PACKAGE LEAFLET

DEMOXIF 0.5% Eye Drops, Solution
Instilled into the eye.
Sterile

Active substance: Each ml solution (0.5%) contains 5.45 mg moxifloxacin hydrochloride equivalent to 5 mg moxifloxacin.
Excipients: Sodium chloride, boric acid (pH adjustment), water for injection, sodium hydroxide and/or hydrochloric acid (pH adjustment).

Read all of this PACKAGE LEAFLET carefully before you start using this medicine because it contains important information for you.
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In this leaflet

1. WHAT DEMOXIF IS AND WHAT IT IS USED FOR

DEMOXIF is a clear, greenish-yellow, particle-free solution.

DEMOXIF contains 5.45 mg moxifloxacin hydrochloride equivalent to 5 mg moxifloxacin as active substance. It does not contain any preservatives.

Its pharmacotherapeutic group is 'Ophthalmologicals, antiinfectives'.

DEMOXIF is available in packages consisting of an opaque, white, low-density polyethylene bottle containing 5 ml eye drops, with a dropper tip and an orange-colored screw cap.

DEMOXIF contains moxifloxacin that belongs to a group of medicines called fluoroquinolone antibiotics and it is used against eye infections.

DEMOXIF is used as a topical treatment against bacterial infections in the front ocular part of the eye caused by the strains sensitive to moxifloxacin.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DEMOXIF

Do not use DEMOXIF if;
- You are allergic (hypersensitive) to moxifloxacin, other quinolones, or any of the other ingredients of DEMOXIF.
- Do not use it for longer than recommended by your doctor.

If your infection worsens during your treatment, contact your doctor IMMEDIATELY.

Take special care with DEMOXIF if;

- You experience any allergic reaction to DEMOXIF. Allergic reactions occur uncommonly and serious reactions occur rarely. If you experience any hypersensitivity (allergic) reaction or any side effect to this medicine, please see section 4.
- You wear contact lenses. Stop wearing contact lenses if you have any signs or symptoms of an eye infection.
- As with other antibiotics, use of DEMOXIF for a long time may lead to other infections.
- Tendon (ligaments that attach muscles to bones) inflammation and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop using DEMOXIF if you develop pain or swelling of the tendons.
- Data are very limited to establish efficacy and safety of moxifloxacin in the treatment of conjunctivitis (a type of eye infection) in neonates. Therefore, use of DEMOXIF to treat conjunctivitis in neonates is not recommended.
- DEMOXIF is not recommended for the treatment of infection caused by a microorganism called *Chlamydia trachomatis* in patients less than 2 years of age, as it has not been evaluated in such patients. Patients older than 2 years of age with eye infections caused by *Chlamydia trachomitis* microorganism should receive appropriate systemic treatment.

Using DEMOXIF with food and drinks
If the product is used as recommended, it does not interact with food or drinks.

Pregnancy
Consult your doctor or pharmacist before using this medicine.
There is not sufficient data regarding the use of DEMOXIF during pregnancy. Do not use DEMOXIF during pregnancy.

During your treatment, if you realize that you are pregnant, consult your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist before using this medicine.
It is unknown whether DEMOXIF is excreted via human breast-milk. After a risk-benefit assessment, your doctor will advise whether you can use this product.

Driving and using machines
If you experience temporary blurring or discomfort in your vision right after using DEMOXIF, do not drive or use machines until these situations disappear.

Taking other medicines
Drug interaction studies have not been conducted with DEMOXIF.
If you are using any other eye drops or eye ointment, leave at least 5 minutes between each application. Eye ointments should be applied last.

Please inform your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

3. HOW TO USE DEMOXIF

Instructions for proper use and dose/administration frequency:

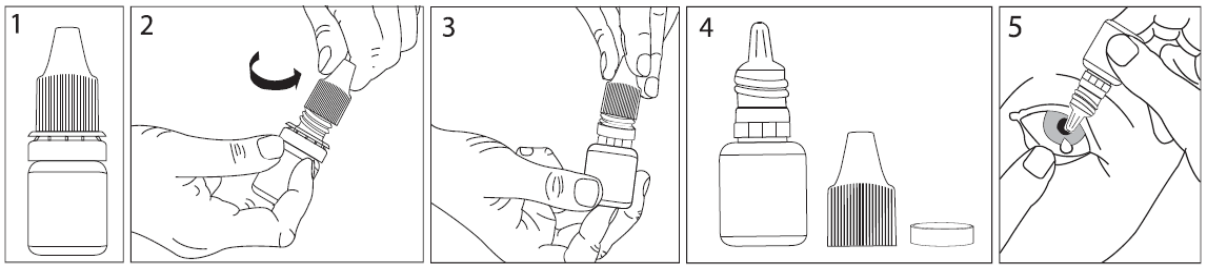
DEMOXIF should only be used by instilling into the eye(s). Do not use it via another route.

Instill 1 drop in the affected eye(s) 3 times a day (in the morning, in the afternoon and at night). If your doctor has told you so, use DEMOXIF in both eyes. Continue using the medicine for as long as your doctor has told you.

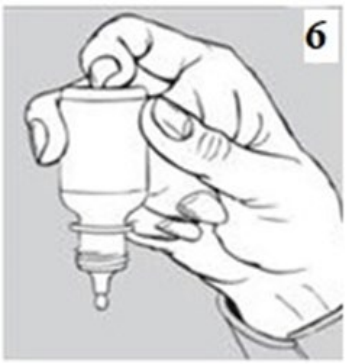
The infection normally improves after 5 days. Treatment should then be continued for a further 2 or 3 days.

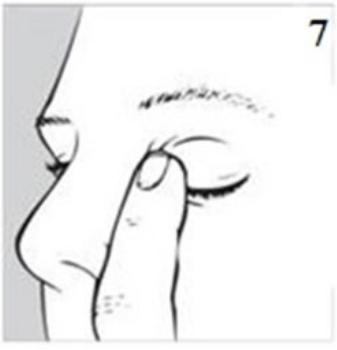
Route and method of administration:

- To ensure that the dropper tip and solution remain clean, care must be taken not to touch the eyelids, surrounding areas, or other surfaces with the dropper tip of the bottle. Keep the bottle tightly closed when not in use.



- Take a mirror and the bottle of DEMOXIF.
- Wash your hands.
- Open the cap of the bottle (see Figure 2).
- Remove the ring under the cap (see Figure 3 and Figure 4).
- Open the bottle, being careful not to touch the dropper tip of the bottle. Hold the bottle, pointing down, between your thumb and index fingers.
- Tilt your head back. Pull down your lower eyelid with a clean finger until a pocket forms between your eyelid and your eye (see Figure 5). The drop will go in there.
- Bring the dropper tip close to your eye. Do this in front of a mirror if it helps.
- Do not touch your eye, eyelid, surrounding areas or other surfaces with the dropper tip. It could infect the drops.
- Gently press on the base of the bottle to release one drop from DEMOXIF at a time (see Figure 6).
- If you will use the drops in both eyes, repeat the same steps for your other eye.
- In order to prevent the drops from being absorbed via the nasal mucosa, particularly in newborn babies or children, the tear ducts should be held closed for 2 to 3 minutes with the fingers after instillation of the drops (see Figure 7).
- Put the bottle cap firmly back on after use.





Different age groups:
Use in children:
DEMOXIF can be used in children. Dose adjustment can be made the same way as in adults. DEMOXIF is not recommended for the treatment of conjunctivitis in newborns and in the treatment of infections caused by *Chlamydia trachomatis* microorganism in patients younger than 2 years of age (for detailed information, see section 2).

Use in the elderly:
DEMOXIF can safely be used in elderly patients older than 65 years of age.

Use in special conditions:
Kidney / Liver impairment
DEMOXIF can safely be used in patients with kidney or liver problems.

If you have an impression that the effect of DEMOXIF is too strong or too weak, talk to your doctor or pharmacist.

If you have used more DEMOXIF than you should:
If you have used more DEMOXIF than you should, do not worry, it can be removed from your eyes by washing with warm water. Do not instill any more drops until it is time for your next regular dose.

Talk to a doctor or pharmacist if you have used more DEMOXIF than you should.

If you forget to use DEMOXIF
Instill the missed dose as soon as you remember, then continue your regular dosing routine.

Do not apply a double dose to make up for a missed dose.

If you accidentally swallow or inject DEMOXIF, see your doctor or pharmacist for advice. Since moxifloxacin is also suitable for use in oral tablets and intravenous solutions, it will not pose a serious safety concern.

4. POSSIBLE SIDE EFFECTS
Like all medicines, DEMOXIF may cause side effects in people sensitive to its ingredients.

If any of the serious allergic reactions and conditions occur, stop using DEMOXIF and tell your doctor IMMEDIATELY or go to the nearest hospital emergency department:
- Swelling of the hands, feet, ankles, face, lips, mouth or throat that may cause difficulty in swallowing or breathing, rash or hives, fluid-filled large blisters, sores and ulceration.

Side effects in this package leaflet are listed as shown in the following categories:
Very common : may occur in at least 1 in 10 patients.
Common : may occur in less than 1 in 10 patients, but more than 1 in 100 patients.
Uncommon : may occur in less than 1 in 100 patients, but more than 1 in 1,000 patients.
Rare : may occur in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
Very rare : may occur in less than 1 in 10,000 patients.
Not known : cannot be estimated from the available data.

Common
- Taste disturbance
- Eye pain
- Eye irritation
- Dry eyes
- Itching of the eye
- Redness of the conjunctiva
- Redness of the eye

Uncommon
- Anemia
- Tingling
- Headache
- Corneal (transparent part of the eye) disorder
- Point inflammation in the front part of the eye
- Corneal spots
- Redness of the eyelid
- Conjunctivitis (a type of eye infection)
- Swelling in the eye
- Eye discomfort
- Blurry vision
- Decrease in visual sharpness
- Eye lid disorders
- Inflammation of the eyelids
- Increased eye sensitivity
- Nose discomfort
- Pain in the throat
- Foreign sensation in the throat
- Vomiting
- Capillary bleeding in the eye
- Swelling of the eyelids
- Increase in liver enzymes (increased alanine aminotransferase, gama-glutamyltransferase)

Not known
- Allergy
- Dizziness
- Infection in the eye
- Tissue loss in the transparent body of the eye (cornea)
- Corneal injury
- Increase in inner eye pressure
- Cloudy cornea
- Ulceration on the cornea
- Eye surface inflammation
- Increased tear production
- Foreign body sensation in eyes
- Sensitivity to light

- Eye discharge
- Irregular heart rhythm
- Shortness of breath
- Nausea
- Redness of the skin
- Itching
- Rash
- Hives

These are mild side effects of DEMOXIF.

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

If you notice any side effect not listed in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE DEMOXIF
Keep DEMOXIF out of the reach and sight of children and in its original package.
Store at room temperature below 25°C.
Use it in accordance with the expiry date.
Do not use DEMOXIF after the expiry date, which is stated on the package.

Once the bottle has been opened, the medicine should be used within 28 days provided it is kept at room temperature below 25°C and then the unused portion should be discarded after.
Do not use the product if you see any color change or cloudiness.
Keep the bottle in its original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:
DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing Site:
DEVA Holding A.Ş.
Kartepe – KOCAELİ / TÜRKİYE

This package leaflet was last approved on 19/02/2024.