

2024 דצמבר

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הגדון: עדכון נוסח ההתוויות בעלון לרופא של התכשירים שלהלן:

SINGULAIR 4 mg granules for kiddies
SINGULAIR 4 mg chewable tablets for pre-school kids
SINGULAIR 5 mg chewable tablets
SINGULAIR 10 mg tablets

סינגוליר 4 מ"ג גרנולות לקטנטנים
סינגוליר 4 מ"ג טבליות ללעיסה לילדי הגן
סינגוליר 5 מ"ג טבליות ללעיסה
סינגוליר 10 מ"ג טבליות

Composition: Montelukast (as sodium)

שלום רב,

חברת אורגנון פארמה ישראל בע"מ, מבקשת ליידע על עדכון נוסח ההתוויות בעלון לרופא לשם הלימה עם הנוסח ברשיונות התכשירים.
אין כל שינוי נוסף.
להלן נוסח ההתוויות הרשומות לתכשירים בישראל:

SINGULAIR 4 mg Granules for Kiddies

4 mg Granules For Kiddies is indicated in adults and pediatric patients 12 months of age and older for the prophylaxis and chronic treatment of asthma, including prevention of daytime and nighttime symptoms, the treatment of aspirin - sensitive asthmatic patients, and the prevention of exercise - induced bronchoconstriction.

SINGULAIR is effective alone or in combination with other agents used in the maintenance treatment of chronic asthma.

SINGULAIR and inhaled corticosteroids may be used concomitantly with additive effects to control asthma or to reduce the inhaled corticosteroid dose while maintaining clinical stability.

Singulair is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.

Because the benefits of Singulair may not outweigh the risk of neuropsychiatric symptoms in patients with seasonal rhinitis [see Warnings and Precautions (5.1)], reserve use for patients who have an intolerance to alternative therapies.

SINGULAIR 4 mg Chewable tablets for Pre-school kids

Singulair 4 mg Chewable Tablets For Preschool Kids is indicated in pediatric patients 2 years of age and older for the prophylaxis and chronic treatment of asthma, including prevention of daytime and nighttime symptoms, the treatment of aspirin - sensitive asthmatic patients, and the prevention of exercise - induced bronchoconstriction.

SINGULAIR is effective alone or in combination with other agents used in the maintenance treatment of chronic asthma.

SINGULAIR and inhaled corticosteroids may be used concomitantly with additive effects to control asthma or to reduce the inhaled corticosteroid dose while maintaining clinical stability.

SINGULAIR is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.

Because the benefits of SINGULAIR may not outweigh the risk of neuropsychiatric symptoms in patients with seasonal rhinitis [see Warnings and Precautions (5.1)], reserve use for patients who have an intolerance to alternative therapies.

SINGULAIR 5 mg Chewable tablets

Singulair 5 mg is indicated in adults and pediatric patients 6 years of age and older for the prophylaxis and chronic treatment of asthma, including prevention of daytime and nighttime symptoms of the treatment of aspirin - sensitive asthmatic patients, and the prevention of exercise - induced bronchoconstriction.

SINGULAIR is effective alone or in combination with other agents used in the maintenance treatment of chronic asthma.

SINGULAIR and inhaled corticosteroids may be used concomitantly with additive effects to control asthma or to reduce the inhaled corticosteroid dose while maintaining clinical stability.

SINGULAIR is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 6 years of age and older.



Because the benefits of SINGULAIR may not outweigh the risk of neuropsychiatric symptoms in patients with seasonal rhinitis [see Warnings and Precautions (5.1)], reserve use for patients who have an intolerance to alternative therapies.

SINGULAIR 10 mg tablets

Singulair 10 mg is indicated in adults and adolescents 15 years of age and older for the prophylaxis and chronic treatment of asthma, including prevention of daytime and nighttime symptoms, the treatment of aspirin - sensitive asthmatic patients, and the prevention of exercise - induced bronchoconstriction.

SINGULAIR is effective alone or in combination with other agents used in the maintenance treatment of chronic asthma.

SINGULAIR and inhaled corticosteroids may be used concomitantly with additive effects to control asthma or to reduce the inhaled corticosteroid dose while maintaining clinical stability.

SINGULAIR is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 15 years of age and older.

Because the benefits of SINGULAIR may not outweigh the risk of neuropsychiatric symptoms in patients with seasonal rhinitis [see Warnings and Precautions (5.1)], reserve use for patients who have an intolerance to alternative therapies.

למידע מלא ולהוראות מתן מפורטות יש לעיין בעלון לרופא ובעלון לצרכן המאושרים על ידי משרד הבריאות.

Singulair מופץ ע"י חברת נובולוג בע"מ.

בברכה,

עלמה שימן
רוקחת ממונה
אורגנון פארמה ישראל