Team Approach to Glaucoma Patient Support

- Ophthalmic professionals can provide communication and education
- Learn about a fixed-combination medication

This supplement is sponsored by Alcon
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This supplement includes highlights from an educational program, sponsored by Alcon, in New York City. Additional educational events took place in Houston, TX and Orange County, CA. The highlights in this supplement focus on patient support as a staff member as well as compliance and treatment.

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Speakers were compensated by Alcon for their time
Robert D. Fechtner, MD: Among the many types of patients for whom ophthalmology practices provide care, glaucoma patients are unique. Because treatment may be lifelong, its quality and effectiveness depends heavily on relationship building and the ongoing level of trust that extends between them and the practice. This relationship and trust can’t be built solely by the doctor. You — the highly skilled, knowledgeable technicians and other ophthalmic professionals on staff — are the crucial “front line.” You’re the ambassadors, and there tends to be less of a barrier between you and the patients than between the doctor and the patients. From your vantage point, you can be the eyes and ears of the doctor, helping him perform his job more effectively. In particular, with glaucoma, you may be the people who actually influence patients to do what they can to preserve their vision. The more you know about available treatment options, the more you can assist the doctor by motivating glaucoma patients to participate in their care and follow treatment recommendations.

Janet Hunter, COMT, BS: As Dr. Fechtner alluded to, a major challenge in the care of glaucoma patients is the widespread lack of adherence to prescribed IOP-lowering treatments. In our roles as ophthalmic professionals, we’re reminded of this challenge just about every day. Exchanges like this one during a 3-month follow-up visit are all too common:

You: Have you been taking the medications Dr. Smith prescribed for your glaucoma?
Patient: Oh, I ran out.
You: When did you run out?
Patient: A month ago.

Even to those of us on the front lines who see this playing out firsthand, the actual published numbers on adherence can be surprising. Nearly 50% of patients taking IOP-lowering therapy stop taking their medication within 6 months of starting therapy.1 Up to 25% of glaucoma patients don’t renew their prescriptions after the initial dispensing.2 Only 10% of patients for whom a doctor has prescribed IOP-lowering drops are persistent with therapy without gaps over the following year.3 Clearly, there is a lack of understanding among patients about the importance of using the IOP-lowering medications that have been prescribed for them. Research also suggests a general lack of awareness and understanding of glaucoma and the consequences of not having it diagnosed and treated. For example, 47% of Americans incorrectly believe...
that glaucoma is preventable, and 50% of Americans have heard of glaucoma but aren’t sure what it is. Consequently, few are aware that they could lose as much as 40% of their vision without experiencing any symptoms at all.

The gap between what patients don’t know and what they should know about glaucoma is one that needs to be closed. We know that’s easier said than done, but we can make meaningful progress through patient engagement.

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— Janet Hunter, COMT, BS

**What is Patient Engagement?**

Patient engagement is the path to providing the highest quality of care. It means we’re working to ensure patients understand their disease and the importance of treatment, so they’ll be actively involved in achieving the best possible outcomes. Engaged patients are more likely to follow the doctor’s treatment recommendations because they understand what he is telling them about their illness. The Glaucoma Adherence and Persistency Study (GAPS) found a direct correlation between future adherence and the quality of the doctor-patient interaction at the time of initial diagnosis. In their published paper, the investigators said, “Doctor-patient communications and health-related beliefs of patients contribute to patient adherence … specifically, knowledge about potential vision loss from glaucoma is a critical element that tends to be missed.” In other words, the information that doctors provide to patients can enhance adherence, and the fact that untreated glaucoma can lead to vision loss is a crucial piece of information that’s not often conveyed.

We can take the knowledge derived from GAPS a step further. The communication and interaction that takes place between technicians, staff and patients can also improve adherence. There’s no reason we shouldn’t be taking a couple of minutes with glaucoma patients to explain the disease and the consequences of non-compliance. We are uniquely positioned to educate patients and serve as the liaison between them and the doctor. Typically, we spend more time with each patient than the doctor. Also, patients are more likely to tell us things that they would be too intimidated or nervous to tell the doctor. By communicating to the doctor what patients are telling us, we strengthen their relationship with the doctor, ourselves and the practice overall. This ultimately will have an impact on their visual outcomes.

**Effective Communication Strategies**

To better communicate with glaucoma patients about the importance of taking their medications as directed, we first need to understand what causes non-compliance. According to the GAPS study, there are several reasons why patients may not adhere to their prescribed medication therapy:

- **Cost.** Drops can be expensive.
- **Tolerability.** We need to ask patients about tolerability as a matter of routine. Do the drops sting when they put them in? We need to talk to them about it in layman’s terms. For example, rather than asking about dysguesia, we should ask if they get a bad taste in their mouth when they put in their drops.
- **Dosing schedules.** As you know, many patients are prescribed numerous IOP-lowering drops. Some of them should be used once a day, some twice a day, and some are needed three times a day. If they’ve had cataract surgery, they’re asked to use additional drops, perhaps four times a day. And if they’re scheduled for a laser treatment, we want them to add even more drops. It’s confusing for them to keep track, and multiple questions may arise. Do I use them all together? Can I use one right after the other? How much time do I have to wait in between using the drops?
- **Denial of the disease itself.** Often, patients think that because they’re eyes feel fine, glaucoma isn’t something to worry about.
- **Lack of education about glaucoma.** Patients often don’t realize or understand why glaucoma is a serious threat to their vision. Typically, unless patients have angle closure glaucoma, they have no
symptoms. Without education, they may not have sufficient motivation to adhere to the prescribed therapy.

- **Forgetfulness.** Sometimes patients, particularly the elderly, may not remember to use their drops on a daily basis.

- **Travel.** Anyone who wears contact lenses can understand how traveling poses problems with medications. How many of us have arrived at our destination and unpacked our bags to discover we forgot our lens case or our disinfecting solution or saline? It’s the same thing with patients who are on numerous medications. They may remember their blood pressure pills. They may remember their diabetes medications. Sometimes they just don’t think of their eye drops the same way they think of their other medications, so they forget and leave home without them.

- **Personal schedules.** We can all identify with this. Everyone is busy. It can be difficult to know where to fit eye drops into a schedule.

Once we’re aware of the reasons patients might not be using their IOP-lowering medications correctly, we can leverage that knowledge to help us engage them with more effective communication. The American Medical Association has published a manual for clinicians called Help Patients Understand, which suggests the following six strategies for improving interpersonal communications with our patients.

- **Speak slowly and spend a little extra time with each patient.** I know what most of us think when we hear that statement. We’re seeing 80 patients a day. Twenty are in the waiting room, upset that their appointment was 45 minutes ago and we called someone else ahead of them. You want me to spend extra time with patients, speaking slowly? Yes, that is exactly what I’m saying. It is definitely possible. It’s not that we need to spend 20 minutes with each patient. Four or 5 minutes is enough to provide them with the “meat and potatoes” education regarding their illness, its consequences, and the potential outcome if they don’t adhere to the prescribed medication regimen.

- **Use plain, non-medical, language.** As I...

**Using the Sink Analogy Helps Patients Better Understand Primary Open-angle Glaucoma**

![FIGURE 1](OPS FINAL.indd)</a>

Each class of medication has a different mechanism of action, which either affects:

1. The flow of fluid from “the faucet”
2. The release of fluid through “the drain”
3. A combination of both

**FIGURE 1.** Ophthalmic professionals should use visuals such as pictures to help patients understand and recall what they’ve learned about glaucoma. The analogy of the sink is a useful aid. Like in the eye, the amount of fluid entering the sink shouldn’t exceed the amount draining out of the sink or problems will occur.
mentioned previously, we should avoid using medical jargon such as “dysgeusia” that can confuse patients. In addition, we can use analogies to help our patients understand glaucoma. The analogy of the sink can be particularly effective (Figure 1). The main part of the sink is the basin. Water comes out of the faucet, filling the basin. As water comes in, it also goes out, through the drain. The same process occurs in the eye. The ciliary body (faucet) secretes aqueous, and the aqueous goes into the anterior chamber (the sink) and then out through the trabecular meshwork (drain). As in a properly functioning sink, in a normal eye, the amount of aqueous coming in shouldn’t exceed the amount of aqueous going out or problems will occur. In an eye with primary open angle glaucoma, the trabecular meshwork, “the drain”, may not be working properly. It’s partially clogged. Aqueous is leaving the eye, but not as much as should be. For the sink, the unfavorable result of such an imbalance is an overflow. The eye, however, is a contained compartment, a closed system, so it doesn’t have that luxury. The result for the eye is an increase in internal pressure, which may eventually affect the optic nerve and damage vision. Primary open angle glaucoma can also be caused by a problem with the faucet, when too much fluid enters the eye even though the drain is working properly. The doctor can prescribe a pressure-lowering eye drop that affects the flow from the faucet, works on the clogged drain, or both.

For patients, we should make the analogy simple but effective. We don’t even need to mention the ciliary body or the trabecular meshwork by name. Even speaking slowly, we can tell the story in a minute or perhaps even less.

► **Show or draw pictures.** Visual images can improve patients’ recall of information. We can use some of the many patient education pamphlets that are available to us for this purpose. I’m sure most offices also have a model eye, which can also be used as a visual aid.

► **Limit the amount of information provided — but repeat it.** It isn’t necessary for us to give a long dissertation on all aspects of glaucoma for patients to come away with a good understanding of their illness. It’s better to limit the amount of information but say it more than once. This is especially true upon initial diagnosis. At that point, patients may be somewhat shocked because a disease diagnosis isn’t something they were expecting. They likely will only be able to absorb a fraction of what we tell them at first, and we should take every opportunity to reinforce and repeat that information.

► **Use the “teach-back” technique.** This is a way of confirming with our patients that they understand what we’re telling them by asking them to repeat the information back to us in their own words. It is a chance to repeat the information and say,

“Okay, Mrs. Jones, we’ve just covered quite a bit of information. I’d like to help you get a good handle on it by telling me in your own words what we talked about, what is happening with your eye and how we can treat it.”

► **Create a shame-free environment and encourage questions.** It’s important to carry out the teach-back technique, and all of our communication with patients, in a shame-free manner. It promotes a healthy dialogue. What we say is important, but so is how we say it. We
also want to show attentiveness and concern in the way
we listen to patients, even if we have 10 other things on
our minds. On a busy day, it’s not unusual for colleagues
to knock on the door and interrupt our patient time.
One or two knocks perhaps are unavoidable, but more
than that is unacceptable. I usually put a sticky note on
the door that says “Do Not Knock.” It sends the message
to patients that I’m there for them. They appreciate that
I care, and not just me but the whole staff. When
patients feel that their healthcare provider is concerned
about their well being, and is invested in their health,
they’re more willing to be invested in their health and
adhere to the prescribed therapy.

Along with being attentive, we want to encourage
patients to ask questions. As was mentioned previously,
patients will often ask us a question they won’t ask the
doctor. It’s crucial they don’t feel as if we’re judging
them no matter what they ask. They should understand
that we are there to help them and want them to ask
questions.

**Time Well-invested**

To summarize, how well patients fare when it comes
to taking ownership of their condition depends on
them, but also on us. As ophthalmic professionals
working in conjunction with doctors, we can help to
improve patient outcomes by helping to convey a
clear treatment plan and the necessary steps for
following that plan. We want to create a positive
patient experience by offering patient-centered
examinations. This means engaging patients in their
own health and healthcare outcomes. We can engage
them using the techniques explained here, such as
speaking slowly, avoiding complicated medical termin-
ology, using visual aids, providing relevant informa-
tion in small portions and repeating the information
several times if needed. We can use the teach-back
method, which helps patients better understand
glaucoma and its treatments and indicates to us that
they do. This needs to be done in a shame-free
environment, so patients will be comfortable
asking questions.

The more you know
about available treatment
options, the more you can
assist the doctor by motivat-
ing glaucoma patients to
participate in their care and
follow treatment
recommendations.”

— Robert D. Fechtner, MD

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Robert D. Fechtner, MD: It seems to me that a different dynamic exists between patients and staff members than between patients and the doctor. Do you agree?

Janet Hunter, COMT, BS: Absolutely. On most days in most practices, the technicians and other staff members are spending more time with each patient than the doctor. That opens the door to a little more familiarity. Also, many patients are intimidated by their doctor. The allied health professionals, on the other hand, are more like the everyday guy, so to speak. So, patients are more likely to open up to us. That’s why it’s really important for us to communicate with patients and work to uncover any medication-related or treatment-regimen issues they may be experiencing and then convey that information to the doctor. We can work in conjunction with the doctor as a unified team by letting him know what a patient is telling us, but may be nervous about telling the doctor.

Dr. Fechtner: In my experience, a good chance for patients to talk about their eye drops is with the technician, not just with the doctor. What are some of the good questions or prompts staff members can use to find out how patients are really doing with their medications, whether they are facing obstacles, and so on.

Ms. Hunter: The key is to ask open-ended questions and avoid questions that can be answered with a simple yes or no. The open-ended questions show that we really want to know if they’re having a problem, which makes them more likely to provide a useful answer. For example, “I know you’re using drops now three times a day. Are you having any problems with getting all of the doses in?” We could be even more specific and ask when they’re taking their drops and point out that associating each dose with a daily task can be a good reminder mechanism. They could use their drops right after they brush their teeth in the morning, right after they eat lunch, and right after they brush their teeth at bedtime.

Open-ended questions usually begin with how or what. For example, “How are you feeling about the drops you’re taking?” This type of query encourages dialogue, in essence inviting patients to open up and giving them permission to tell us what’s on their minds. “During your last visit you talked with the doctor about glaucoma. What information about high eye pressure would you like to know more about?” “Do you have any questions about..."
your eye drops?” The point is to engage patients and determine what they’re thinking about so you can provide whatever information they’re lacking.

Questions to avoid include “Are you taking your medicine? Do you understand? Do you have any questions?” Such questions typically elicit only a yes or no response. Furthermore, they may be misconstrued as confrontational or judgmental.

**Dr. Fechtner:** What is the best way to find out if patients are using their drops correctly without offending them? I’ve seen videos online of patients struggling to get the drops into their eyes. It made me realize that the minute or two staff members are asked to spend with each patient would be well spent going over that.

**Ms. Hunter:** Not being able to get the drops into their eyes is a common reason patients stop adhering to their treatment regimens. This challenge can be used as an opening to show compassion and discuss the issue. “I know how difficult getting drops into the eye can be. Are you having any trouble with that? Do you find that you’re missing your eye? When the drops do go in, do they irritate your eye?” Those types of questions help patients to feel as if we’re seeing things from their point of view, not judging them, and we understand there are reasons they may have stopped using their drops. Most patients don’t become noncompliant for no reason. They stop using their medications for a reason that is significant to them. We have talked today about some of the reasons patients don’t adhere to the treatments recommended for them. We can speak to them about those issues, so they understand it’s not just them having problems. This should prompt them to be a little more open about what they are and are not doing with their drops.

A website that Alcon has created, myglaucomasupport.com, includes a tutorial on using eye drops. We can make the patients aware of the site, which has many other resources for them as well.

**Dr. Fechtner:** What can the doctor do to help?

**Ms. Hunter:** It’s helpful when the doctor encourages the technicians to be proactive and think about what he might need. Sometimes, based on my workup of the patient, I could predict if there was a certain medication the doctor would likely prescribe. I would put that prescription inside the chart, ready for the doctor to sign.

I also used to do a little exercise with the techs I was supervising. We would say, Okay, let’s try to think like the doctor. Whoever was in the room with the doctor would have in his or her pocket the medications they thought the doctor would need. If the doctor told the patient he wanted to write a prescription for Eye Drop X, it would already be there. If the doctor said I want to write a prescription for Eye Drop Y instead, the tech could pull it right out of the pocket as well. Fostering that type of thinking helps to promote the sense that we’re all working as a team. It’s important for techs to know their contribution to the practice is important.

**Dr. Fechtner:** Yes, the message I would give is that technicians can be my eyes and ears. They should call my attention to the things they notice, the things they pick up during their time with the patient. That information, which I may not pick up, are uniquely valuable.
Robert D. Fechtner, MD: As I stated earlier, you may be best suited to influence patients to do what they can to manage their condition. The more you know about available treatment options, the more you can assist the doctor by motivating glaucoma patients to participate in their care and follow treatment recommendations.

With that in mind, let’s take a look at a topical medication option that we have for the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension: SIMBRINZA® Suspension.

Fixed-dose Combination Drop for Lowering IOP
SIMBRINZA® Suspension is a fixed combination of the carbonic anhydrase inhibitor brinzolamide (1.0%) and the alpha2 adrenergic receptor agonist brimonidine tartrate (0.2%). Combining brinzolamide ophthalmic suspension 1% and brimonidine tartrate ophthalmic solution 0.2% in one bottle as SIMBRINZA® Suspension creates a treatment option that has been shown in clinical trials to have powerful efficacy.

SIMBRINZA® Suspension is approved for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension. The recommended dose is the same as the recommended dose for its components, which is three times per day. Because it is a suspension, it’s important that patients are instructed to shake the bottle before each use. If they’re using more than one topical ophthalmic medication, they should administer them at least 5 minutes apart. In addition, they shouldn’t put any of the eye drops on top of their contact lenses. They should remove the lenses, put the drops in and wait 15 minutes before reinserting their contact lenses.

Who Can We Treat With SIMBRINZA® Suspension?
Based on the results of the clinical trials, SIMBRINZA® Suspension demonstrated 1-3 mmHg additional IOP lowering versus individual components. Further, these clinical trial data showed 21-35% IOP lowering efficacy from baseline. Since it contains two medicines in one bottle, it may be used to streamline the therapeutic regimen.

For example, SIMBRINZA® Suspension is a treatment possibility in the following types of cases:

A patient who is on an IOP-lowering medication drop as monotherapy, but needs additional treatment possibilities.
**IOP reduction.** This is a common scenario in many practices. Based on their efficacy and once-daily dosing, prostaglandin analogs (PGAs) tend to be prescribed as initial treatment for elevated IOP. In cases where a patient needs additional IOP lowering, my next step might be to add brinzolamide. With further IOP reduction and tighter disease control as our goal, we could prescribe SIMBRINZA® Suspension in place of brinzolamide (Case 1, below). We’re adding a third medication without increasing the number of bottles or drops.

**A patient who is on both individual components of SIMBRINZA® Suspension (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2%.** When I have patients on a three-bottle treatment regimen, I examine the details of their case to determine if they are candidates for a fixed-combination drop. For someone already taking the components of SIMBRINZA® Suspension separately, prescribing SIMBRINZA® Suspension may be an opportunity to replace the two individual bottles, which may possibly eliminate a copay (Case 2, page 12).

**A patient in need of primary therapy.**

When you are working up and interacting with patients who are in any of the above situations, it is a great time to flag the chart or circle the relevant items on their medication lists.

That brings us to what is often, unfortunately, the missing link in the care of glaucoma patients. The administered topically, is absorbed systemically. Sulfonamide attributable adverse reactions may occur. Fatalities have occurred due to severe reactions to sulfonamides. Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

**Corneal Endothelium—**There is an increased potential for developing corneal edema in patients with low endothelial cell counts.

**Severe Hepatic or Renal Impairment (CrCl <30 mL/min)—** SIMBRINZA® Suspension has not been specifically studied in these patients and is not recommended.

**Acute Angle-Closure Glaucoma—** The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. SIMBRINZA® Suspension has not been studied in patients with acute angle-closure glaucoma.

**Contact Lens Wear**—The preservative in SIMBRINZA® Suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA® Suspension but may be reinserted 15 minutes after instillation.

See additional information continued on the following pages.
Severe Cardiovascular Disease

Brimonidine tartrate, a component of SIMBRINZA® Suspension, had a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies; caution should be exercised in treating patients with severe cardiovascular disease.

Potentiation of Vascular Insufficiency—Brimonidine tartrate, a component of SIMBRINZA® Suspension, may potentiate syndromes associated with vascular insufficiency. It should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud’s phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

Contamination of Topical Ophthalmic Products After Use—There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers have been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

Adverse Reactions SIMBRINZA® Suspension

In two clinical trials of 3 months’ duration with SIMBRINZA® Suspension, the most frequent reactions associated with its use occurring in approximately 3-5% of patients in descending order of

Tools to Assist Your Patients

Patient education begins in our offices, but it can be reinforced at home. We live in an age dominated by technology and information is everywhere. Alcon has created a very useful set of tools for glaucoma patients and their families (myglaucomasupport.com). Through this website, patients can enroll in the OPENINGS® Patient Support Program. This comprehensive patient support program consists of robust disease education, dosing and refill reminders, as well as potential cost savings for eligible patients. The OPENINGS® Program savings card provides costs savings on SIMBRINZA® Suspension (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2%.

The website also offers patient tools, such as an IOP tracker. Patients can use the tracker for recording their pressure each time it’s measured. Having the information all in one place allows them to observe their results over time, including in relation to their target IOP. Patients can also take advantage of a reminder service that notifies them by email or text message when it’s time to refill prescriptions. In addition, they can follow a step-by-step explanation, displayed in words and pictures, of how to administer eye drops.

Going forward, let’s make sure our glaucoma patients are aware of resources such as myglaucomasupport.com and position ourselves and our practices as their number one resource. It is essential that we partner in the effort to better understand and manage their disease.

Case 2. Potential candidate for PGA and Individual Components of SIMBRINZA® Suspension (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2%

Patient Profile

- 78-year-old male
- History of hypertension and non insulin dependent diabetes
- Currently prescribed PGA, brimonidine 0.1% and brinzolamide 1%
- Prefers fewer bottles

Objective Parameters

- Baseline IOP
  - 28 mm Hg OD
  - 25 mm Hg OS
- IOP on PGA alone
  - 24 mm Hg OD
  - 23 mm Hg OS
- VA 20/25 OU

C/D ratio 0.4 OU

Visual fields with slightly enlarged blind spot OD

Current IOP:
  - 19 mm Hg OD
  - 18 mm Hg OS

PATIENTS using a prostaglandin drop along with brinzolamide and brimonidine in separate bottles should be considered for reducing the number of bottles by using SIMBRINZA® Suspension instead of brinzolamide and brimonidine individually.
Efficacy and Safety

SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% was tested in two large, clinical studies1-3 that enrolled 660 and 690 subjects. The objective of the SIMBRINZA® Suspension studies was to compare the IOP-lowering efficacy of SIMBRINZA® Suspension to each of its individual components. The primary endpoint was the mean IOP at the 3-month visit at each of four time points (8 a.m., 10 a.m., 3 p.m. and 5 p.m.).

The results showed that the pressure-lowering power of SIMBRINZA® Suspension, at both its highest and its lowest, was very effective. Its effect at month 3 was 1 to 3 mmHg greater at each time point than either of its individual components (Figure 1).

In addition, SIMBRINZA® Suspension provided a mean IOP lowering of 21% to 35% from baseline (Figure 2). Even at 8 a.m., 10 hours after the previous dose, pressure was lowered by an average ranging from 24.5% to 26.6%.

Efficacy alone is not enough. It is also important to consider a product’s safety profile. One concern incidence included: blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Adverse reaction rates with SIMBRINZA® Suspension were comparable to those of the individual components. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA® Suspension patients.

Brinzolamide 1%
In clinical studies of brinzolamide ophthalmic suspension 1%, the most frequently reported adverse events reported in 5-10% of patients were blurred vision and bitter, sour, or unusual taste. Adverse events occurring in 1-5% of patients were blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus, and rhinitis.

Brimonidine Tartrate 0.2%
In clinical studies of brimonidine tartrate 0.2%, adverse events occurring in approximately 10-30% of the subjects, in descending order of incidence, included oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

Events occurring in approximately 3-9% of the

See additional information continued on the following pages.
that arises when new formulations are developed is whether something unexpected might emerge related to a chemical interaction or an interaction on the eye. SIMBRINZA® Suspension (brinzolamide/brimonidine tartrate ophthalmic suspension 1%/0.2%) passed that test as well. Based on the results of the clinical trials, the new combination formulation, no additional risks were identified with SIMBRINZA® Suspension versus those observed with the individual components.1-3

Drug Interactions—Consider the following when prescribing SIMBRINZA® Suspension:
Concomitant administration with oral carbonic anhydase inhibitors is not recommended due to the potential additive effect. Use with high-dose salicylate may result in acid-base and electrolyte alterations. Use with CNS depressants may result in an additive or potentiating effect. Use with antihypertensives/cardiac glycosides may result in additive or potentiating effect on lowering blood pressure. Use with tricyclic antidepressants may blunt the hypotensive effect of systemic clonidine and it is unknown if use with this class of drugs interferes with IOP lowering. Use with monoamine oxidase inhibitors may result in increased hypotension.

For additional information about SIMBRINZA® Suspension, please see the brief summary on the following page.

References
2. SIMBRINZA® Suspension Package Insert.
CONTRAINDICATIONS

Brimonidine tartrate.

DOSAGE FORMS AND STRENGTHS

If more than one topical ophthalmic drug is being used, the drugs should be administered with at least five (5) minutes apart.

DOSE FORMS AND STRENGTHS

Suspension containing 10 mg/ml, brinzolamide and 2 mg/ml. Brimonidine tartrate.

INFORMATION

CONTRAINDICATIONS

- Hyperчувствительность - SIMBRINZA® Suspension is contraindicated in patients who are hypersensitive to any component of this product.

- Neonates and Infants (under the age of 2 years) - SIMBRINZA® Suspension is contraindicated in neonates and infants (under the age of 2 years).

WARNINGS AND PRECAUTIONS

Sulfonamide Hypersensitivity Reactions - SIMBRINZA® Suspension contains brinzolamide, a sulfonamide, although administered topically is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of SIMBRINZA® Suspension. Fatalities have occurred due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute renal failure, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitization may recur when a sulfonamide is re-administered improperly. Therefore, if adverse reactions or hypersensitivity occur, discontinue the use of this preparation (see Patient Counseling Information).

- General Edema - Cardiac edema has been reported in both the cytophase and around the plasma membranes of the cardiac endothelial. There is an increased cardiac output. In patients with this condition, benzathine could be added to the frequency of blood counts. Caution should be used when prescribing SIMBRINZA® Suspension to this group of patients.

- Severe Renal Impairment - SIMBRINZA® Suspension has not been specifically studied in patients with severe renal impairment (CrCl < 30 mL/min). Since brinzolamide and its metabolite are excreted predominantly by the kidney, SIMBRINZA® Suspension is not recommended in such patients.

- Acute Angle-Closure Glaucoma - The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. SIMBRINZA® Suspension has not been studied in patients with acute angle-closure glaucoma.

- Contact Lens Wear - The preservative in SIMBRINZA® Suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA® Suspension but may be reinserted 15 minutes after instillation (see Patient Counseling Information).

- Cardiovascular Disease - Brimonidine tartrate, a component of SIMBRINZA® Suspension, has a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies. Caution should be exercised in patients with hemodynamic characteristics who have cardiovascular disease.

- Severe Hepatic Impairment - Because brimonidine tartrate, a component of SIMBRINZA® Suspension, has not been studied in patients with hepatic impairment, brimonidine should be exercised in such patients.

- Potentially Useful Ineffectiveness - Brimonidine tartrate, a component of SIMBRINZA® Suspension, has not been studied in patients with hepatic impairment, brimonidine should be exercised in such patients.

- Overdosage - Contamination of Topical Ophthalmic Products After Use - There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These con- tainers have been inadvertently contaminated by patients who, in most cases, had a concurrent conital disease or a disruption of the ocular epithelial surface (see Patient Counseling Information).

- Adverse Reactions

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

- Brinzolamide 1% - In clinical studies of brinzolamide ophthalmic suspension 1%, the most frequently reported adverse reactions reported in 5 to 10% of patients were the following: headache, somnolence, nasal congestion, conjunctivitis, rhinitis, edema, keratoconjunctivitis, nasopharyngitis, and sinusitis.

- Brimonidine tartrate - Adverse reactions that have been reported with SIMBRINZA® Suspension were comparable to adverse reactions reported with the individual components. The most frequently reported adverse reactions reported in 5 to 10% of patients were ophthalmic pain, ocular irritation, conjunctivitis, pupillary dilation, papilledema, cataract, keratitis, corneal edema, dry eye, and ocular discomfort.

- Horse treatment - The management of patients with elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

- INDICATIONS AND USAGE

- BRIEF SUMMARY OF PRESCRIBING INFORMATION

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- INDICATIONS AND USAGE
ADD SIMBRINZA® Suspension to a PGA for Even Lower IOP1*  

INDICATIONS AND USAGE
SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination indicated in the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration
The recommended dose is one drop of SIMBRINZA® Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA® Suspension may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

IMPORTANT SAFETY INFORMATION
Contraindications
SIMBRINZA® Suspension is contraindicated in patients who are hypersensitive to any component of this product and neonates and infants under the age of 2 years.

Warnings and Precautions
Sulfonamide Hypersensitivity Reactions—Brinzolamide is a sulfonamide, and although administered topically, is absorbed systemically. Sulfonamide attributable adverse reactions may occur. Fatalities have occurred due to severe reactions to sulfonamides. Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

Corneal Endothelium—There is an increased potential for developing corneal edema in patients with low endothelial cell counts.

Severe Hepatic or Renal Impairment (CrCl <30 mL/min)—SIMBRINZA® Suspension has not been specifically studied in these patients and is not recommended.

Contact Lens Wear—The preservative in SIMBRINZA® Suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA® Suspension but may be reinserted 15 minutes after instillation.

Severe Cardiovascular Disease—Brimonidine tartrate, a component of SIMBRINZA® Suspension, had a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies; caution should be exercised in treating patients with severe cardiovascular disease.

Adverse Reactions
SIMBRINZA® Suspension
In two clinical trials of 3 months’ duration with SIMBRINZA® Suspension, the most frequent reactions associated with its use occurring in approximately 3-5% of patients in descending order of incidence included blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Adverse reaction rates with SIMBRINZA® Suspension were comparable to those of the individual components. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA® Suspension patients.

Prescribe SIMBRINZA® Suspension as adjunctive therapy to a PGA for appropriate patients
SIMBRINZA® Suspension should be taken at least five (5) minutes apart from other topical ophthalmic drugs

Learn more at myalcon.com/simbrinza

For additional information about SIMBRINZA® Suspension, please see Brief Summary of full Prescribing Information on adjacent page.