ספטמבר 2021

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: INTEGRILIN® 0.75 MG/ML, INTEGRILIN® 2 MG/ML
אינטגרילין 0.75 מ"ג/מ"ל, אינטגרילין 2 מ"ג/מ"ל
Dosage Form: INTEGRILIN® 0.75 MG/ML SOLUTION FOR I.V. INFUSION
INTEGRILIN® 2 MG/ML SOLUTION FOR I.V. INJECTION
Composition: EPTIFIBATIDE

חברת מרק שארפ ודוהם (ישראל-1996), MSD ישראל, מבקשת ליידע על עדכון העלון לרופא של אינטגרילין.

להלן לשון ההתוויה המאושרת לתכשיר:

Integrilin is indicated for the prevention of death and myocardial infarction in patients presenting with high risk unstable angina or non-Q-wave myocardial infarction.
Integrilin is indicated in patients who are managed with standard medical therapies and/or with percutaneous coronary intervention.
Integrilin is also indicated as an adjunct to percutaneous transluminal coronary angioplasty (PTCA) balloon angioplasty, directional atheretomy, transluminal extraction catheter atherectomy, rotational ablation angioplasty, or excimer laser angioplasty for the prevention of abrupt closure of the treated coronary vessel and related acute ischemic cardiac complications (death, myorardial infarction, need for urgent intervention).
Integrilin is intended for use with aspirin and heparin.

למידע מלא ולהוראות מתן מפורטות, יש לעיין בעלון לרופא המאושר על ידי משרד הבריאות.

עדכונים מהותיים בעלון לרופא:
טקסט מהותי שהתווסף מודגש בקו תחתון טקסט שנמחק מופיע עם קו חוצה.
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USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

~~***Pregnancy Category B***~~
~~Teratology~~Risk Summary
Available data on eptifibatide use in pregnant women from published literature and the pharmacovigilance database are insufficient to establish a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Untreated myocardial infarction can be fatal to the pregnant woman and fetus *(see Clinical Considerations)*. In animal reproduction studies, there was no evidence of adverse developmental effects when eptifibatide was administered intravenously to pregnant rats and rabbits at approximately 4 times the recommended maximum daily human dose.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.

Clinical Considerations
Disease-associated maternal and/or embryo/fetal risk
Myocardial infarction is a medical emergency in pregnancy which can be fatal to the pregnant woman and fetus if left untreated. Therapy for the pregnant woman should not be withheld because of potential concerns regarding the effects of INTEGRILIN on the fetus

Data

Animal Data

Embryo-fetal development studies have been performed by continuous intravenous infusion of eptifibatide in pregnant rats during the period of organogenesis at total daily doses of up to 72 mg/kg/day (about 4 times the recommended maximum daily human dose on a body surface area basis) and in pregnant rabbits during the period of organogenesis at total daily doses of up to 36 mg/kg/day (also about 4 times the recommended maximum daily human dose on a body surface area basis). These studies revealed no evidence of harm to the fetus due to eptifibatide. ~~There are, however, no adequate and well-controlled studies in pregnant women with INTEGRILIN. Because animal reproduction studies are not always predictive of human response, INTEGRILIN should be used during pregnancy only if clearly needed.~~

8.~~3~~2 ~~Nursing Mothers~~Lactation

Risk Summary

There are no available data on the presence of eptifibatide in human milk, the effects on the breastfed infant, or the effects on milk production. As eptifibatide is a peptide, it is likely to be destroyed in the infant's gastrointestinal tract and not absorbed orally by the breastfed infant.

~~It is not known whether eptifibatide is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when INTEGRILIN is administered to a nursing mother.~~

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בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו.
העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, חברת MSD, בטלפון 09-9533333.
INTEGRILIN® 0.75 MG/ML, INTEGRILIN® 2 MG/ML מופצות ע"י חברת נובולוג בע"מ.

בברכה,
מיכל סרפר,
רוקחת ממונה
MSD ישראל

References:
Israeli approved PC revised on 9/2021