

דצמבר 2021

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא ובעלון לצרכן של התכשירים:

Prezista 400mg
Prezista 600mg

המאושר להתוויה הבאה:

Prezista, co-administered with 100 mg ritonavir (Prezista/rtv), and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus (HIV-1) infection for over 18 years of age.

השינויים המהותיים בעלונים לרופא (Prezista 400mg, Prezista 600mg) מופיעים בסעיפים הבאים:

עלון לרופא Prezista 400mg

4.2 Posology and method of administration

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Elderly

Limited information is available in this population, and therefore, PREZISTA should be used with caution in this age group (see sections 4.4 and 5.2)

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4.4 Special warnings and precautions for use

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PREZISTA 400mg tablets contain sunset yellow FCF (E110) which may cause an allergic reaction.

PREZISTA 400 mg mg tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

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INTERACTIONS AND DOSE RECOMMENDATIONS WITH OTHER MEDICINAL PRODUCTS		
Medicinal products by therapeutic areas	Interaction Geometric mean change (%)	Recommendations concerning co-administration

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CORTICOSTEROIDS		
Corticosteroids primarily metabolised by CYP3A (including betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone)	Fluticasone: in a clinical study where ritonavir 100 mg capsules twice daily were co-administered with 50 µg intranasal fluticasone propionate (4 times daily) for 7 days in healthy subjects, fluticasone propionate plasma concentrations increased significantly, whereas the intrinsic cortisol levels decreased by approximately 86% (90% CI 82-89%). Greater effects may be expected when fluticasone is inhaled. Systemic corticosteroid effects including Cushing's syndrome and adrenal suppression have been reported in patients receiving ritonavir and inhaled or intranasally administered fluticasone. The effects of high fluticasone systemic exposure on ritonavir plasma levels are unknown. Other corticosteroids: interaction not studied. Plasma concentrations of these medicinal products may be increased when co-administered with boosted PREZISTA, resulting in reduced serum cortisol concentrations.	Concomitant use of boosted PREZISTA and corticosteroids <u>(all routes of administration)</u> that are metabolised by CYP3A (e.g. fluticasone propionate or other inhaled or nasal corticosteroids) may increase the risk of development of systemic corticosteroid effects, including Cushing's syndrome and adrenal suppression. Co-administration with CYP3A-metabolised corticosteroids is not recommended unless the potential benefit to the patient outweighs the risk, in which case patients should be monitored for systemic corticosteroid effects. Alternative corticosteroids which are less dependent on CYP3A metabolism e.g. beclomethasone for intranasal or inhalational use should be considered, particularly for long term use.
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עלון לרופא Prezista 600mg

4.5 Interaction with other medicinal products and other forms of interaction

INTERACTIONS AND DOSE RECOMMENDATIONS WITH OTHER MEDICINAL PRODUCTS		
Medicinal products by therapeutic areas	Interaction Geometric mean change (%)	Recommendations concerning co-administration

...	...	...
CORTICOSTEROIDS		
Corticosteroids primarily metabolised by CYP3A (including betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone..)	Fluticasone: in a clinical study where ritonavir 100 mg capsules twice daily were co-administered with 50 µg intranasal fluticasone propionate (4 times daily) for 7 days in healthy subjects, fluticasone propionate plasma concentrations increased significantly, whereas the intrinsic cortisol levels decreased by approximately 86% (90% CI 82-89%). Greater effects may be expected when fluticasone is inhaled. Systemic corticosteroid effects including Cushing's syndrome and adrenal suppression have been reported in patients receiving ritonavir and inhaled or intranasally administered fluticasone. The effects of high fluticasone systemic exposure on ritonavir plasma levels are unknown. Other corticosteroids: interaction not studied. Plasma concentrations of these medicinal products may be increased when co-administered with PREZISTA with low dose ritonavir, resulting in reduced serum cortisol concentrations.	Concomitant use of PREZISTA with low dose ritonavir and corticosteroids (<u>all routes of administration</u>) that are metabolised by CYP3A (<u>e.g. fluticasone propionate or other inhaled or nasal corticosteroids</u>) may increase the risk of development of systemic corticosteroid effects, including Cushing's syndrome and adrenal suppression. Co-administration with CYP3A-metabolised corticosteroids is not recommended unless the potential benefit to the patient outweighs the risk, in which case patients should be monitored for systemic corticosteroid effects. Alternative corticosteroids which are less dependent on CYP3A metabolism e.g. beclomethasone for <u>intranasal or inhalational use</u> should be considered, particularly for long term use.
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השינויים המהותיים בעלון לצרכן (המשותף) מופיעים בסעיפים הבאים:

תגובות בין תרופתיות

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קורטיקוסטרואידים לרבות בטאמתאזון, בודסוניד, פלוטיקאזון, מומטאזון, פרדניזון, טריאמיניולון. תרופות אלו משמשות לטיפול באלרגיות, אסתמה, מחלות מעי דלקתיות, מצבים דלקתיים בעור, בעיניים, במפרקים ובשרירים ומצבים דלקתיים אחרים. תרופות אלה נלקחות בדרך כלל דרך הפה, בשאיפה, בהזרקה או במריחה על העור. אם לא ניתן לטפל באמצעים חלופיים, יש להשתמש בהן רק לאחר הערכה רפואית ותחת ניטור צמוד של הרופא לתופעות לוואי של קורטיקוסטרואידים.

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6. מידע נוסף

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פרויקט 600 מ"ג:

ליבת הטבלה:

Silicified Microcrystalline cellulose ,crospovidone ,magnesium stearate.

ציפוי הטבלה:

OPADRY ® II Orange85 F 13962 contains :polyvinyl alcohol – partially hydrolyzed ,macrogol/PEG , titanium dioxide ,talc ,FD&C Yellow No/6.Sunset Yellow FCF aluminum lake.

התרופה מכילה פחות מ-1 מילימול סודיום (23 מ"ג) ליחידת מינון, ולכן למעשה ניתן לומר כי היא "ללא נתרן".

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העלון לרופא והעלון לצרכן נשלחו לפרסום במלואם למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבל מודפסים בפניה אלינו לטלפון 09-9591111 .

בברכה,
צפירי כהן
רוקח ממונה