נובמבר 2024

הנדון:

<u>Rotarix™ Suspension/רוטריקס תרחיף</u>

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין (ישראל) בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר רוטריקס תרחיף/ Rotarix suspension + הכנת עלון לצרכן.

בעדכון זה נעשה מעבר ממדינת ייחוס UK לעלון אירופאי. לא נעשה כל שינוי בהתוויות התכשיר ובמשטר המינון.

מרכיב פעיל וחוזקו:

LIVE ATTENUATED HUMAN ROTAVIRUS RIX4414 STRAIN (Not less than 1000000 CCID50)

ההתוויה המעודכנת המאושרת ע"י משרד הבריאות:

Rotarix is indicated for the active immunization of infants from the age of 6 weeks for prevention of gastro-enteritis due to rotavirus infection.
In clinical trials, efficacy was demonstrated against gastro-enteritis due to rotavirus of types G1P [8], G2P[4], G3P[8], G4P[8] and G9P[8].
The use of Rotarix should be based on official recommendations.

בהודעה זו כלולים השינויים המהותיים בלבד. בעלון לרופא ישנם שינויים נוספים.

מקרא לעדכונים המסומנים:

- מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~
- תוספת – כתב כחול
- תוספת החמרה - כתב כחול – מסומן בצהוב מרקר
- שינוי מיקום טקסט- כתב ירוק

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

1. Name of the medicinal product

Rotarix Suspension

~~Rotavirus vaccine, live~~

2. Qualitative and quantitative composition

1 dose (1.5 ~~ml~~mL) contains:

Human rotavirus RIX4414 strain (live, attenuated)*	not less than $10^{6.0}$ $CCID_{50}$

*Produced on Vero cells

Excipients with known effect:

This product contains ~~sucrose 1,073 mg and sodium 32 mg~~1073 mg of sucrose, 32 mg of sodium, 10 micrograms of glucose and 0.15 microgram of phenylalanine per dose (see section 4.4).

…

4.4 Special warnings and precautions for use

…

Asymptomatic and mildly symptomatic HIV infections are not expected to affect the safety or efficacy of Rotarix. A clinical study in a limited number of asymptomatic or mildly symptomatic HIV positive infants showed no apparent safety problems (see section 4.8).

Administration of Rotarix to infants who have known or suspected immunodeficiency, including in *utero* exposure to an immunosuppressive treatment, should be based on careful consideration of potential benefits and risks.

…

Excipients

This ~~The~~ vaccine contains sucrose and glucose as ~~an excipient~~excipients. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this vaccine.

This vaccine contains 0.15 microgram phenylalanine in each dose. Phenylalanine may be harmful for patients with phenylketonuria (PKU).

This vaccine contains 32 mg sodium ~~per~~in each dose. ~~To be taken into consideration by patients on a controlled sodium diet.~~

Traceability
order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

…

4.8 Undesirable effects

…

System Organ Class	Frequency	Adverse reactions
Gastrointestinal disorders	Common	Diarrhoea
	Uncommon	Abdominal pain, flatulence
	Very rare	Intussusception (see section 4.4)
	Not known*	Haematochezia
	Not known*	Gastroenteritis with vaccine viral shedding in infants with Severe Combined Immunodeficiency (SCID) disorder
Skin and subcutaneous tissue disorders	Uncommon	Dermatitis
	Very rare	Urticaria
General disorders and administration site conditions	Common	Irritability
Respiratory, thoracic and mediastinal disorders	Not known*	Apnoea in very premature infants (≤ 28 weeks of gestation) (see section 4.4)

***** Because these events were reported spontaneously, it is not possible to reliably estimate their frequency.

…

Other special populations

…

Safety in infants with human immunodeficiency (HIV) infection

In a clinical study, 100 infants with HIV infection were administered Rotarix lyophilised formulation or placebo. The safety profile was similar between Rotarix and placebo recipients.

~~Post-marketing surveillance data~~

~~Gastrointestinal disorders:~~

~~Intussusception (including death), recurrent intussusception (including death)~~

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il

~~(http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il).~~

Additionally, you should also report to GSK Israel (il.safety@gsk.com).

…

6. Pharmaceutical Particulars

6.1 List of excipients

Sucrose

Di-sodium Adipate

Dulbecco's Modified Eagle Medium (DMEM) (containing phenylalanine, sodium, glucose, and other substances)

~~Water for injection~~

Sterile water

…

6.5 Nature and contents of container

~~Oral~~Pre-filled oral applicator

1.5 ~~ml~~mL of **oral** suspension in a pre-filled **oral** applicator (type I glass) with a plunger stopper (rubber butyl) and a protective tip cap (rubber butyl), in pack sizes of 1 or 10.

~~Tube~~

Squeezable tube

1.5 ~~ml~~mL of **oral** suspension in a squeezable tube (polyethylene) fitted with a ~~tip seal~~membrane and a tube cap (~~polyethylene)~~polypropylene), in pack sizes of 1, 10 or 50.

Not all pack sizes may be marketed.

…

למידע נוסף יש לעיין בעלון לרופא ולצרכן המעודכנים.

העלון לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות: מאגר התרופות וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,

מירי עזר שניידר

רוקחת ממונה