

**הודעה על החמרה (מידע בטיחות) בעלון לרופא**  
(מעודכן 3102.50)

תאריך **19/10/2014**

**שם תכשיר באנגלית ומספר הרישום 109-12-29094-00 Meliane**

שם בעל הרישום \_\_\_\_\_ באייר ישראל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
Table: Risk factors for ATE (please see below in the form)		4.3 Special warnings and precautions for use

**Table: Risk factors for ATE**

Risk factor	Comment
Increasing age	Particularly above 35 years.
Smoking	Women should be advised not to smoke if they wish to use a CHC. Women over 35 who continue to smoke should be strongly advised to use a different method of contraception.
Hypertension	
Obesity (body mass index over 30 kg/m <sup>2</sup> )	Risk increases substantially as BMI rises.  Particularly important to consider if other risk factors also present.
Positive family history (venous thromboembolism ever in a sibling or parent especially at a relatively early age e.g. before 50).	If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any CHC use.
Migraine	An increase in frequency or severity of migraine during CHC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation
Other medical conditions associated with adverse vascular events	Diabetes mellitus, hyperhomocystenaemia, valvular heart disease and atrial fibrillation, dyslipoproteinaemia and systemic lupus erythematosus