germany
http://www.esoprs2010.org/

September 10-11, 2010
Atlantic Eye Symposium
Halifax, NS
http://www.atlanticeye.ca

September 16–20, 2010
APAO-AAO Joint Congress
Beijing, China
http://www.apao2010beijing.org/index00_1.shtml

September 30–October 2, 2010
Sally Letson Symposium
Pediatric Ophthalmology and Genetics Update
Ottawa, ON
http://www.eyesite.ca/SallyLetson/

October 16–19, 2010
AAO-MEACO Joint Meeting
Chicago, Illinois
http://www.aao.org/meetings/annual_meeting/

October 21–24, 2010
23rd International Congress of German Ophthalmic Surgeons
Hamburg, Germany
http://www.doc-nuernberg.de/