פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

דצמבר 2022

רופא/ה, רוקח/ת נכבד/ה, ברצוננו להודיעך על עדכון בעלון לרופא ולצרכן עבור:

IXIFI 162-94-35522-00

אִיקְסִיפִי

Indicated for :

Adult Crohn's disease

IXIFI is indicated for treatment:

• of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and

adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

• treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).

Ulcerative colitis

•IXIFI is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

Rheumatoid arthritis

IXIFI, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in:

•adult patients with active disease when the response to disease modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate.

•adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs.

In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X ray, has been demonstrated.

Ankylosing spondylitis

IXIFI is indicated for treatment of severe, active ankylosing spondylitis, in adult patients who have responded inadequately to conventional therapy.

Psoriatic arthritis

IXIFI is indicated for treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate.

* IXIFI should be administered:

• in combination with methotrexate

• or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated.

Infliximab has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X ray in patients with polyarticular symmetrical subtypes of the disease.

Psoriasis

IXIFI is indicated for treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen ultra-violet A (PUVA)

להלן העדכונים העיקריים בעלון לרופא:

4.4 Special warnings and precautions for use

Infant exposure *in utero*

In infants exposed *in utero* to infliximab, fatal outcome due to disseminated Bacillus Calmette-Guérin (BCG) infection has been reported following administration of BCG vaccine after birth. Administration of live vaccines to infants exposed to infliximab *in utero* is not recommended for 6 months after birth. A twelve month waiting period following birth is recommended before the administration of BCG vaccine to infants exposed *in utero* to infliximab.. If infant infliximab serum levels are undetectable or infliximab administration was limited to the first trimester of pregnancy, administration of a live vaccine might be considered at an earlier timepoint if there is a clear clinical benefit for the individual infant (see section 4.6).

Infant exposure via breast milk

~~Administration of a live vaccine to a breastfed infant while the mother is receiving infliximab is not recommended unless infant infliximab serum levels are undetectable (see section 4.6).~~ live vaccines can be administered to a breastfed infant when the mother is receiving infliximab as long as infant infliximab serum levels are monitored.

4.5 Interaction with other medicinal products and other forms of interaction

It is recommended that live vaccines not be given concurrently with Ixifi®. It is also recommended that live vaccines not be given to infants after *in utero* exposure to infliximab for ~~12~~ 6 months following birth, except to BCG vaccine where administration is not recommended for 12 months after birth. If infant infliximab serum levels are undetectable or infliximab administration was limited to the first trimester of pregnancy, administration of a live vaccine might be considered at
an earlier timepoint if there is a clear clinical benefit for the individual infant (see section 4.4).

~~Administration of a~~ A live vaccine can be administered to a breastfed infant while the mother is receiving infliximab ~~is not recommended~~ as long as ~~unless~~ infant infliximab serum levels are ~~undetectable~~ monitored (see sections 4.4 and 4.6).

4.6 Fertility, pregnancy and lactation

Infliximab crosses the placenta and has been detected in the serum of infants up to 12 months following birth. After *in utero* exposure to infliximab, infants may be at increased risk of infection, including serious disseminated infection that can become fatal. Administration of live vaccines (~~e.g. BCG vaccine~~) to infants exposed to infliximab *in utero* is not recommended for ~~12~~ 6 months after birth except to BCG vaccine where administration is not recommended for 12 months after birth (see sections 4.4 and 4.5). If infant infliximab serum levels are undetectable or infliximab administration was limited to the first trimester of pregnancy, administration of a live vaccine might be considered at an earlier timepoint if there is a clear clinical benefit for the individual infant.
Cases of agranulocytosis have also been reported (see section 4.8).

Breast-feeding

Limited data from published literature indicate infliximab has been detected at low levels in human milk at concentrations up to 5% of the maternal serum level. Infliximab has also been detected in infant serum after exposure to infliximab via breast milk. ~~While~~ systemic exposure in a breastfed infant is expected to be low because infliximab is largely degraded in the gastrointestinal tract, ~~the administration of~~ live vaccines can be administered to a breastfed infant when the mother is receiving infliximab ~~is not recommended~~ as long as infant infliximab serum levels are ~~undetectable~~ monitored. Infliximab could be considered for use during breast-feeding

<u>להלן העדכונים העיקריים בעלון לצרכן:</u>

אזהרות מיוחדות הנוגעות לשימוש בתרופה

היריון, הנקה ופוריות

- חשוב לידע את הרופא של תינוקך ואנשי צוות רפואי אחרים בנוגע לשימוש שלך באיקסיפי לפני שהתינוק מקבל כל חיסון. אם קיבלת איקסיפי במהלך ההיריון, ~~מתן~~ אין לתת חיסון BCG (המשמש למנוע שחפת) לתינוקך ~~תוך~~ במשך 12 חודשים מהלידה ~~עלול לגרום לזיהום עם סיבוכים חמורים, כולל מוות~~. אין לתת חיסונים 'חיים', ~~כדוגמת חיסון BCG~~ , לתינוקך במשך ~~12~~ 6 חודשים ~~אחרי~~ מהלידה אלא אם הרופא של תינוקך ממליץ אחרת. למידע נוסף ראי סעיף "חיסונים".
- אם את מניקה, חשוב ליידע את רופא הילדים והצוות הרפואי שאת נוטלת איקסיפי לפני שתינוקך מקבל חיסון כלשהו. ~~אין~~ ניתן לתת חיסונים חיים לתינוקך בזמן שאת מניקה, בכפוף לניטור רמות התרופה בדם. ~~אלא אם הרופא של תינוקך ממליץ אחרת.~~

העלונים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
.http://www.health.gov.il/units/pharmacy/trufot/index.asp
לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת: פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133 , הרצליה פיתוח, 46725

בכבוד רב,
אורטל עבודי
רוקחת ממונה