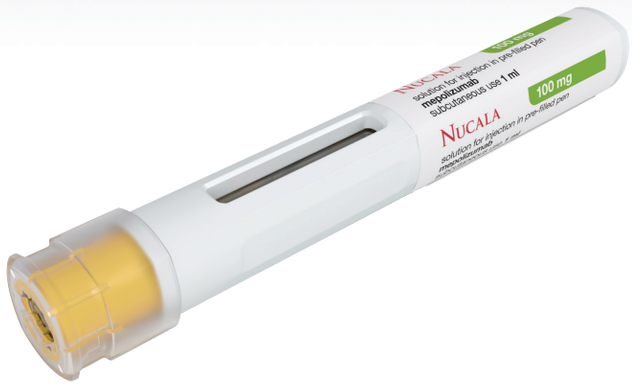
Nucala
mepolizumab

gsk

זמין בכל הקופות



רופא/ה, אח/ות, רוקח/ת נכבד/ה,

חברת GSK שמחה לבשר כי מהיום נוקלה תמיסה להזרקה בעט מזרק מוכן לשימוש זמין בכל הקופות.

Indications: *Severe Asthma:* Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adult patients. *Eosinophilic Granulomatosis with Polyangiitis:* Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

- נוקלה תמיסה להזרקה בעט מזרק מוכן לשימוש מיועד להזרקה עצמית או ע"י מטפל וההחלטה על מעבר לשימוש בו נתונה בידי הרופא המטפל. המעבר לשימוש בעט הוא קל ופשוט ומצריך רק מרשם מתאים.
- ההנחיות להזרקת נוקלה תמיסה להזרקה בעט מזרק מוכן לשימוש נמצאות בעלון לצרכן המצוי באריזת התרופה וזמינות בצורת ברושורים מודפסים ודיגיטליים.
- **קיימת האפשרות לקבל שרות הדרכה למטופלים, הניתן על ידי אחות מוסמכת, בבית המטופל וללא עלות.**

בחר Nucala לשמירה על איזון לטווח ארוך

86%
ירידה בהחמרות ביחס לבייסליין[2]

65%
מהמטופלים נגמלו מ OCS לאחר שנתיים[2]

ירידה ברמות האאוזינופילים בדם לרמות נורמליות[3,4,5]

מהיום גם בעט מזרק מוכן לשימוש המיועד להזרקה עצמית

לצפייה והדגמה נוחה באמצעות סרטון אנא הכנס לכתובת:

www.nucala.co.il

סיסמה: נוקלה

לרשותכם בכל שאלה,

בברכה,

נתלי שומרוני בנאי
מנהלת מוצר

קארין איינהורן
יועצת מדעית

References

1. Nucala PI approved by MOH.
2. Taille C, Chanez P, Devouassoux G *et al*. Mepolizumab in a population with severe eosinophilic asthma and corticosteroid dependence: results from a French early access programme. *Eur Respir j* 2020; 55:1902345; doi: 10.1183/13993003.02345-2019.
3. Hartl S *et al*. balood eosinophil cound in the general population: typical values and potential cofounders. *E ur Respir J 2020;* pii: 1901874. Doi: 10/1183/13993003.01874-2019 [Epub ahead of print].
4. Yancey SW *et al*. Biomarkers for severe eosinophilic asthma. *J. AllergyClin Immunol* 2017; 140:1509-1518.
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Nucala solution for injection in pre-filled pen V1/2021

For full information see MOH approved prescribing information

Indication: Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adult patients and for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Posology and method of administration: Severe Asthma - the recommended dose of mepolizumab is 100 mg administered subcutaneously once every 4 weeks. Nucala is intended for long-term treatment. The need for continued therapy should be considered at least on an annual basis as determined by physician assessment of the patient's disease severity and level of control of exacerbations. Eosinophilic Granulomatosis with Polyangiitis- the recommended dosage of Nucala is 300 mg administered once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections into the upper arm, thigh, or abdomen. Administer individual 100-mg injections at least 5cm (approximately 2 inches) apart.

Method of administration: The pre-filled pen should be used for subcutaneous injection only. Nucala may be self-administered by the patient or administered by a caregiver if their healthcare professional determines that it is appropriate, and the patient or caregiver are trained in injection techniques. For self-administration the recommended injection sites are the abdomen or thigh. A caregiver can also inject Nucala into the upper arm

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions: Mepolizumab should not be used to treat acute asthma exacerbations. Asthma-related adverse symptoms or exacerbations may occur during treatment. Patients should be instructed to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment. Abrupt discontinuation of corticosteroids after initiation of Mepolizumab therapy is not recommended. Reduction In corticosteroid doses, if required, should be gradual and performed under the supervision of a physician. Acute and delayed systemic reactions, including hypersensitivity reactions (e.g. anaphylaxis, urticaria, angioedema, rash, bronchospasm, hypotension), have occurred following administration of Nucala. These reactions generally occur within hours of administration, but in some instances have a delayed onset (i.e. typically within several days). These reactions may occur for the first time after a long duration of treatment. In the event of a hypersensitivity reaction, appropriate treatment as clinically indicated should be initiated. Patients with preexisting helminth infections should be treated before starting therapy. If patients become infected whilst receiving treatment with Nucala and do not respond to anti-helminth treatment, temporary discontinuation of therapy should be considered.

Undesirable effects: in placebo controlled clinical studies in subjects with severe refractory eosinophilic asthma, the most commonly reported adverse reactions during treatment were headache(20%), injection site reactions(8%) and back pain(6%). Very common: headache. Common: lower respiratory tract infection, urinary tract infection, pharyngitis, hypersensitivity reactions (systemic allergic*), nasal congestion, abdominal pain upper, eczema, back pain, administration-related reactions (systemic non allergic**)local injection site reactions, pyrexia.

*Systemic reactions including hypersensitivity have been reported at an overall incidence comparable to that of placebo.

** The most common manifestations associated with reports of systemic non-allergic administration-related reactions were rash, flushing and myalgia; these manifestations were reported infrequently and in <1% of subjects receiving mepolizumab 100 mg subcutaneously

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For full information see MOH approved prescribing information

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