

אוקטובר 2022

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: עדכון בעל הרישום וכתובתו ושם היצרן וכתובתו בעלונים לרופא ולצרכן
בעקבות העברת בעל הרישום של תכשירים מ-MSD ל-ORGANON

בהמשך להודעתנו מפברואר 2022, על העברת בעל הרישום החל מ- 01/03/2022 מחברת מרק שארפ ודוהם (ישראל- 1996) בע"מ ("MSD") לחברת אורגנון פארמה ישראל בע"מ ("ORGANON Pharma Israel Ltd."), חלו השינויים הבאים בעלונים לרופא ולצרכן של התכשירים המפורטים בטבלה מטה.

- שם בעל הרישום שונה ל-אורגנון פארמה ישראל בע"מ, עתיר ידע 1, כפר סבא
- שם היצרן שונה ל-אורגנון LLC, ניו ג'רזי ארה"ב

העלונים לרופא והעלונים לצרכן נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, חברת אורגנון פארמה ישראל, במייל: organon.ra.israel@organon.com

כל התכשירים מופצים ע"י חברת נובולוג בע"מ.

בברכה,

עלמה שימן
רוקחת ממונה
אורגנון פארמה ישראל

שם התכשיר באנגלית	שם התכשיר בעברית	צורה	הרכב וחוזק	התוויה
Aerius tablets	אריוס טבליות	Tablets	Desloratadine 5mg	indicated in adults and adolescents aged 12 years and older for the relief of symptoms associated with: - allergic rhinitis - urticaria
Arcoxia 30 mg Tablets	ארקוקסיה 30 מ"ג טבליות	Tablets	Etoricoxib 30 mg	Arcoxia tablets are indicated for the symptomatic relief of osteoarthritis (OA).
Arcoxia 60 mg Tablets	ארקוקסיה 60 מ"ג טבליות	Tablets	Etoricoxib 60 mg	Arcoxia 60 mg tablets are indicated for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis.
Arcoxia 90 mg Tablets	ארקוקסיה 90 מ"ג טבליות	Tablets	Etoricoxib 90 mg	Arcoxia 90 mg tablets are indicated for the symptomatic relief of rheumatoid arthritis (RA) and ankylosing spondylitis. For the short-term treatment of moderate pain

				associated with dental surgery.
Arcoxia 120 mg Tablets	ארקוקסיה 120 מ"ג טבליות	Tablets	Etoricoxib 120 mg	Arcoxia 120 mg tablets are indicated for the symptomatic relief of the pain and signs of inflammation associated with acute gouty arthritis
Atozet 10 mg/10 mg	אטוזט 10 מ"ג/10 מ"ג	Film coated tablets	Atorvastatin 10 mg Ezetimibe 10 mg	Prevention of Cardiovascular Events Atozet is indicated to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not. - Hypercholesterolaemia Atozet is indicated as adjunctive therapy to diet for use in adults with primary (heterozygous familial and nonfamilial) hypercholesterolaemia or mixed hyperlipidaemia where use of a combination product is appropriate •patients not appropriately controlled with a statin alone •patients already treated with a statin and ezetimibe - Homozygous Familial Hypercholesterolaemia (HoFH) Atozet is indicated as adjunctive therapy to diet for use in adults with HoFH. Patients may also receive adjunctive treatments (e.g., low-density lipoprotein [LDL] apheresis).
Atozet 10 mg/20 mg	אטוזט 10 מ"ג/20 מ"ג	Film coated tablets	Atorvastatin 10 mg Ezetimibe 20 mg	
Atozet 10 mg/40 mg	אטוזט 10 מ"ג/40 מ"ג	Film coated tablets	Atorvastatin 10 mg Ezetimibe 40 mg	
Atozet 10 mg/80 mg	אטוזט 10 מ"ג/80 מ"ג	Film coated tablets	Atorvastatin 10 mg Ezetimibe 80 mg	
Celestone Chronodose	צלסטון כרונודוז	Suspension for Injection	Betamethasone Acetate 3 mg/mL Betamethasone Sodium Phosphate 3.945 mg/mL	Indicated in the management of conditions known to be responsive to corticosteroid therapy.
Cerazette	סרזט	Film coated tablets	Desogestrel 0.075 mg	Contraceptive.
Diprogenta Cream	דיפרוג'נטה קרם	Cream	Gentamicin (as sulfate) 1 mg/g Betamethasone (as dipropionate) 0.5 mg/g	For the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses when complicated by secondary infections caused by organisms susceptible to gentamycin.

Diprogenta Ointment	דיפרוג'נטה משחה	Ointment	Betamethasone (as dipropionate) 0.5 mg/g Gentamicin (as sulfate) 1 mg/g	Topical treatment of dermatosis complicated by secondary infection caused by organisms sensitive to Gentamicin
Diprosalic Lotion	דיפרוסאליק תרחיץ	Lotion	Salicylic acid 20 mg/g Betamethasone (as dipropionate) 0.5 mg/g	Provides anti-inflammatory, antipruritic, anti-allergic and keratinolytic activity in the topical management of subacute and chronic hyperkeratotic and dry dermatoses responsive to corticosteroid therapy
Diprosalic Ointment	דיפרוסאליק משחה	Ointment	Salicylic acid 30 mg/g Betamethasone (as dipropionate) 0.5 mg/g	Provides anti inflammatory, antipruritic, anti allergic and chronic hyperkeratotic and dry keratolytic activity in the topical management of subacute dermatoses responsive to corticosteroid therapy.
Diprospan Injection	דיפרוספאן זריקה	Suspension for Injection	Betmethasone sodium phosphate 2 mg/mL Betamethasone (as dipropionate) 5 mg/mL	Produces anti-inflammatory, anti rheumatic and anti-allergic action and is indicated for systemic and local therapy of acute and chronic corticosteroid-responsive disorders.
Elocom cream	אלוקום קרם	Cream	Mometasone furoate 0.1%	For the relief of the inflammatory and pruritic manifestations of corticosteroid - responsive dermatoses such as psoriasis and atopic dermatitis.
Elocom ointment	אלוקום משחה	Ointment	Mometasone furoate 0.1%	For the relief of the inflammatory and pruritic manifestations of corticosteroid - responsive dermatoses such as psoriasis and atopic dermatitis.
Elocom lotion	אלוקום תרחיץ	Lotion	Mometasone furoate 1 mg/g	The relief of the inflammatory and pruritic manifestations of corticosteroid - responsive dermatoses, such as psoriasis and atopic dermatitis.
Elonva 100 mcg/0.5 ml	אלונבה 100 מק"ג/0.5 מ"ל	Solution for Injection	Corifollitropin alfa 100 mcg/0.5 mL	Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program.
Elonva 150 mcg/0.5 ml	אלונבה 150 מק"ג/0.5 מ"ל	Solution for Injection	Corifollitropin alfa 150 mcg/0.5 mL	

Ezetrol 10 mg	מ"ג טבליות אזטרול 10	Tablets	ezetimibe	<p>Primary hypercholesterolemia: Ezetrol administered with an HMG-CoA reductase inhibitor (statin) or alone are indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolemia. Homozygous familial hypercholesterolemia (HoFH): Ezetrol administered with a statin are indicated for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis). Homozygous sitosterolemia (Phytosterolemia): Ezetrol are indicated for use in patients with homozygous familial sitosterolemia.</p>
Fosalan Once-Weekly 70 mg	פוסאלאן פעם בשבוע 70 מ"ג	Tablets	Alendronate (as sodium) 70 mg	<p>Fosalan is indicated for the treatment of osteoporosis in postmenopausal women to prevent fractures, including those of the hip and spine (vertebral compression fractures). Treatment to increase bone mass in men with osteoporosis.</p>
Fosavance 70 mg/ 5600 I.U. Tablets	פוסאוונס 70 מ"ג/ג 5600 יחב"ל טבליות	Tablets	Colecalciferol 140 mcg Alendronic acid (as alendronate sodium trihydrate) 70 mg	<p>Fosavance is indicated for:</p> <ul style="list-style-type: none"> - Treatment of Osteoporosis in postmenopausal women: Fosavance increases bone mass and reduces the incidence of fractures, including those of the hip and spine (vertebral compression fractures). - Treatment to increase bone mass in men with osteoporosis.
Livial 2.5 mg	מ"ג ליויאל 2.5	Tablets	Tibolone 2.5 mg	<ul style="list-style-type: none"> • Complaints resulting from the natural or artificial menopause. <p>Treatment of oestrogen deficiency symptoms in postmenopausal women, more than one year after menopause. Women above 60 years of age should only start with Livial treatment when they are intolerant of, or</p>

				<p>contraindicated for, other medicinal products approved for the treatment of oestrogen deficiency symptoms.</p> <ul style="list-style-type: none"> • Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. <p>For all women the decision to prescribe tibolone Livial should be based on an assessment of the individual patient's overall risks and, particularly in the over 60s, should include consideration of the risk of stroke.</p>
Mercilon	מרסילון	Tablets	Desogestrel 150 mcg Ethinylestradiol 20 mcg	Oral contraception
NuvaRing	נובריןג	Vaginal Ring	Ethinylestradiol 2.7 mg Etonogestrel 11.7 mg	Contraception. The safety and efficacy has been established in women aged 18 to 40 years.
Ocsaar 50 mg	אוקסאאר 50 מ"ג	Tablets	Losartan potassium 50 mg	<p>Hypertension: Ocsaar 50 mg is indicated for the treatment of hypertension</p> <p>Heart failure: Ocsaar 50 mg is indicated for the treatment of heart failure, usually in addition to diuretics and/or digitalis, if use of an ACE inhibitor is not appropriate.</p> <p>Switching patients with heart failure who are stable on an ACE inhibitor to Ocsaar 50 mg is not recommended.</p> <p>Renal protection in Type-2 diabetic patients with proteinuria: Ocsaar 50 mg is indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or</p>

				<p>death; and to reduce proteinuria.</p> <p>Reduction in the risk of cardiovascular morbidity and mortality in hypertensive patients with left ventricular hypertrophy.</p> <p>Ocsaar 50 mg is indicated to reduce the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke, and myocardial infarction in hypertensive patients with left ventricular hypertrophy.</p> <p>The benefit of Ocsaar 50 mg on the primary composite endpoint was largely driven by reduction in the risk of stroke.</p>
Ocsaar Plus	אוקסאאר פלוס	Tablets	Losartan potassium 50 mg Hydrochlorothiazide 12.5 mg	Ocsaar plus is indicated for the treatment of hypertension, for patients in whom combination therapy is appropriate. To reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy.
Orgalutran 0.25mg / 0.5ml pre-filled Syringe	אורגלוטרן 0.25 מ"ג/0.5 מ"ל	Solution for Injection	Ganirelix 0.25 mg/ 0.5 mL	The prevention of premature luteinizing hormone (LT) surges in women undergoing controlled ovarian hyperstimulation (COH) for assisted reproduction techniques (ART).
Propecia	פרופסיה	Film coated tablets	Finasteride 1 mg	Propecia is indicated for the treatment of men with male pattern hair loss (androgenetic alopecia) to increase hair growth and prevent further hair loss
Puregon solution for injection	פירגון תמיסה להזרקה	Solution for injection	Follitropin Beta	Puregon is indicated for the treatment of female infertility in the following clinical situations: Anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with clomiphene citrate. Controlled ovarian hyperstimulation to induce the development of multiple follicles in medically assisted reproduction programs [e.g. in vitro fertilisation/embryo transfer

				(IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)]. In the male: Deficient spermatogenesis due to hypogonadotrophic hypogonadism.
Rizalt 10 mg Tablets	ריזלט 10 מ"ג טבליות	Tablets	Rizatriptan (as benzoate) 10 mg	Rizalt is indicated for the acute treatment of migraine attacks with or without aura in adults.
Rizalt RPD 10 mg Wafers	ריזלט אר.פי.די 10 מ"ג טבליות מסיסות	Soluble in mouth tablets	Rizatriptan (as benzoate) 10 mg	Rizalt is indicated for the acute treatment of migraine attacks with or without aura in adults.
Sinemet CR	סינמט CR	Controlled release tablets	Levidopa 200 mg Carbidopa (as monohydrate) 50 mg	Idiopathic parkinson's disease. Postencephalitic parkinsonism. Symptomatic parkinsonism. To reduce "off" time in patients previously treated with levodopa/ decarboxylase inhibitor preparations, or with levodopa alone, who have had motor fluctuations characterized by end-of dose deterioration ("wearing-off" phenomenon), peak dose dyskinesias, akinesia, or similar evidence of short-duration motor disturbances.
Singulair 4 mg Chewable Tablets for Preschool Kids	סינגוליר 4 מ"ג טבליות ללעיסה לילדי הגן	Chewable tablets	Montelukast (as sodium) 4 mg	Singulair 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.

				Singular is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.
Singulair 4 mg Granules for Kiddies	סינגוליייר 4 מ"ג גרנולות לקטנטנים	Granules	Montelukast (as sodium) 4 mg	Singulair is indicated in adult 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 5 mg Chewable Tablets	סינגוליייר 5 מ"ג טבליות ללעיסה	Chewable tablets	Montelukast (as sodium) 5 mg	Singulair is indicated in adult and pediatric patients 6 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.

Singular 10 mg Tablets	סינגוליר 10 מ"ג טבליות	Tablets	Montelukast (as sodium) 10 mg	Singular is indicated in adult and 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. Singular is effective alone or in combination with other agents used in the maintenance treatment of chronic asthma. Singular and inhaled corticosteroids may be used concomitantly with additive effects to control asthma or to reduce the inhaled corticosteroid dose while maintaining clinical stability. Singular is indicated for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.
Triderm Cream	טרידרם קרם	Cream	Clotrimazole 10 mg/g Betamethasone (as dipropionate) 0.5 mg/g Gentamicin (as sulfate) 1 mg/g	Treatment of corticosteroid-responsive dermatoses when complicated by infections caused by bacteria (sensitive to gentamicin) and fungi (sensitive to clotrimazole) or when the possibility of such infections is suspected. The cream is suitable for the use of oozing eczema.