



# New Drug Update

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## Byetta® (exenatide)

**Authors:** Dustin Hanchock, Pharm.D. Candidate  
School of Pharmacy

Kristy Lucas, Pharm.D.  
Clinical Associate Professor  
Schools of Pharmacy and Medicine  
West Virginia University – Charleston

Prasuna Jami, MD  
Assistant Professor  
Department of Internal Medicine  
West Virginia University - Charleston

### Introduction

Byetta® [exenatide (synthetic exendin-4)(ex-EN-ate)] is the first available in a new class of diabetes medications known as incretin mimetics. Exenatide is a glucagon-like peptide-1 (GLP-1) agonist that is approved for adjunctive therapy in patients with Type II diabetes who exhibit poor glycemic control. Exenatide is currently the only drug available in this class and should be available commercially as of 6/1/05, although Liraglutide, another long acting GLP-1 analog also has shown efficacy in reducing HgbA1c without causing any weight gain when compared with glimipiride in type 2 DM patients in one trial.

### Therapeutic Recommendation

**Exenatide has shown efficacy in improving glycemic control and therapeutic endpoints in Type II diabetes mellitus. It currently does not have approval for use as monotherapy, but studies indicate that exenatide in combination with metformin and/or sulfonylureas allows for tighter glycemic control, in addition to significantly decreasing HbA1c. These studies were conducted in patients who failed to achieve glycemic control on metformin and/or sulfonylureas. The studies also showed that no weight gain was associated with**

**exenatide and that weight loss actually occurred in many patients. Exenatide has not been compared head to head with any of the current medications indicated for Type II diabetes mellitus, which makes assessment of its role difficult. It also has the disadvantage of requiring multiple daily injections, but there is a long-acting release formulation that is currently in phase II clinical trials. This long acting formulation uses *Medisorb* sustained release technology for injectable medications and may allow for once weekly or even once monthly dosing, if approved. There is a lack of current and trial data available which makes it difficult to determine exenatide's exact place in therapy. As more information becomes available exenatide's indications may change, but currently it is considered adjunctive therapy in patients failing to achieve glycemic control on metformin and/or sulfonylureas.**

### Dosage and Administration

Byetta® is available as a 250 mcg/ml solution in two package sizes: 1) a 5 mcg/dose, 1.2 ml pre-filled syringe pen, and 2) a 10 mcg/dose, 2.4 ml pre-filled syringe pen, each of which provides 60 doses. Each new pen must be setup before the first use, but this only needs to be done once. The recommended starting dose is 5 mcg twice daily administered at any time within 1 hour before morning and evening meals. Response is assessed after 1 month of therapy, and if needed the dose may be increased to 10 mcg twice daily. If no increase is necessary, the dose may be left at 5 mcg twice daily. If exenatide is prescribed for a patient already on metformin, no reduction in the

### In This Issue:

- ◆ Byetta® (exenatide)
- ◆ Sensipar® (cinacalcet)
- ◆ Elistat® (epinastine)

metformin dose is necessary as there is a low risk of hypoglycemia, however if the patient is on a sulfonylurea, the dose of the sulfonylurea will likely need to be reduced to decrease the risk of hypoglycemia. Exenatide should be given as a subcutaneous injection in either the thigh, abdomen or upper arm. The maximum recommended dose is 10 mcg twice daily. The lower starting dose and slow titration are recommended to reduce side effects and improve tolerability.

## Contraindication

Exenatide is contraindicated in patients with a known hypersensitivity to the drug or any of the components in the formulation.

## Warnings/Precautions

Exenatide is not an insulin substitute and hence should not be given to Type I or insulin dependent patients. It also has not been studied concurrently with oral antidiabetic agents other than metformin and sulfonylureas, therefore its use with other agents should be monitored closely or avoided until further studies are available.

Exenatide has not been studied in patients with severe GI disease, and since it can cause nausea, vomiting, and diarrhea, its use should be avoided in patients with GI disease.

Caution should be noted when using exenatide in patients who have conditions predisposing them to hypoglycemia. These conditions include high fever, uncontrolled hypercortisolism, psychological stress, malnutrition, adrenal or pituitary insufficiency, psychological disorders, and/or being in a debilitated state. Exenatide should also be used with caution in patients who have hyper/hypothyroidism, and in patients who are pregnant.

Lastly, exenatide should be used cautiously in combination with sulfonylureas due to a significantly increased incidence of hypoglycemia.

## Cost Comparison

Medication/Dose	Cost		
	CVS	Rite Aid	Kroger
Byetta® 1.2 ml 5 mcg/dose syringe	215.99	183.75	205.99
Byetta® 2.4 ml 10 mcg/dose syringe	250.99	215.63	241.09

## Special Populations

**Renal Impairment:** Clearance of exenatide in mild to moderate renal impairment (CrCl 30-80 ml/min) is only slightly altered, thus no dose modification is needed. In severe renal impairment and patients on dialysis, clearance is decreased from 9.1 L/hr to 0.9 L/hr and use is not recommended. Tolerability is also significantly decreased in these patients due to the GI side effects.

**Hepatic Impairment:** No studies have been performed and no data exist to date on pharmacokinetics in liver disease. Hepatic dysfunction is not expected to alter clearance since exenatide is eliminated primarily by the renal route.

**Geriatric:** There does not appear to be any influence of age on the pharmacokinetics of exenatide.

**Pediatric:** No studies have been performed on pediatric patients, and as such no data exist on its use in children.

**Obesity:** Obesity also does not appear to have a significant effect on exenatide pharmacokinetics.

**Pregnancy/Lactation:** Pregnancy category C. There have been no human studies to date, but it caused reduced fetal and neonatal growth and skeletal effects in mice. It is not known whether exenatide is excreted in breast milk, however its use while nursing is not recommended.



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West Virginia University  
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EDITOR-IN-CHIEF - Kristy Lucas, Pharm.D.  
CO-EDITOR - Greg Rosencrance, M.D.  
MANAGING EDITOR - Tara White

Departments of Internal Medicine  
and Clinical Pharmacy

3110 MacCorkle Ave., SE  
Charleston, WV 25304

(304) 347-1377 • Fax: (304) 347-1350

E-mail: [klucas@hsc.wvu.edu](mailto:klucas@hsc.wvu.edu)

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## Drug Interactions

Exenatide slows gastric emptying and hence may decrease the extent/rate of absorption of many drugs given orally. It should be used cautiously in patients who are receiving drugs that require rapid GI absorption. Other oral medications that need to be taken with food should be taken with a snack where exenatide is not administered. Oral contraceptives and antibiotics should be taken at least 1 hour before exenatide injections to ensure that adequate concentrations are reached.

Digoxin: exenatide can decrease C<sub>max</sub> and delay T<sub>max</sub>, but overall steady state pharmacokinetics are not changed.

Lovastatin: AUC and C<sub>max</sub> were decreased and T<sub>max</sub> was delayed, however use in patients already receiving HMG CoA reductase inhibitors did not result in any consistent changes in lipid profiles.

Lisinopril: Steady state T<sub>max</sub> was delayed but no alteration in C<sub>max</sub> or AUC and no alteration in 24 hour systolic and diastolic blood pressure was observed.

Acetaminophen: AUC and C<sub>max</sub> were decreased and T<sub>max</sub> was increased when given with exenatide. No alterations were noted if acetaminophen was given 1 hour before exenatide injection.

## Adverse Effects

The most frequently noted adverse effects with exenatide include nausea, vomiting, diarrhea, a feeling of jitteriness, dizziness, headache, and dyspepsia. Of these, nausea was the most common and appeared to be dose dependent, but patients also became tolerant to it during the course of therapy. Less common events included asthenia, decreased appetite, GERD, and hyperhidrosis. It should be noted that the rate of hypoglycemia is significantly increased when exenatide is given in combination with sulfonylureas.

## Pharmacology

Mechanism of Action: Incretins such as exenatide work to enhance glucose dependent insulin secretion in addition to having other antihyperglycemic actions. Exenatide appears to bind and activate human GLP-1 receptors in vitro, leading to an increase in glucose dependent synthesis of insulin and its in vivo secretion from pancreatic Beta cells. Exenatide works by promoting insulin release from Beta cells in the presence of elevated glucose con-

centrations. It also moderates glucagon secretion, but does not alter the glucagon response to hypoglycemia.

Absorption/Distribution: Peak plasma concentration is reached in approximately 2.1 hours following subcutaneous injection. Average Volume of distribution is approximately 28.3 L

Metabolism/Excretion: Exenatide appears to be predominately eliminated by glomerular filtration followed by proteolytic degradation. Average clearance is approximately 9.1 L/hr and average terminal half life is approximately 2.4 hours, independent of dose. Concentrations can typically be measured for approximately 10 hours after a dose is given.

## Patient Information

1. Byetta® should be taken with your morning and evening meal, within 1 hour before eating. Do not take Byetta® after eating.
2. Do not change your dose unless directed to do so by your health care provider. Use this medication exactly as instructed.
3. Ask your health care provider which pen needle size is right for you. Pen needles are not included with your Byetta® prefilled syringe pen and will need to be purchased separately in order to properly inject the medication. Do not reuse pen needles, they are only good for 1 injection. Properly dispose of each used needle in an appropriate container.
4. You will need to setup each new syringe pen before using it for the first time. The method for doing this is clearly outlined in the patient information leaflet that accompanies each Byetta® prescription. Once the pen is setup it is ready for routine use and the setup does not have to be repeated until a new pen is acquired.
5. This medication should be injected subcutaneously (under the skin) in your thigh, stomach, or upper arm. Specific directions for administration are also included in the patient information leaflet and should be followed exactly.
6. If a dose is missed, skip it and resume your normal dosing schedule. Do not take extra doses or increase your dose.
7. If too much Byetta® is injected, contact your health care provider or poison center right away.
8. Store Byetta® in the refrigerator between 36-46° F (2-8° C) and protect it from light. Do not freeze. Do not store you pen with pen needles attached.

9. Each pen is only good for 30 days once opened. Do not use after this time or after the printed expiration date.
10. You may notice nausea, vomiting, diarrhea, headache, drowsiness, weakness, jitteriness, and other side effects while using Byetta®. Talk to your health care provider about side effects that are bothersome or do not disappear with time.

### References

1. Byetta® (exenatide) prescribing information and patient information. Amylin Pharmaceuticals, Inc., and Eli Lilly and Co. San Diego, California and Indianapolis, IN. April 2005.
2. Joy SV, Rodgers PT, Scates AC. Incretin mimetics as emerging treatments for type 2 diabetes. *Ann Pharmacother.* 2005;39:110-17.
3. DeFronzo RA, Ratner RE, Han J, et al. Effects of exenatide (exendin-4) on glycemic control and weight over 30 weeks in metformin treated patients with type 2 diabetes. *Diabetes Care.* 2005;28(5):1092-100.
4. Buse JB, Henry RR, Han J, et al. Effects of exenatide (exendin-4) on glycemic control over 30 weeks in patients with type 2 diabetes. *Diabetes Care.* 2004;27(11):2628-35.
5. O'Mara NB. New Drug: Exenatide (Byetta). *Pharmacist's Letter.* 2005;21(6):210603.

ten candidates for parathyroidectomy, but this is only a last resort as post surgical effects include hypocalcemia, hypophosphatemia, and hypomagnesemia. Cinacalcet lowers the level of parathyroid hormone while also lowering serum levels of calcium and phosphorus. In clinical trials, patients treated with cinacalcet showed rapid reductions in parathyroid hormone levels accompanied by reductions in levels of phosphorus and calcium. Parathyroid level decreased regardless of vitamin D levels. However, more studies are needed to see if parathyroid levels can be further decreased when cinacalcet and vitamin D therapy are used together. Nausea and vomiting (32 % and 30 % respectively) were the most common complaints for patients on cinacalcet. Vomiting occurred mostly at higher cinacalcet doses but nausea was unrelated to dosage level.

### Dosing and Administration

Cinacalcet is available in 30 mg, 60 mg, and 90 mg oral tablets. Tablets should be taken with food and should not be broken or divided. Patients on dialysis that have secondary hyperparathyroidism should begin with 30 mg once daily. The dosage can be titrated up to 180 mg once daily but should not exceed increases of greater than 30 mg at a time over a 2-4 week period. Patients that have parathyroid carcinoma should begin with 30 mg twice daily. Doses should be titrated every 2-4 weeks with increases of 60 mg at each titration.

### Contraindications

Do not administer cinacalcet to patients with cinacalcet hypersensitivity or if the patient has hypersensitivity to any of the other inactive ingredients.

### Cost Comparison

Medication/Dose	Cost		
	CVS	Fruth	Rite Aid
*Tums® (Calcium carboante)	4.39	3.49	3.88
*Rocaltrol® (Calcitriol) 0.25 mg QD	42.39	40.99	40.88
ReneGel® (sevelamer HCL) 403 mg 2TID	166.99	138.08	148.99
Sensipar® (cinacalcet) 30 mg QD	338.98	312.08	339.99

Cost to patient for 30-day supply at starting doses.

\*Cost indicates generic price

## Sensipar® (cinacalcet HCL)

**Author:** Rachel Whittington, Pharm.D.

**Kristy Lucas, Pharm.D.**  
Clinical Associate Professor  
Schools of Pharmacy and Medicine  
West Virginia University – Charleston

### Introduction

Sensipar® (cinacalcet [sin·a·KAL·cet]), a calcimimetic agent, decreases the secretion of parathyroid hormone (PTH) and the concentration of serum calcium by causing the calcium-sensing receptor (CaR) to be more sensitive to activation by serum calcium. Sensipar® was FDA approved on March 8, 2004 for the treatment of secondary hyperparathyroidism in patients on dialysis and for the treatment of hypercalcemia in patients with parathyroid carcinoma.

### Therapeutic Recommendations

**Current treatment for hyperparathyroidism includes phosphate-binding agents, calcium supplementation, and vitamin D therapy. Often patients must be on at least one or more of these therapies. Patients who fail to respond to this therapy or have severe disease are of-**

## Warnings/Precautions

Patients should be monitored for hypocalcemia because cinacalcet lowers serum levels of calcium. Symptoms of this include tetany, cramping, myalgias, paresthesias, and convulsions. Monitor calcium levels (normal range 8.4—10.2 mg/dL) within one week of cinacalcet initiation or any dosage changes. Withhold cinacalcet if levels are below 7.4 mg/dL.

## Special populations

**Pediatric:** No cinacalcet studies have been performed in patients < 18 years of age.

**Geriatric:** No dosage adjustment is needed for geriatric patients.

**Pregnancy:** Cinacalcet is pregnancy category C. Studies in pregnant rats and rabbits did not show any teratogenic effects. However, rat fetal body weights were decreased and both pregnant rats and rabbits showed maternal toxicity. There are currently no adequate and well-controlled studies in humans. Cinacalcet should only be used in pregnant patients if the potential benefits justify the potential fetal risks.

**Nursing Women:** It is not known if cinacalcet is excreted into the breast milk. However, because infants are potentially at risk for clinically significant adverse effects from cinacalcet, it is recommended that nursing mothers carefully evaluate benefits versus risks.

**Renal Impairment:** No dosage adjustments are necessary for renal impairment.

**Hepatic Impairment:** Patients with moderate to severe hepatic impairment may exhibit AUC 2.4 to 4.2 times higher than in patients with normal hepatic function. Half-life can be prolonged by 33-70%. Therefore, moderate to severe hepatically impaired patients should have close monitoring of PTH and serum calcium concentrations while taking cinacalcet.

## Drug Interactions

Cinacalcet is primarily metabolized by CYP3A4. Serum levels of cinacalcet may show a two-fold increase if given with ketoconazole, a strong inhibitor of CYP3A4. Monitor levels of PTH and serum calcium if a patient initiates or discontinues any medication that is a strong CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, erythromycin).

Cinacalcet strongly inhibits the CYP2D6 enzyme. Adjust dosages of medications that are primarily metabolized by CYP2D6 or that have a narrow therapeutic index (e.g. flecainide, thioridazine, vinblastine, and most tricyclic antidepressants).

Cinacalcet is also inhibited by CYP1A2 and dosage adjustments should be made for drugs that also use this pathway.

## Common Adverse Effects

Three double-blind, placebo-controlled studies were done on patients with chronic kidney disease on dialysis that received either cinacalcet or placebo. The most common adverse effects of cinacalcet were nausea and vomiting, 31% and 27%, respectively. Other events like diarrhea, myalgia, dizziness, and hypertension were all similar to placebo. Hypocalcemia occurred in 66% of patients, indicating that serum calcium levels should be monitored closely.

## Pharmacology

**Mechanism of Action:** Patients with chronic kidney disease can have secondary hyperparathyroidism which causes increased levels of PTH. When PTH levels increase, osteoclasts are stimulated to resorb cortical bone and cause marrow fibrosis. PTH causes alterations in calcium and phosphorus metabolism which results in increased levels of each. Treatment for secondary hyperparathyroidism consists of lowering the levels of PTH, calcium, and phosphorus. PTH secretion is mainly regulated by a receptor on the parathyroid gland that senses calcium. By increasing the sensitivity of the calcium-sensing receptor to extracellular calcium, PTH secretion is inhibited.

**Absorption/Distribution:** Peak plasma concentrations (C<sub>max</sub>) are met within 2-6 hours after administration of oral cinacalcet. Concurrent high fat food intake can increase the C<sub>max</sub> by 82% and the area under the curve (AUC) by 68% when compared to fasting levels. Also compared to fasting levels, low fat meals increase C<sub>max</sub> and AUC by 65% and 50% respectively. Cinacalcet has a half life of 30-40 hours and a time to steady state of 7 days. Linear pharmacokinetics are seen in cinacalcet. The volume of distribution is extensive at about 1000L. Cinacalcet is also highly (93-97%) bound to plasma proteins.

**Metabolism/Excretion:** Cinacalcet is metabolized by CYP3A4, CYP2D6, and CYP1A2. Many

metabolites are generated as cinacalcet undergoes oxidative N-dealkylation to hydrocinnamic acid and hydroxy-hydrocinnamic acid. These metabolites are further broken down by  $\beta$ -oxidation and glycine conjugation. Naphthalene rings are formed during N-dealkylation. Oxidation of the naphthalene ring forms dihydrodiols which undergo glucuronic acid conjugation. These metabolite concentrations are much larger than the concentrations of the parent compound. Metabolites are excreted renally. Cinacalcet is excreted into the urine and feces as unchanged drug (80% and 15% respectively).

### Patient Information

1. Take cinacalcet with meals.
2. Do not divide tablets; take whole.
3. Side effects of cinacalcet include nausea and vomiting.
4. Tell your doctor if these become bothersome or if you experience any other side effects while taking cinacalcet. Tell your doctor if you take ketoconazole, itraconazole, erythromycin, flecainide, thioridazine, vinblastine, or tricyclic antidepressants.
5. Your doctor should monitor calcium levels within one week of cinacalcet initiation or with any dosage changes.
6. If you have liver impairment, your doctor may monitor hepatic function.

### References

1. Sensipar® (cinacalcet HCL) prescribing information. Amgen Inc. Thousand Oaks, CA. March 2004.
2. Block, G., et al. Cinacalcet for Secondary Hyperthyroidism in Patients Receiving Hemodialysis. *N Engl J Med* 2004 April 18;350:1516-1525.
3. O'Mara, NB., New Drug: Cinacalcet (Sensipar®). *Pharmacist's Letter*. 2004 April. Vol. 20.

## Elistat® (epinastine)

**Authors:** Kristy Bay, Pharm.D.

**Kristy Lucas, Pharm.D.**  
Clinical Professor  
Schools of Pharmacy and Medicine  
West Virginia University – Charleston

### Introduction

Elestat® [epinastine (eh PIH na steen) hydrochloride] 0.05% ophthalmic solution is a histamine-1 (H-1) receptor antagonist and inhibits the release

of histamine from mast cells. Epinastine is approved for the prevention of itching associated with allergic conjunctivitis. The FDA approved epinastine ophthalmic solution on October 17, 2003.

### Therapeutic Recommendation

**There are several ophthalmic solutions for seasonal allergic conjunctivitis available on the market. Epinastine exhibits dual mechanisms of action: H-1 receptor antagonism and mast cell stabilization. Other available ophthalmic solutions that exhibit both mechanisms include Optivar® (azelastine hydrochloride), Zaditor® (ketotifen fumarate), and Patanol® (olopatadine hydrochloride). To decrease confusion among the many available ophthalmic antihistamine products, some antagonize H-1 receptors, but do not affect mast cell stabilization. These products include Emadine® (emedastine difumarate) and Livostin® (levocabastine hydrochloride).**

**Epinastine has only been compared to placebo and levocabastine in clinical trials. Epinastine was more effective than placebo and demonstrated similar efficacy to levocabastine in the treatment of ocular itching. Tolerability of this drug is similar to that of the placebo. Epinastine ophthalmic solution is considered similar to comparator products in this class. Until studies further distinguish epinastine's role, pricing and patient preference may be used as a basis for prescribing decisions.**

### Dosing and Administration

Epinastine 0.05% ophthalmic solution is available in 5 mL bottles. The recommended daily dosage is one (1) drop instilled into each eye twice daily for the treatment of itching associated with allergic conjunctivitis. Treatment with epinastine should be continued throughout exposure to the allergen (i.e. throughout the duration of pollen season). It should be used on a scheduled basis rather than only when symptoms are present.

### Warnings/Precautions

Remove contact lenses before use. They may be reinserted 10 minutes after use.

Do not take this medication by mouth. It must be instilled into the eye.

## Cost Comparison

Medication/Dose	Cost		
	<u>Kroger</u>	<u>Rite Aid</u>	<u>Wal-Mart</u>
Elestat® (epinastine) 5 mL bottle	87.09	87.99	76.32
Zaditor® (ketotifen) 5 mL bottle	74.69	75.99	64.72
Patanol® (olopatadine) 5 mL bottle	92.89	82.99	79.62
Optivar® (azelastine) 6 mL bottle	84.89	80.99	72.84
Emadine® (emedastine) 5 mL bottle	79.29	76.99	63.32
Livostin® (levocabastine) 5mL bottle	75.89	66.99	56.46

Prices given are for an estimated 25 day supply

## Contraindications

Patients with a hypersensitivity to epinastine hydrochloride or to any of the inactive ingredients contained within the product.

## Special Populations

**Pediatric:** Epinastine is not recommended for infants and children younger than 3 years of age.

**Geriatric:** No differences in safety or effectiveness have been seen in the elderly as compared to younger patients.

**Pregnancy:** Epinastine has been classified as Pregnancy Category C. In this category, no adequate and well-controlled studies involving epinastine have been conducted in pregnant women; however, studies involving animal reproduction have demonstrated adverse effects in the fetus. Epinastine should only be used if the benefits outweigh the risks to the mother and fetus.

**Nursing Women:** It is not known if epinastine is excreted into breast milk. In a study involving lactating rats, excretion of epinastine was seen in the milk. Although epinastine is only slightly absorbed systemically, patients should yield caution.

**Renal impairment:** No dosage adjustments are needed in patients with renal impairment.

**Hepatic Impairment:** No dosage adjustments are needed in patients with hepatic impairment.

## Drug Interactions

No drug interactions have been identified with epi-

nastine ophthalmic solution.

## Common Adverse Effects

Epinastine is generally well tolerated. Mild ocular and non-ocular side effects may occur. The most common treatment related adverse effect of epinastine was a stinging sensation.

The following ocular side effects occurred in 1-10% of patients: hyperemia, folliculosis, pruritis and irritation. Other adverse reactions seen include cough, headache, rhinitis, sinusitis, and pharyngitis. These occurred in 1-3% of patients. In about 10% of patients, infection (cold symptoms and upper respiratory infections) were seen. It is important to note that some of these events may have been due to the underlying disease being treated.

## Pharmacology

**Mechanism of Action:** Epinastine directly antagonizes H-1 receptors, blocking histamine from reaching the receptors in the eye. Epinastine also inhibits the release of histamine from the mast cell. Epinastine is selective for H-1 receptors, but it also shows affinity for H-2, alpha-1, alpha-2, and 5-HT<sub>2</sub> receptors.

**Absorption/Distribution:** Epinastine has low systemic absorption and does not cross the blood brain barrier. The onset of action of epinastine is 3-5 minutes, and the duration is 8 hours or greater. Epinastine is 64% bound to plasma proteins.

**Metabolism/Elimination:** Less than 10% of epinastine is metabolized. The elimination half-life is 12 hours. When administered IV, 55% of epinastine is excreted in urine and 30% in the feces.

## Patient Information

1. To instill a drop, tilt head back slightly. Pull the lower eyelid down with the index finger and thumb forming a sac. Squeeze the drop(s) into the sac. Close eyes and wait 1-2 minutes. Do not blink.
2. Wash hands before and after administration.
3. Remove contact lenses before applying drops. Wait 10 minutes before re-inserting contact lenses.
4. Avoid touching the end of the dropper to the eye, your finger, or any other object.

5. Use this medication only in your eyes; do not take it by mouth.
6. Do not use this product more often than is prescribed.
7. Use this medication throughout the duration of exposure to the allergen (i.e. pollen season) even if you have no symptoms.
8. When the allergen is present, use this medication on a regular basis, not just when you experience symptoms.
9. Inform your physician if you are pregnant or plan to become pregnant.
10. Store the medication at room temperature, away from heat and light. Keep tightly closed.

#### References

1. Elestat™ (epinastine hydrochloride) prescribing information. Allergan, Inc., Irvine, CA. 2003.
2. *The Medical Letter*. 26 April 2004; 46(1181):33-36.
3. Whitcup SM, et al. Efficacy and tolerability of ophthalmic epinastine: a randomized, double-masked, parallel-group, active and vehicle-controlled environmental trial in patients with seasonal allergic conjunctivitis. *Clinical Therapeutics*. 2004;26:29-34.

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Page 6



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