

BILAXTEN 20 mg 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 BILAXTEN 20 mg tablets is and what it is used for
2. What you need to know before you take BILAXTEN 20 mg tablets
3. How to take BILAXTEN 20 mg tablets
4. Possible side effects
5. How to store BILAXTEN 20 mg tablets
6. Contents of the pack and other information

1. What BILAXTEN 20 mg tablets is and what it is used for

BILAXTEN 20 mg tablets contains the active substance bilastine which is an antihistamine. BILAXTEN 20 mg tablets is used to relieve the symptoms of hay fever (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 BILAXTEN 20 mg tablets

Do not take BILAXTEN 20 mg tablets: 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 Bilaxten 20 mg tablets if you have moderate or severe renal impairment and in addition you are taking other medicines (see Other medicines and Bilaxten 20 mg tablets).

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 BILAXTEN 20 mg tablets

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)
- Rilovir (to treat AIDS)
- Rifampicin (an antibiotic)

BILAXTEN 20 mg 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 BILAXTEN 20 mg tablets

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 wait for 1 hour after taking bilastine (see section 2, BILAXTEN 20 mg tablets 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 BILAXTEN 20 mg tablets.

Use in children

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

If you take more BILAXTEN 20 mg tablets than you should

If you, or anyone else, have taken too many BILAXTEN 20 mg tablets, contact your doctor or pharmacist immediately.

If you forget to take BILAXTEN 20 mg tablets

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 1 to 10 users in 1,000

- 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

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BILAXTEN 20 mg, comprimé

Bilastine

Veillez lire attentivement cette notice avant de prendre ce médicament car elle contient des informations importantes pour vous.

- Gardez cette notice, vous pourriez avoir besoin de la relire.
- Si vous avez d'autres questions, interrogez votre médecin ou votre pharmacien.
- Ce médicament vous a été personnellement prescrit. Ne le donnez jamais à d'autres personnes. Il pourrait leur être nocif, même si les signes de leur maladie sont identiques aux vôtres.
- Si vous ressentez un quelconque effet indésirable, parlez-en à votre médecin ou votre pharmacien. Ceci s'applique aussi à tout effet indésirable qui ne serait pas mentionné dans cette notice. Voir rubrique 4.

Que contient cette notice :

1. Qu'est-ce que BILAXTEN et dans quel cas est-il utilisé ?
2. Quelles sont les informations à connaître avant de prendre BILAXTEN 20 mg comprimés ?
3. Comment prendre BILAXTEN 20 mg comprimés ?
4. Quels sont les effets indésirables éventuels ?
5. Comment conserver BILAXTEN 20 mg comprimés ?
6. Contenu de l'emballage et autres informations.

1. Qu'est-ce que BILAXTEN 20 mg comprimés et dans quel cas est-il utilisé ?

BILAXTEN contient la substance active bilastine qui est un antihistaminique. BILAXTEN soulage les symptômes de la rhino-conjonctivite allergique (éternuement, démangeaison nasale, écoulement nasal, congestion nasale ainsi que rougeur et larmoiement oculaires) et autres symptômes d'origine allergique. BILAXTEN peut également être utilisé pour traiter les éruptions cutanées accompagnées de démangeaisons (urticaire).

2. Quelles sont les informations à connaître avant de prendre BILAXTEN 20 mg comprimés ?**Ne prenez jamais BILAXTEN :**

Si vous êtes allergique à la bilastine ou à l'un des autres composants contenus dans ce médicament (mentionnés dans la rubrique 6).

Avertissements et précautions

Adressez-vous à votre médecin ou pharmacien avant de prendre BILAXTEN 20 mg comprimés si vous avez une insuffisance rénale modérée à sévère ou si vous prenez d'autres médicaments (voir « Autres médicaments et BILAXTEN 20 mg comprimés »).

Enfants

Ne donnez pas ce médicament aux enfants de moins de 12 ans.
Ne pas dépasser la dose prescrite. Si les symptômes persistent, consultez votre médecin.

Autres médicaments et BILAXTEN 20 mg comprimés

Informez votre médecin ou pharmacien si vous prenez, avez récemment pris ou pourriez prendre tout autre médicament, y compris un médicament obtenu sans ordonnance.

En particulier, veuillez informer votre médecin si vous prenez l'un des médicaments suivants :

- ketoconazole (anti-fongique utilisé dans les mycoses)
- érythromycine (antibiotique)
- diltiazem (utilisé pour le traitement de l'angine de poitrine)
- ciclosporine (immunosuppresseur utilisé chez les sujets ayant subi une greffe pour diminuer le risque de rejet de greffe ou dans le traitement des maladies auto-immunes tels que le psoriasis, la dermatite atopique ou la polyarthrite rhumatoïde)
- ritonavir (médicament utilisé pour traiter le VIH)
- rifampicine (antibiotique).

BILAXTEN avec des aliments, boissons et de l'alcool

Les comprimés ne doivent pas être pris avec de la nourriture, ni avec du jus de pamplemousse ou, d'autres jus de fruits car cela diminuerait l'efficacité de la bilastine. Pour éviter cela vous pouvez :

- prendre un comprimé et attendre une heure avant de prendre de la nourriture ou un jus de fruits ou
- si vous avez pris de la nourriture ou un jus de fruits, attendre deux heures avant de prendre un comprimé.

A la dose recommandée (20 mg) la bilastine n'augmente pas la somnolence induite par l'alcool.

Grossesse, allaitement et fertilité

Il n'y a pas ou un nombre limité de données sur l'utilisation de la bilastine chez les femmes enceintes et pendant l'allaitement et sur les effets sur la fertilité.

Si vous êtes enceinte ou que vous allaitez, si vous pensez être enceinte ou planifiez une grossesse, demandez conseil à votre médecin ou votre pharmacien avant de prendre ce médicament.

Consultez votre médecin ou votre pharmacien avant de prendre des médicaments.

Conduite de véhicules et utilisation de machines

Une étude a montré que la bilastine 20 mg n'avait pas d'effet sur les tests réalisés pour évaluer l'aptitude à conduire des véhicules. Cependant, très rarement quelques personnes ont ressenti de la somnolence, ce qui pourrait affecter leur aptitude à conduire ou utiliser des machines.

3. Comment prendre BILAXTEN 20 mg comprimés ?

Veillez à toujours prendre ce médicament en suivant exactement les indications de votre médecin ou pharmacien. Vérifiez auprès de votre médecin ou pharmacien en cas de doute.

La dose recommandée chez les adultes, y compris les personnes âgées et les adolescents âgés de plus de 12 ans, est de 1 comprimé (20 mg) par jour.

- Comprimé par voie orale.
- Le comprimé doit être pris à jeun, par exemple le matin avant le petit-déjeuner. Vous ne devez pas manger durant l'heure suivant la prise de la bilastine (voir rubrique « BILAXTEN 20 mg comprimés avec des aliments, boissons et de l'alcool »).

• Avalez le comprimé avec un verre d'eau. La barre de cassure n'est là que pour faciliter la prise orale du comprimé si vous avez des difficultés à l'avaler en entier. Concernant la durée du traitement, votre médecin déterminera la nature de la maladie dont vous souffrez et fixera la durée pendant laquelle vous devez prendre BILAXTEN 20 mg comprimés.

Utilisation chez les enfants

Ne donnez pas ce médicament aux enfants de moins de 12 ans.

Si vous avez pris plus de BILAXTEN 20 mg comprimés que vous n'auriez dû :
Si vous, ou quelqu'un d'autre, avez pris

plus de BILAXTEN que vous n'auriez dû, contactez immédiatement votre médecin ou votre pharmacien.

Si vous oubliez de prendre BILAXTEN 20 mg comprimés

Ne prenez pas de dose double pour compenser la dose que vous avez oubliée de prendre.

Si vous oubliez de prendre votre dose à l'heure, prenez la dose oubliée dès que possible, puis continuez selon le rythme habituel.

Si vous avez d'autres questions sur l'utilisation de ce médicament, demandez plus d'informations à votre médecin ou à votre pharmacien.

4. Quels sont les effets indésirables éventuels ?

Comme tous les médicaments, ce médicament peut provoquer des effets indésirables, mais ils ne surviennent pas systématiquement chez tout le monde.

Les effets indésirables sont :

Fréquents : peuvent concerner plus de 1 personne sur 10

- Maux de tête
- Somnolence.

Peu fréquents : peuvent concerner plus de 1 personne sur 100 à 1000 utilisateurs sur 1000

- Anomalie de l'électrocardiogramme
- Modification du bilan sanguin hépatique
- Sensations vertigineuses
- Douleur au niveau de l'estomac
- Sensation de fatigue
- Augmentation de l'appétit
- Battements cardiaques irréguliers
- Prise de poids
- Nausées
- Anxiété
- Sécheresse ou inconfort nasal
- Douleur abdominale
- Diarrhées
- Gastrite (inflammation de la paroi de l'estomac)
- Vertiges (une sensation de vertige ou manque d'équilibre)
- Sensation de faiblesse générale
- Soif
- Dyspnée (difficulté à respirer)
- Sécheresse buccale
- Indigestion
- Démangeaisons
- Herpès labial
- Fièvre
- Acouphènes (bourdonnements dans les oreilles)
- Trouble du sommeil
- Modification du bilan sanguin rénal
- Augmentation des taux de lipides (graisses) mesurés dans le sang.

Fréquence inconnue : ne peut être estimée sur la base des données disponibles

- Palpitations (battements perceptibles du cœur)
- Tachycardie (battements rapides du cœur)
- Réactions allergiques, pouvant se manifester par une difficulté à respirer, des vertiges, un évanouissement ou une perte de connaissance, le gonflement du visage, des lèvres, de la langue ou de la gorge, et/ou gonflement et une rougeur de la peau. Si vous ressentez l'un de ces effets indésirables graves, arrêtez de prendre le médicament et consultez d'urgence un médecin.

Déclaration des effets secondaires

Si vous ressentez un quelconque effet indésirable, parlez-en à votre médecin ou à votre pharmacien. Ceci s'applique aussi à tout effet indésirable qui ne serait pas mentionné dans cette notice. Vous pouvez également déclarer les effets indésirables directement via le Système National de Pharmacovigilance.

En signalant les effets indésirables, vous contribuez à fournir davantage d'informations sur la sécurité du médicament.

5. Comment conserver BILAXTEN 20 mg comprimés ?

Tenir ce médicament hors de la vue et de la portée des enfants.
N'utilisez pas ce médicament après la date de péremption indiquée sur la boîte et les plaquettes thermomformées après PEREMPT. La date de péremption fait référence au dernier jour de ce mois.

Conserver à une température inférieure à 30 °C.

Ne jetez aucun médicament au tout-à-l'égout ou avec les ordures ménagères. Demandez à votre pharmacien d'utiliser les médicaments que vous n'utilisez plus. Ces mesures contribueront à protéger l'environnement.

6. Contenu de l'emballage et autres informations

Ce qui contient BILAXTEN 20 mg comprimés :

La substance active est la bilastine. Chaque comprimé contient 20 mg de bilastine. Les autres composants sont : Cellulose microcristalline, carboxyméthylamidon sodique type A (dérivé de la pomme de terre), silice colloïdale anhydre, stéarate de magnésium.

Qu'est-ce que BILAXTEN et contenu de l'emballage extérieur ?

Ce médicament se présente sous forme de comprimés.

Les comprimés de BILAXTEN sont blancs, ovales, biconvexes, avec une barre de cassure (longueur 10 mm, largeur 5 mm). Les comprimés sont conditionnés sous plaquettes thermomformées, boîtes de 10, 20, 30, 40 ou 50 comprimés.

Toutes les présentations peuvent ne pas être commercialisées.

Titulaire de l'autorisation de mise sur le marché

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La dernière date à laquelle cette notice a été révisée est le : 10/2015