

Drynol 10 mg orodispersible tablets

For children aged 6 to 11 years with a body weight of at least 20 kg
bilastine

Read all of this leaflet carefully before your child starts 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 your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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).

Drynol 10 mg orodispersible tablets are indicated in children aged 6 to 11 years with a body weight of at least 20 kg.

2. What you need to know before you use Drynol

Do not use Drynol:

- if your child is 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 your child has moderate or severe renal or hepatic impairment or if your child is taking other medicines (see "Other medicines and Drynol").

Children

Do not give this medicine to children under 6 years of age with a body weight below 20 kg since no sufficient data are available.

Other medicines and Drynol

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines should not be taken together and others may need their doses to be altered when taken together.

Always inform your doctor or pharmacist if your child is using or receiving any of the following medicines in addition to Drynol:

- 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 with food, drink and alcohol

These orodispersible tablet 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:

- give your child the orodispersible tablet and wait for one hour before your child takes food or fruit juice or
- if your child has taken food or fruit juice, wait for two hours before giving him the orodispersible tablet.

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

Pregnancy, breast-feeding and fertility

This medicine is for use in children from 6 to 11 years of age with a body weight of at least 20 kg. However, the following information should be noted regarding the safe use of this medicine. 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.

In case of pregnancy or breast-feeding, or when planning to have a baby, it is recommended to ask to the 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 your child, before you let your child ride bicycles or drive other vehicles or operate machinery.

Drynol contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium free'.

3. How to take 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.

Use in children

The recommended dose in children 6 to 11 years of age with a body weight of at least 20 kg is 10 mg bilastine (1 orodispersible tablet) once daily for the relief of symptoms of allergic rhinoconjunctivitis and urticaria.

Do not give this medicine to children under 6 years of age with a body weight below 20 kg since no sufficient data are available.

For adults, including elderly and adolescents aged 12 years and over, the recommended dose is 20 mg bilastine once daily. For this patient population a more suitable dosage form – tablet - is available, ask your doctor or pharmacist.

- The orodispersible tablet is for oral use.
- Please place the orodispersible tablet in the mouth of your child. It will disperse rapidly in saliva and can then be easily swallowed.
- Alternatively, you may disperse the orodispersible tablet in a tea-spoon of water before giving it to your child. It has to be ensured that no rest of sediment remains in the spoon.
- **You should use exclusively water for dispersion**, do not use grapefruit juice or any other fruit juices.
- You should give the orodispersible tablet to your child one hour before or two hours after your child has taken any food or fruit juice.

As the duration of treatment depends on your child's underlying disease, your physician will determine for how long your child should take Drynol.

If you use more Drynol than you should

If your child, or anyone else, use too much of this medicine, tell your doctor 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 use Drynol

If you forget to give your child the daily dose on time, give it on the same day as soon as you remember. Then, give the next dose on the next day at the usual time as prescribed by the doctor.

In any case, do not give a double dose to make up for a forgotten one.



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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.

If your child experiences symptoms of an allergic reaction the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of the face, lips, tongue or throat, and/or swelling and redness of the skin, stop giving the medicine and seek urgent medical advice straight away.

Other side effects that may be experienced in children are:

Common: may affect up to 1 in 10 people

- rhinitis (nasal irritation)
- allergic conjunctivitis (eye irritation)
- headache
- stomach pain (abdominal /upper abdominal pain)

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

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

Reporting of side effects

If your child gets 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 10 mg of bilastine.
- The other ingredients are mannitol, croscarmellose sodium, sodium stearyl fumarate, sucralose, red grape flavour (major components: gum arabic, ethyl butyrate, triacetin, methyl anthranilate, ethanol, d-limonene, linalool)

What Drynol looks like and contents of the pack

Drynol orodispersible tablets are round, slightly biconvex, white, of 8 mm diameter.

The orodispersible tablets are supplied in blisters of 10, 20, 30 or 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

A. Menarini Manufacturing Logistics and Services S.r.L.,
Via Campo di Pile 67100, L'Aquila,
Italy

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

Austria: Nasitop 10 mg Schmelztabletten
Belgium: Bellozal 10 mg orodispersible tablets
Bulgaria: Фортекал за деца 10 mg диспергиращи се в устата таблетки
Cyprus: Bilaz 10 mg δισκία διασπειρόμενα στο στόμα
Czech Republic: Xados
Denmark: Revitelle smeltetabletter 10 mg
Estonia: Opexa
Finland: Revitelle
France: Bilaska 10 mg comprimé orodispersible
Germany: Bilaxten 10 mg Schmelztabletten
Greece: Bilaz 10 mg δισκία διασπειρόμενα στο στόμα
Hungary: Lendin
Iceland: Bilaxten 10 mg munndreifitöflur
Ireland: Drynol
Latvia: Opexa 10 mg mutē disperģejamās tabletes
Lithuania: Opexa
Luxembourg: Bellozal 10 mg orodispersible tablets
Malta: Gosall 10 mg orodispersible tab
Norway: Zilas 10 mg smeltetablett
Poland: Clatra
Portugal: Lergonix 10 mg comprimido orodispersível
Romania: Borenar 10 mg comprimate orodispersabile
Slovak Republic: Omarit 10 mg orodispersgovatneľ tablety
Slovenia: Bilador 10 mg orodispersibilne tablete
Spain: Ibis 10 mg comprimidos bucodispersables
Sweden: Bilaxten
United Kingdom: Ilaxten

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