Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
The medicine is dispensed with a doctor's prescription only

Bromsite
0.075%
Eye drops

Active ingredient and quantity: Each gram contains 0.75 mg bromfenac (as sodium sesquihydrate)

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Bromsite is intended for the treatment of postoperative inflammation and prevention of ocular pain in adult patients undergoing cataract surgery.

Therapeutic group:
Nonsteroidal anti-inflammatory drug (NSAID)

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to bromfenac or any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Use of topical nonsteroidal anti-inflammatory drugs more than 24 hours prior to surgery or use beyond 14 days postsurgery may increase patient risk for the occurrence and severity of corneal adverse events.

Do not use Bromsite while wearing contact lenses. See section 2 under 'Important information about some of this medicine's ingredients'.

Before using Bromsite, tell your doctor if:

- You have a bleeding tendency
- You suffer from:
  - Diabetes,
  - Ocular surface diseases (e.g., dry eye syndrome),
  - Rheumatoid arthritis,
  - Repeat ocular surgeries within a short period of time.

If you suffer from one of the above conditions, you may be at increased risk for corneal adverse events which may become sight threatening. Use topical nonsteroidal anti-inflammatory drugs with caution.

Children and adolescents
The safety and efficacy of the medicine in children below the age of 18 is unknown.

The elderly
There is no evidence that the efficacy or safety profiles for Bromsite differ in patients 65 years of age or older compared to younger adult patients.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Topical steroids; may slow or delay healing. All topical nonsteroidal anti-inflammatory drugs (NSAIDs), including Bromsite, may also slow or delay healing. Therefore, concomitant use of topical nonsteroidal anti-inflammatory drugs with topical steroids may increase the potential for healing problems.
- Topical ophthalmic nonsteroidal anti-inflammatory drugs (NSAIDs); may cause increased bleeding of ocular tissues during ocular surgery.
- There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other topical nonsteroidal anti-inflammatory drugs (NSAIDs), including Bromsite. Therefore, caution should be used when treating individuals who have previously exhibited sensitivity to these drugs.

Pregnancy and breastfeeding
Consult your doctor or pharmacist if you are pregnant, planning to become pregnant or breastfeeding.
Pregnancy
Do not use this medicine if you are pregnant, unless you have been told otherwise by your doctor. Use during late pregnancy should be particularly avoided, as the medicine may affect the fetal cardiovascular system. Your doctor will consider the benefits and risks of using the medicine.
Breastfeeding
There is no information about the use of the medicine during breastfeeding. Consult your doctor if you are breastfeeding. Your doctor will consider the benefit compared to the risk.

Important information about some of this medicine's ingredients
Bromsite eye drops contain benzalkonium chloride, which may be absorbed by soft contact lenses and change their color. Remove contact lenses before use of the eye drops, and they may be reinserted at least 15 minutes after the medicine has been instilled in your eye.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
The standard dose is generally:
1 drop in the affected eye twice daily (morning and evening) 1 day prior to surgery, the day of surgery, and 14 days postsurgery.
Do not exceed the recommended dose.

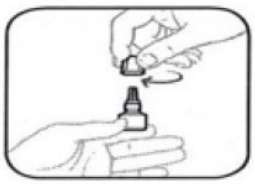
Use with other topical ophthalmic medications
Bromsite should be administered **at least 5 minutes after** instillation of other topical medications. Bromsite may be administered in conjunction with other topical ophthalmic medications such as alpha-agonists, beta-blockers, carbonic anhydrase inhibitors, cycloplegics and mydriatics.

Directions for use:

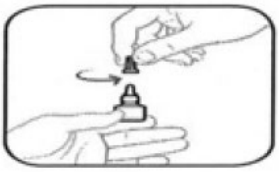
- To prevent infection, do not let the bottle tip touch any surface (including your finger or the eye itself).
- Put the gray cap back on after each use.

Before you use Bromsite for the first time

- Tear open the foil pouch using the perforated notch and remove the Bromsite bottle. Throw away the foil pouch. Remove the white cap by turning it in the clockwise direction (see figure below), and throw it away.



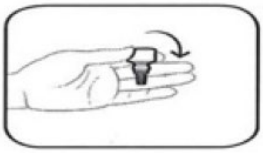
- Hold the bottle upright, and remove the gray cap by turning it in the counterclockwise direction (according to the figure below).



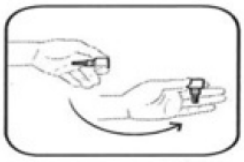
Replace the gray cap on the bottle and close tightly.

Each time you use Bromsite

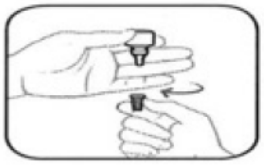
- Wash your hands well.
- Turn the closed bottle upside down (according to the figure below).



- Flick the bottle firmly 1 time (according to the figure below) to move the medicine into the tip of the bottle.



- Hold the bottle upside down and remove the gray cap by turning it in the clockwise direction (see the figure below).



- Tilt your head back. Gently squeeze the bottle to place 1 drop in the affected eye (according to the figure below). Replace the gray cap on the bottle and close tightly.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately go to a hospital emergency room, and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the medicine as soon as possible. However, if it is close to the time of the next dose, skip the forgotten dose and go back to the normal dose regimen with the next dose.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using Bromsite may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Severe side effects (see also section 2, under *"Drug interactions"*)

- Slow or delayed healing
- Potential for cross-sensitivity
- Increased bleeding time of ocular tissue
- Keratitis and corneal reactions: Use of topical nonsteroidal anti-inflammatory drugs may result in keratitis. In some susceptible patients, continued use of topical nonsteroidal anti-inflammatory drugs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical nonsteroidal anti-inflammatory drugs, including Bromsite, and should be closely monitored for corneal health.

Additional side effects
Anterior chamber inflammation, headache, vitreous floaters, iritis, eye pain and ocular hypertension.

If you experience any side effects, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Report side effects:
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the carton/label. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C.
- After the first opening of the bottle, it should be used within 32 days.
- Each bottle is provided in a sealed foil laminated pouch. Do not use the drops if the pouch is damaged.

6. Additional information:

In addition to the active ingredients, this medicine also contains:
Polycarbophil, sodium borate, boric acid, sodium chloride, citric acid anhydrous, poloxamer 407, sodium citrate dihydrate, edetate disodium dihydrate, benzalkonium chloride, 2N sodium hydroxide, water for injection.

What the medicine looks like and contents of the pack:
The preparation is a greenish-yellow cloudy to semi-clear solution packaged in a plastic bottle that contains 2.5 or 5 ml. Not all pack sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer's name and address: Woodstock Sterile Solutions, Inc
2210 Lake Shore Drive, Woodstock, IL 60098 USA

Approved in December 2020

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
166.23.35657