PACKAGE LEAFLET

Package leaflet: Information for the patient

Drynol 20 mg orodispersible tablets
bilastine

Read all of this leaflet carefully before you start taking 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

Drynolcontains 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 in adults and adolescents aged 12 years and older. It may also be used to treat itchy skin rashes (hives or urticaria).

2. What you need to know before you use Drynol

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, low blood levels of potassium, magnesium, calcium, if you have or had heart rhythm problems or if your heart rate is very low, if you are taking medicines that may affect the heart rhythm, if you have or had a certain abnormal pattern to your heart beat (known as prolongation of the QT_C interval on the Electrocardiogram) which can occur in some forms of heart disease and in addition you are taking other medicines (see"Other medicines and Drynol").

Children

Do not give Drynol 20 mg orodispersible tablets to children under 12 years of age. For alternative dosage forms of bilastine suitable for use in children under 12 years of age, see Section 3 "Use in children".

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 tablets (used to treat Cushing´s syndrome when the body produces an excess of cortisol)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina pectoris – pain or tightness in the chest area)
- 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 HIV)
- Rifampicin (an antibiotic)

Drynol with food, drink and alcohol
These orodispersible 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 orodispersible 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 orodispersible tablet.

Bilastine, at the dose recommended (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
It has been demonstrated that bilastine 20 mg does not affect the driving performance in adults. However, the response from each patient to the medicine may be different. Therefore, you should check how this medicine affects you, before driving or operating machinery

Drynolcontains sodium and ethanol
This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially ‘sodium-free’.

This medicine contains 0.0030 mg of alcohol (ethanol) in each orodispersible tablet which is equivalent to 1,6 mg/100g (0.0016 % w/w). The amount in one orodispersible tablet weighing 185 mg is equivalent to less than 1 ml beer or 1 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Drynol

Always take 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 in adults, including elderly and adolescents aged 12 years and over, is 1 orodispersible tablet (20 mg bilastine) once daily.

- The orodispersible tablet is for oral use.
- Please place the orodispersible tablet in the mouth. It will disperse rapidly in saliva and can then be easily swallowed.
- Alternatively, you may disperse the orodispersible tablet in water before taking it.

- **You should use exclusively water for dispersion,** do not use grapefruit juice or any other fruit juices.
- You should take the orodispersible tablet one hour before or two hours after intake of any food or fruit juice (see section 2, “Drynol with food, drink and alcohol”).

Duration of treatment
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

Other forms of this medicine – bilastine 10 mg orodispersible tablets or bilastine 2.5 mg/mL oral solution - may be more suitable for children 2 to 11 years of age with a body weight of at least 15 kg - ask your doctor or pharmacist.

Do not give bilastine to children under 2 years of age or with a body weight below 15 kg since no sufficient data are available.

If you take more Drynol than you should
If you, or anyone else, have taken too many Drynol orodispersible tablets, contact your doctor or pharmacist **immediately** or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

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.

If you stop using Drynol
Generally, there will be no after-effects when treatment with Drynol is stopped.

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.
Stop taking the medicine and seek urgent medical advice straight away, in case you experience symptoms of an allergic reaction 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.

Other side effects that may be experienced in adults and adolescents 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)
- vomiting

Side effects that may be experienced in children are:
Common: may affect up to 1 in 10 people
- allergic conjunctivitis (eye inflammation caused by an allergic reaction)
- headache

Uncommon: may affect up to 1 in 100 people
- eye irritation
- dizziness
- loss of consciousness
- diarrhoea
- nausea (the feeling of being sick)
- lip swelling
- eczema
- urticaria (hives)
- fatigue
- rhinitis (nasal irritation)
- stomach pain (abdominal /upper abdominal pain)

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 carton and the blister 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 protect the environment.

6. Contents of the pack and other information

What Drynol contains
- The active substance is bilastine. Each orodispersible tablet contains 20 mg of bilastine.
- The other ingredients are mannitol (E421), croscarmellose sodium, sodium stearyl fumarate, sucralose (E955), red grape flavour (major components: gum arabic, ethyl butyrate, triacetin, methyl anthranilate, ethanol, d-limonene, linalool).

See section 2 “Drynol contains sodium and ethanol”

What Drynol looks like and contents of the pack
Drynol orodispersible tablets are round, flat, white, engraved with “20” on one side and of 8 mm diameter.
Drynolis available in perforated unit-dose blisters of 10 x 1, 20 x 1, 30 x 1, 40 x1 or 50 x 1 orodispersible tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

FAES FARMA, S.A.
Máximo Aguirre, 14. 48.940 – Leioa (Vizcaya)
Spain

Faes Farma, S.A.
Parque Cientifico y Tecnologico de Bizkaia,
Ibaizabal Bidea, Edificio 901, 48160
Derio (Bizkaia)
SPAIN

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

Austria: Olisir 20 mg Schmelztabletten
Belgium: Bellozal 20 mg orodispersible tablets
Bulgaria: Фортекал за деца 20 mg диспергиращи се в устата таблетки
Croatia: Nixar Alergija 20 mg raspadljive tablete za usta
Cyprus: Bilaz 20 mg δισκία διασπειρόμενα στο στόμα
Czech Republic: Xados
Estonia: Opexa
Finland: Revitelle 20 mg tabletti, suussa hajoava
France: Bilaska 20 mg comprimé orodispersible
Germany: Bilaxten 20 mg Schmelztabletten
Greece: Bilaz 20 mg δισκία διασπειρόμενα στο στόμα
Hungary: Lendin Neo 20 mg szájban diszpergálódó tabletta
Ireland: Drynol 20 mg orodispersible tablets

Italy: Bysabel 20 mg compressa orodispersibile
Latvia: Opexa 20 mg mutē disperģējamās tabletes
Lithuania: Opexa 20 mg burnoje disperguojamos tabletės
Luxembourg: Bellozal 20 mg orodispersible tablets
Malta: Gosall 20 mg orodispersible tablets
Poland: Clatra
Portugal: Lergonix 20 mg comprimido orodispersível
Romania: Borenar 20 mg comprimate orodispersabile
Slovak Republic: Omarit 20 mg orodispergovateľné tablety
Slovenia: Bilador 20 mg orodisperzibilne tablete
Spain: Ibis 20 mg comprimidos bucodispersables

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