מרץ 2022

Glucomin®, caplets

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא ולצרכן של התכשיר **גלוקומין**. בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלונים.

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000

הרכב התכשיר:

Each caplet contains Metformin Hydrochloride 850mg

ההתוויה המאושרת:

Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control.
• In adults, Glucomin may be used as monotherapy or in combination with other oral anti-diabetic agents or with insulin.
• In children from 10 years of age and adolescents, Glucomin may be used as monotherapy or in combination with insulin.
A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure.

העלון לרופא עודכן במרץ 2022 להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

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4. CLINICAL PARTICULARS

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4.6 Fertility, pregnancy and lactation

Pregnancy

Uncontrolled hyperglycaemia in the periconceptional phase and during pregnancy is associated with increased risk of congenital abnormalities, pregnancy loss, pregnancy-induced hypertension, preeclampsia, and perinatal mortality. It is important to maintain blood glucose levels as close to normal as possible throughout pregnancy, to reduce the risk of adverse hyperglycaemia-related outcomes to the mother and her child.

Metformin crosses the placenta with levels that can be as high as maternal concentrations.

A large amount of data on pregnant women (more than 1000 exposed outcomes) from a register-based cohort study and published data (meta-analyses, clinical studies, and registries) indicates no increased risk of congenital abnormalities nor feto/neonatal toxicity after exposure to metformin in the periconceptional phase and/or during pregnancy.

There is limited and inconclusive evidence on the metformin effect on the long-term weight outcome of children exposed in utero. Metformin does not appear to affect motor and social development up to 4 years of age in children exposed during pregnancy although data on long term outcomes are limited.

If clinically needed, the use of metformin can be considered during pregnancy and in the periconceptional phase as an addition or an alternative to insulin.

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