Package leaflet: Information for the patient

Drynol 2.5 mg/ml oral solution

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

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 2.5 mg/ml oral solution is 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 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 AIDS)
- Rifampicin (an antibiotic)

Drynol with food, drink and alcohol

The oral solution 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 oral solution 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 oral solution.

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 methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)** which may cause allergic reactions (possibly delayed).

Drynol contains ethanol and sodium
This medicine contains 0.44 mg of alcohol (ethanol) in each dose (4 mL) which is equivalent to 11 mg/100 mL (0.011% w/v). The amount in 4mL of this medicine is equivalent to less than 0.02 ml beer or 0.005 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per 4 ml, 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 (4 ml of oral solution) 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 appropriate dosage form - tablet- is available, ask your doctor or pharmacist.

- The oral solution is for oral use
- The bottle of oral solution is provided with a child-proof cap and must be opened as follows: press the plastic screw-cap downwards and turn anti-clockwise at the same time
- The oral solution is accompanied by a cup for dosage with a mark of 4 ml (= 10 mg bilastine per dosing), which will help you to dose the oral solution correctly
- Fill the cup with 4 ml of oral solution
- Administer directly from the cup
- Wash the cup after use
- You should give the oral solution 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.

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 bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C

The shelf life after first opening is 6 months.

Do not use this medicine if you notice any visible signs of particles.

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. One milliliter of the oral solution contains 2.5 mg of bilastine.

- The other ingredients are Betadex (E459), Hydroxyethylcellulose, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Sucralose (E955), Raspberry flavour (major components: ethanol, triacetin, water, ethyl butyrate, linalyl acetate), Hydrochloric acid 37% or 10% (for pH-adjustment), Sodium hydroxide (for pH-adjustment), Water, purified

What Drynol looks like and contents of the pack
Drynol oral solution is a clear, colourless, slightly viscous aqueous solution of pH 3.0-4.0, without precipitate.

Drynol 2.5 mg/ml oral solution is packaged in an amber glass bottle, sealed with an aluminium screw cap or with a polypropylene child-resistant cap, including a 15 or 25 ml cup for dosage with a mark of 4 ml. Each bottle contains 120 ml of oral solution.

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

Berlin Chemie AG,
Glienicker Weg 125, 12489 Berlin,
Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria: Nasitop 2,5 mg/ml Lösung zum Einnehmen

Belgium: Bellozal 2,5 mg oral solution

Bulgaria: Фортекал за деца 2.5 mg/ml перорален разтвор

Cyprus: Bilaz 2.5 mg/mL πόσιμο διάλυμα

Czech Republic: Xados

Denmark: Revitelle, oral opløsning 2,5 mg/ml

Estonia: Opexa

Finland: Revitelle

France: Bilaska 2.5 mg/ ml solution buvable

Germany: Bilaxten 2,5 mg/ml Lösung zum Einnehmen

Greece: Bilaz

Hungary: Lendin

Iceland: Bilaxten 2,5 mg/ml mixtúra, lausn

Ireland: Drynol

Latvia: Opexa 2,5 mg/ml šķīdums iekšķīgai lietošanai

Lithuania: Opexa

Luxembourg: Bellozal 2,5 mg oral solution

Malta: Gosall 2.5 mg/ml oral solution

Norway: Zilas 2,5 mg/ml mikstur, oppløsning

Poland: Clatra

Portugal: Lergonix 2,5 mg/ml solução oral Romania: Borenar 2,5 mg/ml soluţie orală

Slovak Republic: Omarit 2,5 mg/ml perorálny roztok

Slovenia: Bilador 2,5 mg peroralna raztopina

Spain: Ibis 2,5 mg/ml solución oral

Sweden: Bilaxten

United Kingdom (Northen Ireland): Ilaxten

This leaflet was last revised in 12/2022.