

תאריך: 12.2015

שם תכשיר באנגלית: Polio Sabin One and Three

מספר הרישום: 152-84-34035

שם בעל הרישום: GlaxoSmithKline (ISRAEL) Ltd

טופס זה מיועד לפרוט החמרות בלבד!

בעלון לרופא

ההחמרות המבוקשות

פרק בעלון	טקסט נוכחי	טקסט חדש
Fertility, Pregnancy and lactation	<p><u>Pregnancy</u> There is limited data, and even no data, on the use in the pregnant woman of live attenuated poliomyelitis virus from Sabin strains of Type 1 (LSc, 2ab) and of Type 3 (Leon 12a, 1b). Animal studies are insufficient to allow conclusions to be drawn about the toxicity on reproductions (see section 5.3).</p>	<p><u>Pregnancy</u> There is limited data, and even no data, on the use in the pregnant woman of live attenuated poliomyelitis virus from Sabin strains of Type 1 (LSc, 2ab) and of Type 3 (Leon 12a, 1b). Animal studies are insufficient to allow conclusions to be drawn about the toxicity on reproductions (see section 5.3). Polio Sabin One and Three (oral) is not recommended during pregnancy or in woman of childbearing age who do not use contraception.</p>
Undesirable effects		<p>Fever, vomiting and diarrhoea have been observed after immunisation with the Polio Sabin One and Three (oral). Allergic/anaphylactoid reactions have been described after immunisation with GlaxoSmithKline Biological's trivalent oral poliomyelitis vaccine.</p> <p>General disorders and administration site condition Very rare Fever</p> <p>Gastrointestinal disorders Very rare Diarrhoea, vomiting</p> <p>Immune system disorders Very rare Allergic/anaphylactoid reactions</p> <p>Infections and infestations Very rare Vaccine-associated paralysis</p>

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב. שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק.