


 Tona Nanna
 04/11/2021

Product: BILOR SYRUP	Market: IMEX 2 (FR+PT+EN)	Size: (L x H) 339 X 200 mm
Component: Leaflet	Artwork code: 1300XXXX	Pack Size: ----
Color Shades: Black	Date of Initiation: 28-09-2021	Mfg Location: Dortmund
Barcode: N.A.	Substrate: 40 gsm Bible Paper	
Reason for Issue: Excipients change		Superceded Code: ----
Designer	Rajesh	Change Control No.: ----
Path: E:\DUSANE\YD\PACKAGING\Suresh P\Imex_for DMP Registration\Bilor Syrup\Bilor Syrup 60 ml (Trilingual)_DMP Registration.cdr		

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER BILOR[®] Loratadine Syrup Please read this leaflet completely before taking this medicine as it contains important information: - Keep this leaflet, as you may need to read it again. - Ask your doctor or pharmacist if you have further questions. - This medicine was prescribed for you only. Do not give it to others. It may harm them, even if their symptoms are identical to yours. - If you have any side effects, including some that are not listed in this leaflet, inform your doctor or pharmacist. See section 4. What is this leaflet? - What is BILOR[®] Syrup, and when to use it? - What you need to know before taking BILOR[®] Syrup? - How to take BILOR[®] Syrup? - Possible side effects - How to store BILOR[®] Syrup? - Pack content and other information. 1. WHAT IS BILOR[®] SYRUP AND WHEN TO USE IT? Pharmaceutical active substance: ANTI-HISTAMINE (FOR SYSTEMIC USE) - ATC code: R06AX13 BILOR[®] Syrup belongs to the class of antihistamines. Antihistamines are used to relieve allergic symptoms by preventing the effects of a substance, the histamine, on your organism when you have an allergic reaction. BILOR[®] Syrup is indicated to relieve the symptoms associated with allergic rhinitis (e.g., hay fever), such as sneezing, itchy or runny nose, itchy or watery eyes. BILOR[®] Syrup is also used to relieve the symptoms associated to chronic idiopathic urticaria (itching, redness and number and size of blisters). 2. WHAT YOU NEED TO KNOW BEFORE TAKING BILOR[®] SYRUP? Never take BILOR[®] Syrup: - If you are allergic (hypersensitive) to the active ingredient (loratadine) or to any of the other ingredients in this medicine, see section 4 for details. Warnings and precautions Consult your doctor or pharmacist before taking BILOR[®] Syrup. Inform your doctor or pharmacist if you have severe liver disease. If you have been diagnosed with intolerance to certain sugars, consult your doctor before taking this medication. This medication is unsuitable for patients with future intolerance. Inform your doctor that you have taken this medication if a test skin has been prescribed as part of an allergy diagnosis. In that event, the treatment should be discontinued 48 hours prior to the skin test as the result may be inaccurate. IN CASE OF COURT USE, ADVISE FROM YOUR DOCTOR OR PHARMACIST. Children Non-contraindications: BILOR[®] Syrup and other medications Inform your doctor or pharmacist if you take, have taken or are likely to take any other medication. BILOR[®] Syrup with food, drinks and alcohol BILOR[®] Syrup can be taken during or outside meals. Pregnancy and breastfeeding Ask your doctor or pharmacist before taking this medication if you are pregnant or breastfeeding. If you suspect a pregnancy or plan a pregnancy. Unless otherwise specified by your doctor, this medication should not be used during pregnancy. If you become pregnant while being treated with this medication consult your doctor as soon as possible: he alone can decide what treatment is better adapted to your condition. This medication passes into breast milk. Consequently, it is not recommended when breastfeeding. Driving and using machines BILOR[®] Syrup in therapeutic dose does not usually cause drowsiness and does not impact alertness. However, very rare cases of drowsiness impacting the ability to drive or use machines have been observed. 3. HOW TO TAKE BILOR[®] SYRUP? Always comply with the doctor or pharmacist's prescription. If in doubt ask your doctor or pharmacist. Dosage: - Children and teenagers (12 years old and over): 10 mg once a day, i.e.: 10 ml (2 measuring spoons of 5 ml) of syrup once a day. - Children aged 2 to 12 years old: - Children weighing 30 kg or more: 10 ml (10 mg) i.e.: 2 measuring spoons of 5 ml of syrup once a day. - Children weighing under 30 kg: 5 ml (5 mg) i.e.: 1 measuring spoon of 5 ml of syrup once a day. - Patients with severe hepatic impairment: the dosage should be decreased. - Children weighing 30 kg or more: 10 ml (10 mg) i.e.: 2 measuring spoons of 5 ml of syrup once a day every 2 days. - Children weighing under 30 kg: 5 ml (5 mg) i.e.: 1 measuring spoon of 5 ml of syrup once a day every 2 days. BILOR[®] Syrup is not recommended in children under the age of 2. IN ANY EVENT ALWAYS STRICTLY COMPLY WITH THE DOCTOR'S PRESCRIPTION.	If you feel that the effect of BILOR[®] Syrup is too strong or too weak, consult your doctor or pharmacist. Administration Children Use the measuring spoon to measure how much product to administer. This medication can be taken during or outside meals. If you have taken more BILOR[®] Syrup than you should have Overdose of BILOR[®] Syrup, can cause drowsiness, increased heart rate and headaches. Consult your doctor or pharmacist immediately. If you have forgotten to take BILOR[®] Syrup Do not take a double dose to compensate for the forgotten dose. If you stop taking BILOR[®] Syrup Inform your doctor. If you have any further questions regarding the use of this medication ask your doctor or pharmacist. 4. WHAT ARE THE POSSIBLE SIDE EFFECTS? As with all medication, BILOR[®] Syrup can cause side effects. Although not every patient experiences them. The most common side effects with loratadine in children aged 2 to 12 years old are headaches, restlessness and fatigue. The most common side effects in adults and adolescents are drowsiness, headaches, increased appetite and trouble sleeping. Since BILOR[®] Syrup was released on the market, very rare cases of allergic reactions, dizziness, convulsions, acceleration or irregular heartbeat, nausea, dry mouth, upset stomach, liver disorders, hives, rash or skin rash have been reported. There have also been cases of weight gain reported, through their frequency is unknown. Reporting side effects Should you experience any side effects, even some not mentioned in this leaflet, consult your doctor or pharmacist. By reporting side effects you will help provide further information on this medication and make it safer. 5. HOW TO STORE BILOR[®] SYRUP? Store below 30°C, protect from light. Keep out of the reach and sight of children. Do not use after the expiry date indicated after EXP on the box and vial. The expiry date refers to the last day of that month. Shake the bottle after reconstitution, dilution or opening after the first opening. The syrup is stable for 1 month. Do not freeze. Keep the vial in the original packaging in order to protect from light. Do not use this medicine if you notice a change in the appearance of the syrup. Do not dispose of in the sewer or with household wastes. Ask your pharmacist how to dispose of unused drugs. These measures allow protecting the environment. 6. PACK CONTENT AND OTHER INFORMATION What BILOR[®] Syrup contains: Each 5 ml of solution contains: Loratadine 5 mg Flavour Syrup base q.s.p. Excipients with known effect: Sucrose, propylene glycol Other Excipients: Citric acid, methylparaben, propylparaben, citric acid, methylflavour, purified water. What is BILOR[®] Syrup, and outer packaging content BILOR[®] Syrup is packaged in a 60 ml plastic bottle. This leaflet was last updated in 09/2021. If you have any questions about this product or would like to report an adverse reaction contact us by phone : +225 27 21 25 52 38. Manufacturer & operator: MEI PHARMA Rose Belle Building, Unit 3, Rose Belle Business Park, Mauritius. Manufactured by: Dortmund Laboratoires Pvt. Ltd. Dortmund - 421 201, INDIA.	NOTICE INFORMATION DE L'UTILISATEUR BILOR[®] Loratadine Syrup Lisez l'intégralité de cette notice avant de prendre ce médicament car elle contient des informations importantes: - Gardez cette notice, vous pourriez avoir besoin de la relire. - Si vous avez des questions, demandez à votre médecin ou à votre pharmacien. - Ce médicament vous a été personnellement prescrit. Ne le donnez pas à d'autres personnes. Il pourrait leur être nocif, même si les signes de leur maladie sont identiques aux vôtres. - Si vous avez des effets secondaires, y compris les effets secondaires indésirables non mentionnés dans cette notice, faites en part à votre médecin ou à votre pharmacien. Que contient cette notice ? - Qu'est-ce que BILOR[®] Syrup et dans quels cas on en utilise ? - Quelles sont les informations à connaître avant de prendre BILOR[®] Syrup ? - Comment prendre BILOR[®] Syrup ? - Quels sont les effets indésirables éventuels ? - Comment conserver BILOR[®] Syrup ? - Contenu de l'emballage et autres informations. 1. QU'EST-CE QUE BILOR[®] SYRUP ET DANS QUELS CAS EST-IL UTILISÉ ? Principe pharmacologique: substance ANTI-HISTAMINE (USAGE SYSTÉMIQUE) - code ATC: R06AX13 BILOR[®] Syrup est un médicament qui appartient à la classe des antihistaminiques. Les antihistaminiques permettent de réduire les symptômes de l'allergie en évitant les effets d'une substance, l'histamine, qui agit sur votre organisme lorsque vous faites une réaction allergique. BILOR[®] Syrup est indiqué pour soulager les symptômes associés à la rhinite allergique (par exemple: le rhume des foies) tels que les éternuements, le nez qui coule ou qui démange, les yeux qui démangent ou larmoiement. BILOR[®] Syrup est aussi utilisé pour soulager les symptômes associés à l'urticaire chronique idiopathique (démangeaisons, rougeurs, et nombre et taille des plaques d'urticaire). 2. QUELLES SONT LES INFORMATIONS À CONNAÎTRE AVANT DE PRENDRE BILOR[®] SYRUP ? Ne prenez jamais BILOR[®] Syrup: - si vous êtes allergique (hypersensible) à la substance active (loratadine) ou à l'un des autres composants contenus dans ce médicament, mentionnés dans la notice. Avertissements et précautions Adressez-vous à votre médecin ou pharmacien avant de prendre BILOR[®] Syrup. Prévenez votre médecin ou votre pharmacien en cas de maladie grave du foie. Si votre médecin vous a informé d'une intolérance à certains sucres, contactez-le avant de prendre ce médicament. L'utilisation de ce médicament est déconseillée chez les patients présentant une intolérance au fructose. Signalez à votre médecin que vous prenez ce médicament si vous présentez un test cutané pour le diagnostic d'une allergie. Quel que soit le traitement, il doit être interrompu 48 heures avant le test car ce médicament peut en fausser le résultat. EN CAS DE DOUTE, IL EST INDISPENSABLE DE DEMANDER L'AVIS DE VOTRE MÉDECIN OU DE VOTRE PHARMACIEN. Enfants Autres médicaments et BILOR[®] Syrup Informez votre médecin ou pharmacien si vous prenez, avez récemment pris ou pourriez prendre tout autre médicament. BILOR[®] Syrup avec des aliments, boissons et de l'alcool BILOR[®] Syrup peut être pris pendant ou en dehors des repas. Grossesse et allaitement Si vous êtes enceinte ou que vous allaitez, si vous pensez être enceinte ou planifiez une grossesse, demandez conseil à votre médecin ou pharmacien avant de prendre ce médicament. L'utilisation de ce médicament est déconseillée, sauf avis contraire de votre médecin, pendant la grossesse. Si vous découvrez que vous êtes enceinte pendant le traitement, consultez rapidement votre médecin. Il s'agit pour juger du traitement adapté à votre état. Ce médicament passe dans le lait maternel. En conséquence, l'utilisation de ce médicament est déconseillée en cas d'allaitement. Conduite de véhicules et utilisation de machines A la dose thérapeutique, BILOR[®] Syrup ne rend généralement pas somnolent et ne diminue pas la vigilance. Cependant, très rarement ont été rapportés des cas de somnolence susceptible d'affecter l'aptitude à conduire ou à utiliser des machines. 3. COMMENT PRENDRE BILOR[®] SYRUP ? Validez à chaque fois la prise de médicament en suivant soigneusement les indications de votre médecin ou pharmacien. Vérifiez auprès de votre médecin ou pharmacien en cas de doute. Possibilité: - Adultes et adolescents (12 ans et plus): 10 mg une fois par jour soit 10 ml (2 cuillères-mesure de 5 ml) de sirop une fois par jour. - Enfants de 2 à 12 ans: - Enfant pesant plus de 30 kg: 10 ml (10 mg) soit 2 cuillères-mesure de 5 ml de sirop une fois par jour. - Enfant pesant moins de 30 kg: 5 ml (5 mg) soit 1 cuillère-mesure de 5 ml de sirop une fois par jour. - Siège d'une insuffisance hépatique sévère: la dose devra être diminuée.
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English

English

Front

French