What is in this leaflet
• This medicine has been prescribed for you only.

for you.

this medicine because it contains important information

Read all of this leaflet carefully before you start using

based on the fact that one way in which cancer cells differ

ways. The therapeutic use of cytostatics in cancer therapy is

medicine which prevents or considerably delays the division

Mitomycin is a medicine for the treatment of cancer, i.e. a

An increased risk of a particular form of kidney disease

mitomycin with other medicines.

recommends.

The use of mitomycin in children and adolescents is not

Adriamycin (doxorubicin, 5-fluorouracil or tamoxifen).

mitomycin treatment because this may put you at an

There are reports from animal experiments that the effect of

• if you are undergoing any other treatment (e.g. surgery, radiation) which also have a harmful effect on the

Mitomycin passes into breast milk. Breast-feeding must be

and to seek advice on sperm conservation before starting

treated with mitomycin you are therefore advised not to

a high tanner.

An increased risk in a particular form of kidney disease

In the event of injection or leakage of mitomycin into the

bruises and bleeding

• localised skin rash (local exanthema)

• allergic skin rash

Possible side effects following instillation in the bladder

• numbness, swelling and painful redness of palms

• calcium deposits in the bladder wall (bladder wall

calcification)

(difficulties breathing), cough,

• lung disorder presenting as shortness of breath, dry

• hair loss (alopecia)

• difficulties breathing (dyspnoea), cough,

• kidney disorders (renal dysfunction, nephrotoxicity,

• incontinence

• diarrhoea

• loss of appetite (anorexia)

• inflammation of connective tissue (cellulitis)

• weight loss

• diarrhoea, stomach cramps

• nausea and vomiting

• nausea

• increased heart rate

• headache

• depression (your bone marrow is not able to make

• decreased number of white blood cells (leukopenia)

• infection may be aggravated due to bone

• fever

• kidney disease (renal dysfunction) where you pass little or

• loss of appetite (anorexia)

• weight loss

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5. How to store Mitomycin

From a microbiological point of view, unless the method of reconstitution can guarantee uncontaminated dilution, the product should be used immediately. From a chemical and physical point of view the reconstituted product should be used within 24 hours.

6. Contents of the pack and other information

What Mitomycin contains

- The active substance is mitomycin.

- The other ingredients are: Sodium chloride and water for injections (solvent for intravesical solution: 0.9% sodium chloride solution and catheters).

- Solvent for intravesical solution:
  - Powder for solution for intravesical use: Mitomycin, 20 mg, powder and solvent for intravesical solution: Sodium chloride and water for injections (0.9% sodium chloride solution).
  - The urine pH should be higher than pH 6.

- The content of the vials is intended for single use/single entry use -- do not remove the vial. Only clear solutions may be used.

- Reconstitution of the solution for intravesical use ready for use:
  - For each vial, an isotonic sodium chloride solution is included.

Fig. 1 – 7:

(1) Instructions for use for the solvent for intravesical solution

(2) Mitomycin powder for solution for intravesical use

(3) Mitomycin and solvent for intravesical use: aluminium seal. Instillation sets for intravesical instillation also include 1, 4, 5 or 6 PVC bags with a volume of 20 ml protected from contamination until the last minute.

(4) Remove the caps from the vial and the bag

(5) Hold the vial vertically, push it firmly protected from contamination until the last minute.

(6) Completely. Connect the catheter to the adapter of the instillation system:

(7) Invert the entire system. Hold the vial vertical position, break the upper mechanism in the tube section by with the catheter to the disposal bag.

(8) Do not remove the vial.

(9) In a vertical position, break the upper mechanism in the tube section by

(10) Do not remove the vial.

(11) Draw the dissolved mitomycin into the instillation set bag ready to hand.

(12) Do not remove completely! This will

(13) If not used immediately, in-use storage times and conditions should be observed.

(14) The content of the vials is intended for single use/single entry use -- do not remove the vial.

(15) Only clear solutions may be used.

(16) Protect the reconstituted solution from light.

(17) Do not use this medicine after the expiry date which is stated on the package.

(18) Keep this medicine out of the sight and reach of children.

(19) Do not use this medicine after the expiry date.

(20) The expiry date is stated on the package.

(21) For reconstitution of the solution for intravesical use:

(22) The active substance is mitomycin.

(23) The other ingredients are: Sodium chloride and water for injections (solvent for intravesical solution: 0.9% sodium chloride solution).

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