Nucala
mepolizumab

נוקלה מותווית גם לטיפול ב- NP

gsk

רופא/ה, אח/ות, רוקח/ת נכבד/ה,

GSK שמחה לבשר על תוספת אינדיקציה ל- **Nucala** (Mepolizumab) לטיפול בחולים הסובלים מ-
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP).

Indications:

Chronic rhinosinusitis with nasal polyps (CRSwNP)
Nucala is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with corticosteroids and surgery in the last 10 years do not provide adequate disease control.

Severe eosinophilic asthma
Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adult patients.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Hypereosinophilic syndrome (HES)
Nucala is indicated as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause.

Nucala הינה התרופה הביולוגית היחידה המאושרת לטיפול ב- 4 מחלות דלקתיות המאופיינות ברמות גבוהות של אאוזינופילים.

המחקר הקליני ב- Nucala ל- CRSwNP[3,4]

CRSwNP מאופיינת בדלקת כרונית בריריות מעברי האף או בגתות, העלולה להוביל להתפתחות גידולי רקמה רכה המכונים פוליפים באף, ומתאפיינת לעתים קרובות ברמות גבוהות של אאוזינופילים, כאשר לציטוקין IL-5 תפקיד משמעותי בפתולוגיה של המחלה.

מטופלים עם CRSwNP, ובעיקר אלה הסובלים ממחלה חמורה, עשויים להיות תלויים בטיפול בסטרואידים פומיים, ועלולים להזדקק לטיפולים כירורגיים חוזרים ונשנים על רקע הופעה מחודשת של גידולים כדי להתמודד עם המחלה.

Nucala מאושרת כיום כטיפול משלים לקורטיקוסטרואידים במתן לתוך האף למטופלים בוגרים עם CRSwNP חמורה, שלא ניתן לאזן את מחלתם במידה מספקת באמצעות טיפול מערכתי בקורטיקוסטרואידים ו/או ניתוחים.

המחקר הקליני הראה כי בקרב מטופלים בוגרים עם CRSwNP, אשר עברו לפחות ניתוח קודם אחד, כאשר יותר מ-70% מהם סבלו גם מאסתמה, הטיפול ב-Nucala גרם לשיפור מובהק הן בגודלם של הפוליפים באף (בסוף המחקר שנמשך 52 שבועות) והן במידת החסימה של האף במהלך השבועות 49-52, בהשוואה לפלצבו, כאשר התרופה הוספה לטיפול המקובל. כמו כן, הטיפול הפחית את מספר הניתוחים הנוספים שנדרשו עד לשבוע 52.

בנוסף, מטופלים שקיבלו נוקלה חוו שינוי ממוצע גדול יותר בשיפור חוש הריח ביחס למטופלים שקיבלו פלסבו.

צורת מתן Nucala לטיפול ב- CRSwNP[1,2]

Nucala ניתנת בהזרקה תת עורית פעם ב-4 שבועות

Nucala ניתנת במינון קבוע של 100 מ"ג ללא תלות במשקל המטופל

Nucala משווקת ב-2 פרזנטציות:

- **Nucala powder for solution for injection (100mg)** - המוזרקת ע"י איש צוות רפואי[1].
- **Nucala solution for injection in pre-filled pen (100mg/ml)** - הניתנת להזרקה עצמית[2].

למידע מלא ופרופיל בטיחות, יש לפנות לעלון לרופא המאושר ע"י משרד הבריאות.

לרשותכם בכל שאלה

בברכה,

נתלי שומרוני בנאי
מנהלת מוצר

קארין איינהורן
יועצת מדעית

References

1 Nucala powder for solution for injection - העלון לרופא המאושר ע"י משרד הבריאות

2. Nucala solution for injection in pre-filled pen - העלון לרופא המאושר ע"י משרד הבריאות

3. Hopkins et al. Lancet Respir Med 2021; 9: 1141–53

4. Poster 481; Mullol j;American Academy of Allergy Asthma & Immunology Annual Meeting;2022

Main safety for Nucala solution for injection and Nucala powder for solution for injection V4_5/2022

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. **Chronic rhinosinusitis with nasal polyps (CRSwNP)** Nucala is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with corticosteroids and surgery in the last 10 years do not provide adequate disease control. Eosinophilic Granulomatosis with Polyangiitis (EGPA) Nucala is indicated for the treatment of adult patients with **eosinophilic granulomatosis with polyangiitis (EGPA)**. Hypereosinophilic syndrome (HES) Nucala is indicated as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause. **Posology and method of administration:** Nucala should be prescribed by physicians experienced in the diagnosis and treatment of severe refractory eosinophilic asthma, CRSwNP, EGPA or HES. Severe eosinophilic asthma Adults 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. CRSwNP Adults The recommended dose of mepolizumab is 100 mg administered subcutaneously once every 4 weeks. Nucala is intended for long-term treatment. Consideration can be given to alternative treatments in patients who have shown no response after 24 weeks of treatment for CRSwNP. Some patients with initial partial response may subsequently improve with continued treatment beyond 24 weeks. EGPA Adults 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 [see Special precautions for disposal and other handling (6.6)]. Administer individual 100-mg injections at least 5 cm (approximately 2 inches) apart. HES Adults The recommended dose of mepolizumab is 300 mg administered subcutaneously once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections into the upper arm, thigh, or abdomen [see Special precautions for disposal and other handling (6.6)]. Administer individual 100-mg injections at least 5 cm (approximately 2 inches) apart. Nucala is intended for long-term treatment. The need for continued therapy should be reviewed at least on an annual basis as determined by physician assessment of the patient's disease severity and level of symptom control. Patients who develop life-threatening manifestations of HES should also be evaluated for the need for continued therapy, as Nucala has not been studied in this population. **Method of administration for Nucala solution for injection only:** 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. **Method of administration for Nucala powder only:** Each vial contains 100 mg mepolizumab. After reconstitution, each ml of solution contains 100 mg mepolizumab. Nucala is for subcutaneous injection only and should be administered by a healthcare professional. It may be injected into the upper arm, thigh, or abdomen. The powder should be reconstituted prior to administration and the reconstituted solution should be used immediately. Each vial of mepolizumab should be used for a single patient, and any remainder of the vial should be discarded. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Traceability In order to improve the traceability of biological medicinal products, the name of the administered product should be clearly recorded. it is recommended to record the batch number as well. Asthma exacerbations 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. Corticosteroids 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. **Hypersensitivity and administration-related reactions** Acute and delayed systemic reactions, including hypersensitivity reactions (e.g. anaphylaxis, urticaria, angioedema, rash, bronchospasm, hypotension), have occurred following administration of mepolizumab. 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 (see section 4.8). In the event of a hypersensitivity reaction, appropriate treatment as clinically indicated should be initiated. Parasitic infections Eosinophils may be involved in the immunological response to some helminth infections. Patients with pre-existing helminth infections should be treated before starting therapy. If patients become infected whilst receiving treatment with mepolizumab and do not respond to anti-helminth treatment, temporary discontinuation of therapy should be considered. **Undesirable effects** Summary of the safety profile Severe eosinophilic asthma In placebo-controlled 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%).CRSwNP In a placebo-controlled study in patients with CRSwNP, the most commonly reported adverse reactions during treatment were headache (18%) and back pain (7%). EGPA In a placebo-controlled study in patients with EGPA, the most commonly reported adverse reactions during treatment were headache (32%), injection site reactions (15%) and back pain (13%). Systemic allergic/hypersensitivity reactions were reported by 4% of EGPA patients. HES In a placebo-controlled study in patients with HES, the most commonly reported adverse reactions during treatment were headache (13%), urinary tract infection (9%), injection site reactions and pyrexia (7% each). **Special data from clinical studies:** HES Haemorrhage In phase 3 placebo-controlled study 200622, a higher number of subjects reporting hemorrhages was observed for mepolizumab 300 mg SC group (10/54 patients, 19%) compared to the placebo arm, (4/54 patients, 7%). The majority of cases were mild or moderate in intensity and resolved. 5 out of 10 of the patients treated mepolizumab had concomitant medications that could increase the risk of bleeding (including anticoagulants). No causal relationship with mepolizumab has been determined yet.

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