

אוגוסט 2025

MITOCIN 20 MG, POWDER FOR SOLUTION FOR INJ/INF

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר מיטוצין 20 מ"ג.

בהודעה זו מפורטים העדכונים המהווים החמרה ושינויים מהותיים במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלון.

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

הרכב התכשיר:

Each vial contains Mitomycin 20 mg.

התוויות מאושרות:

Intravenous, intra-arterial (hepatic artery), and local (intraserosal) administration for treatment of adenocarcinomas of the stomach, pancreas, colon, rectum, breast and their metastases.

Intravesical administration for the prevention of recurrence in superficial cancer of bladder after transurethral resection.

העלון לרופא עודכן בתאריך אוגוסט 2025. להלן העדכונים המהווים החמרה או שינויים מהותיים במידע הבטיחותי (מסומנים באדום):

[...]

4. CLINICAL PARTICULARS

[...]

4.4. Special warnings and precautions for use

Special warnings

Due to the toxic effects of mitomycin on the bone marrow, other myelotoxic treatments (in particular, other cytostatics, radiotherapy) should be administered with particular caution to minimize the risk of additive myelosuppression.

[...]

4.5. Interaction with other medicinal products and other forms of interaction

[...]

Interactions with other treatment methods which are toxic to bone marrow (particularly other cytotoxic agents and radiotherapy) are possible.

4.6. Fertility, pregnancy and lactation

Contraception in women of childbearing age and in men

Female patients of childbearing age must use a method of contraception during treatment with mitomycin and for up to 6 months after the end of treatment. Men being treated with mitomycin are advised to use a contraception method during treatment and for up to 3 months after the end of treatment.

Pregnancy

There is no data on the use of mitomycin in pregnant women. Animal studies have shown toxicity on reproductive functions (see Section 5.3). Mitomycin has a mutagenic, teratogenic and carcinogenic effect and may therefore harm the development of the fetus. Mitomycin is contraindicated during pregnancy (see Section 4.3). In case of a vital indication for the treatment of a pregnant patient, a medical consultation must be conducted regarding the risks of harmful effects of the treatment on the unborn child.

[...]

Fertility

Because of the possibility of irreversible sterility due to mitomycin treatment (see Section 5.3), men should be advised before treatment to consider sperm preservation.

5. PHARMACOLOGICAL PROPERTIES

5.3. Preclinic safety data

In animal studies, mitomycin is toxic to all proliferating tissues, including bone marrow cells and the mucosa of the gastrointestinal tract. Furthermore, it can lead to inhibition of spermatogenesis.

Mitomycin has mutagenic, carcinogenic and teratogenic effects that have been demonstrated in appropriate experimental models.

Local tolerance

Mitomycin causes severe necrosis if injected perivenously or extravasated into surrounding tissues.