

Package leaflet: Information for the patient

Drynol 6 mg/mL eye drops, solution

bilastine

Read all of this 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Drynol is and what it is used for
2. What you need to know before you use Drynol
3. How to use Drynol
4. Possible side effects
5. How to store Drynol
6. Contents of the pack and other information

1. What Drynol is and what it is used for

This medicine contains bilastine which belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of a substance called histamine that the body produces as part of an allergic reaction.

This medicine is used to treat signs and symptoms of eye disorders which you get with **seasonal allergic conjunctivitis** in adults.

This medicine is also used to treat signs and symptoms of eye disorders caused by an allergy to substances such as house dust mites or animal hair (**perennial allergic conjunctivitis**) in adults.

2. What you need to know before you use Drynol

Do not use Drynol

-if you are allergic to bilastine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Drynol if during the treatment adverse events, such as eye irritation, pain, redness or change in vision occur or if your condition is worsened. It might be necessary to discontinue the treatment.

After dropping Drynol anti-allergic eye drops into the conjunctival sac of the eye, the visual acuity can deteriorate for a few minutes due to the formation of streaks.

In the event of inflammation, including allergic conjunctivitis, ask your ophthalmologist whether you can wear contact lenses despite the symptoms.

Children and adolescents

Drynol is indicated in adults only.

Do not give this medicine to children and adolescents because the efficacy and safety in these populations has not been studied yet.

Other medicines and Drynol

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you are using other medicinal products for ocular use, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

Pregnancy, breast-feeding and fertility

Drynol can be used during pregnancy and breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Temporary blurred vision or other visual disturbances affecting the ability to drive or use machines may occur after instillation of this medicine. Please wait until the vision clears before driving or using machinery.

Contact lenses

The use of this medicine does not affect the properties of the contact lenses. You can continue wearing contact lenses during use of this medicine.

Remove contact lenses before use and replace them not before 15 minutes after administration of the eye drops.

3. How to use Drynol

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is one drop in each affected eye(s) once daily.

This medicine can be used for up to 8 weeks. Your doctor will decide and advise on how long you should use it based on your condition.

For ocular use only.

Method of administration

1. Always wash your hands and dry them with a clean towel first before administering this medicine.
2. Gently clean the eyelids if they are crusty with discharge by wiping the lid from the inner corner to the outer corner with the eye closed using a cotton ball dampened with warm water.
3. Open the bottle and avoid touching the dropper tip against your eye or anything else - eyedrops and droppers must be kept clean.
4. Tilt back the head, or lie down, and look upward (Figure 1). Using your finger, gently pull the lower eyelid downward (Figure 2).
5. Look up and squeeze one eye drop into the eye.
6. Release your lower eye lid and keep your eye closed a few time to spread the drop across the surface of your eye (Figure 3).
7. Repeat the above for the other eye if necessary.



Figure 1

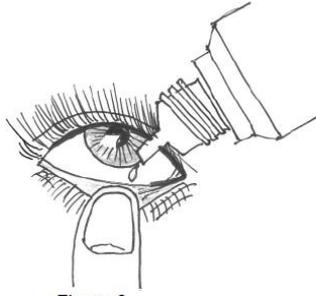


Figure 2



Figure 3

To avoid contamination during the use of this medicine do not touch any surfaces (eyelids, surrounding areas of the eye, or other surfaces) with the dropper tip and clean the tip of the nozzle with a clean tissue after use to remove any residual liquid.

If you use more Drynol than you should

You can rinse it out with warm water.

If you forget to use Drynol

Do not use a double dose to make up for a forgotten dose.

If you forget to apply the drop on time, apply the forgotten drop as soon as possible and then go back to your regular dosing schedule.

If you stop using Drynol

The treatment with this medicine should be done regularly if possible until a relief of symptoms is reached. If you stop using Drynol while you are still exposed to the allergen(s) you have to expect that the typical allergic symptoms return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported.

Uncommon side effects (may affect up to 1 in 100 people):

Distortion of the sense of taste (dysgeusia), headache.

Dry eye, eye discharge, eye irritation, increased tear production, ocular discomfort.

In case one of the above described side-effects occur please stop using this medicine and consult your doctor directly. The side-effects mentioned usually mild and disappear quickly all cases. Therefore no specific measures are required.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Drynol

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

After first opening of the bottle: do not use this medicine if the bottle has been opened for longer than 2 months.

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.

6. Contents of the pack and other information

What Drynol contains

- The active substance is bilastine 6 mg/mL
One drop contains 0.2 mg bilastine
- The other ingredients are hydroxypropyl β -cyclodextrine, methyl cellulose, sodium hyaluronate, glycerol (E 422), sodium hydroxide 1 N (for pH-adjustment), water for injections

What Drynol looks like and contents of the pack

Drynol are clear, colourless eye drops, filled in 1 multi-dose LDPE white bottle containing 5 mL of preservative free solution, having a white HDPE nozzle with tamper evident system cap.

Pack sizes: 1 x 5 mL bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Menarini International Operations Luxembourg S.A.
1 Avenue de La Gare
L-1611 Luxembourg

Manufacturer

FAMAR Health Care Services Madrid S.A.U.
Avenida de Leganés 62,
28923 Alcorcón,
Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

DE/H/2300/005

Austria: Olisir 6 mg/ml Augentropfen, Lösung

Belgium: Bellozal 6 mg/ml eye drops, solution

Croatia: Nixar 6 mg/ml kapi za oko, otopina

Cyprus: Bilaz 6mg/ml οφθαλμικές σταγόνες

Czech Republic: Xados

Estonia: Opexa

France: Bilaska 6 mg/ml collyre en solution
Germany: Bilaxten 6 mg/ml Augentropfen, Lösung
Greece: Bilaz
Hungary: Lendin 6 mg/ml szemcsepp
Ireland: Drynol 6 mg/ml eye drops, solution
Italy: Olisir 6 mg/ml collirio, soluzione
Latvia: Opexa 6 mg/ml acu pilieni, šķīdums
Lithuania: Opexa 6 mg/ml akių lašai, tirpalas
Luxembourg: Bellozal 6 mg/ml eye drops, solution
Malta: Gosall 6 mg/ml eye drops, solution
Poland: Clatra
Portugal: Lergonix 6 mg/ml colírio, solução
Romania: Borenar 6 mg/ml picături oftalmice, soluție
Slovak Republic: Omarit 6 mg/ml očné roztokové kvapky
Slovenia: Bilador 6 mg/ml kapljice za oko, raztopina
Spain: Ibis 6 mg/ml colirio en solución
DE/H/2301/005
Germany: Antires 6 mg/ml Augentropfen, Lösung
France: Inorial 6 mg/ml collyre en solution
Greece: Bilargen
Italy: Robilas 6 mg/ml collirio, soluzione
Poland: Bilaxten
Portugal: Bilaxten 6 mg/ml colírio, solução
Spain: Bilaxten 6 mg/ml colirio en solución
DE/H/2302/005
Germany: Bitosen 6 mg/ml Augentropfen, Lösung
Italy: Ayrinal 6 mg/ml collirio, soluzione

This leaflet was last revised in 07/2022