

Package leaflet: Information for the patient

Drynol® 20 mg Tablets

bilastine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you only.

- 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 take Drynol
3. How to take 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

Drynol contains the active substance bilastine which is an antihistamine. Drynol is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria).

2. What you need to know before you take Drynol 20 mg tablets

Do not take 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 you have moderate or severe renal impairment and in addition you are taking other medicines (see "Other medicines and Drynol").

Children

Do not give this medicine to children under 12 years of age

Do not exceed the recommended dose. If symptoms persist, consult your doctor.

Other medicines and Drynol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, please discuss with your doctor if you are taking any of the following medicines:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina)
- Cyclosporine (to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- Ritonavir (to treat AIDS)
- Rifampicin (an antibiotic)

Drynol tablets with food, drink and alcohol

These tablets should **not** be taken with **food or with grapefruit juice or other fruit juices**, as this will decrease the effect of bilastine. To avoid this, you can:

- take the tablet and wait for one hour before taking food or fruit juice or
- if you have taken food or fruit juice, wait for two hours before taking the tablet.

Bilastine, at the recommended dose (20 mg), does not increase the drowsiness produced by alcohol.

Pregnancy, breast-feeding and fertility

There are no or limited amount of data from the use of bilastine in pregnant women and during breast-feeding and on the effects on fertility.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

A study performed to establish the effect of bilastine on the ability to drive demonstrated that treatment with 20 mg bilastine does not affect the driving performance. However very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

3. How to take Drynol

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

The recommended dose in adults, including the elderly and adolescents aged 12 years and over, is 1 tablet (20 mg) a day.

- The tablet is for oral use. The tablet must be taken on an empty stomach, for example in the morning prior to breakfast. You must not eat for 1 hour after taking bilastine (see section 2, Drynol with food, drink and alcohol").
- Swallow your tablet with a glass of water.
- The score line is only here to help you break the tablet if you have difficulty swallowing it whole.

Regarding the duration of treatment, your physician will determine the type of disease you are suffering from and will determine for how long you should take Drynol.

Use in children

Do not give this medicine to children under 12 years of age.

If you take more Drynol than you should

If you, or anyone else, have taken too many Drynol tablets, contact your doctor or pharmacist **immediately**.

If you forget to take Drynol

Do not take a double dose to make up for a forgotten dose. If you forget to take your dose on time, take it as soon as possible, and then go back to your regular dosing schedule.

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.

Side effects that may be experienced are:

Common: may affect up to 1 in 10 people

- headache
- drowsiness

Uncommon: may affect up to 1 in 100 people

- abnormal ECG heart tracing
- blood tests which show changes in the way the liver is working
- dizziness
- stomach pain
- tiredness

- increased appetite
- irregular heartbeat
- increased weight
- nausea (the feeling of being sick)
- anxiety
- dry or uncomfortable nose
- belly pain
- diarrhoea
- gastritis (inflammation of the stomach wall)
- vertigo (a feeling of dizziness or spinning)
- feeling of weakness
- thirst
- dyspnoea (difficulty in breathing)
- dry mouth
- indigestion
- itching
- cold sores (oral herpes)
- fever
- tinnitus (ringing in the ears)
- difficulty in sleeping
- blood tests which show changes in the way kidney is working
- blood fats increased

Frequency not known: cannot be estimated from the available data

- palpitations (feeling your heart beat)
- tachycardia (fast heart beat)
- allergic reactions the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 carton and blisters after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 to protect the environment.

6. Contents of the pack and other information

What Drynol contains:

- The active substance is bilastine. Each tablet contains 20 mg of bilastine.
- The other ingredients are cellulose microcrystalline, sodium starch glycolate, type A (derived from potato), colloidal anhydrous silica, magnesium stearate.

What Drynol looks like and contents of the pack

- Drynol tablets are white, oval, biconvex and scored. The tablets are supplied in blisters of 30 tablets.

Product Procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

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Manufacturer

Faes farma S.A., Maximo Aguirre, 14 Leioa, Spain or A. Menarini Manufacturing Logistics and Services S.r.l., Campo de Pile, L'Aquila, Italy or Menarini-Von Heyden GmbH, Leipziger Strasse 7-13; 01097 Dresden, Germany.

Drynol is a registered trademark of Faes Farma S.A.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Nasitop 20 mg Tabletten
Belgium: Bellozal 20 mg Tablet
Bulgaria: Fortecal 20 mg Таблетка
Cyprus: Bilaz 20 mg Δισκίο
Czech Republic: Xados 20 mg Tablety
Denmark: Revitelle 20 mg Tablet
Estonia: Opexa
Finland: Revitelle 20 mg Tabletti
France: Bilaska 20 mg Comprimé
Germany: Bilaxten 20 mg Tabletten
Greece: Bilaz 20 mg Δισκίο
Hungary: Lendin 20 mg tableta
Iceland: Bilaxten 20 mg Tafla
Ireland: Drynol 20 mg tablets
Italy: Olisir 20 mg Compresa
Latvia: Opexa 20 mg Tabletes
Lithuania: Opexa 20 mg Tabletis
Luxembourg: Bellozal 20 mg Tablet
Malta: Gosall 20 mg tablets
Norway: Zilas 20 mg Tablett
Poland: Clatra
Portugal: Lergonix 20 mg Comprimido
Romania: Borenar 20 mg Comprimate
Slovak Republic: Omarit 20 mg Tableta
Slovenia: Bilador 20 mg tablete
Spain: Ibis 20 mg Comprimido
Sweden: Bilaxten 20 mg Tablett
United Kingdom: Ilaxten 20 mg tablets

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