What is in this Leaflet

This leaflet answers some of the common questions about Mitomycin-C Kyowa, but it does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with Mitomycin-C Kyowa against the benefits they expect it will have for you.

If you have any concerns about being treated with Mitomycin-C Kyowa ask your doctor or pharmacist.

Keep this leaflet, because you may need to read it again.

What Mitomycin-C Kyowa is used for

Mitomycin-C Kyowa contains mitomycin, which is an anti-cancer agent. It is used to treat cancer of the stomach, pancreas, colon, lung (non-small cell), breast, cervix, head and neck, liver and bladder.

Mitomycin-C Kyowa works by stopping cancer cells from growing.

Ask your doctor if you have any question about why Mitomycin-C Kyowa was prescribed for you.

Before you are given Mitomycin-C Kyowa

You must tell your doctor if:
- you have ever had an allergic reaction to any medicine, or other substances such as food, preservatives or dyes
- you have ever had a condition which caused you to bleed very easily.
- you have an infection now or had one recently
- you have ever had a problem with your kidneys
- you are pregnant or likely to become pregnant
- you are breast-feeding

Taking other medicines

You must tell your doctor if you are taking any medicines, including the ones you buy without a prescription from a pharmacy, supermarket or health food shop. The medicines you take may be affected by Mitomycin-C Kyowa, or may affect how well it works. You may need different amounts of your medicine, or you may need to take or use different medicines. Your doctor will advise you, they may have more information on medicines to be careful with or avoid while you are being given Mitomycin-C Kyowa.

How Mitomycin-C Kyowa is given

Mitomycin-C Kyowa is given to you in hospital. It will always be given to you by a doctor or by a nurse. Mitomycin-C Kyowa may be given alone or with other anti-cancer medicines.

How much is given

The amount (dose) you will be given is worked out by your doctor. It is based on your size and on the type of cancer. The dose worked out for you may be different to the dose for another patient.

How it is given

Mitomycin-C Kyowa is mixed with an intravenous fluid and given as an infusion (drip) into a vein. It may be given as a single dose, or divided into 10 daily doses given each day for five days then after 2 treatment-free days, given for another 5 five days. This may all be repeated at intervals of 6 to 8 weeks.

Mitomycin-C Kyowa may also be given directly into the bladder via a small tube and retained in the bladder for as long as possible, until you urinate.
Overdose

Mitomycin-C Kyowa will be given to you under the supervision of a doctor so it is most unlikely that you will receive too much.

However if you experience severe side effects you must tell your doctor or a nurse immediately. You may need urgent medical attention.

While you are being given Mitomycin-C Kyowa

Things you must do

Be sure to keep all your doctor’s appointments so your progress can be checked. You will require blood tests to see how Mitomycin-C Kyowa is affecting your blood, particularly your white cell count, or if it is affecting any other organs such as your kidneys or liver. If the numbers of white cells in your blood are significantly reduced, your doctor may reduce the amount of Mitomycin-C Kyowa you are given or may stop treatment until the numbers of white cells increase. Mitomycin-C Kyowa can affect your white cell count for up to 8 weeks after you received your Mitomycin-C Kyowa.

Due to the effect on your blood cells, the following precautions should be taken to reduce your risk if infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.

- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.

- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.

- Avoid contact sports or other situations where you may bruise or get injured.

Tell your doctor or nurse if you have any concerns before during or after your treatment with Mitomycin-C Kyowa.

Tell any other doctors, dentists or pharmacists who are treating you that you are being given Mitomycin-C Kyowa.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Mitomycin-C Kyowa.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Mitomycin-C Kyowa, or have been given Mitomycin-C Kyowa within the last 12 months.

If you become pregnant while being treated with Mitomycin-C Kyowa, tell your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how being treated with Mitomycin-C Kyowa affects you.

As with other medicines used to treat cancer Mitomycin-C Kyowa may cause tiredness, drowsiness and blurring of vision in some people. Make sure you know how you react to Mitomycin-C Kyowa before you drive a car, operate machinery, or do anything else that could be dangerous if you are tired or drowsy. If this occurs do not drive.

Side effects

Tell your doctor or a nurse as soon as possible if you do not feel well while you are being given Mitomycin-C Kyowa.

Like other cancer medicines, Mitomycin-C Kyowa helps most people who have cancer, but it may have unwanted side effects. Some of these side effects may be prevented or treated by therapy with other medicines. If side effects do occur, their severity usually depends on the dose of Mitomycin-C Kyowa you have received.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you.

- fever, loss of appetite, nausea, vomiting, diarrhoea

- headache, blurred vision, confusion, tiredness,

- irregular heart beat (palpitations), fatigue

- oedema, pain, swelling

- When administered into the bladder, side effects may include irritation of the bladder, change in the frequency of urination, itchy rash on the hands and genital area, bladder damage, skin damage to the genital area

Tell your doctor or nurse as soon as possible if you notice any of the following:

- tiredness, headaches, short of breath when exercising, dizziness, looking pale, fast heart rate

- infection; fever, chills, sore throat

- bruising easily, bleeding longer than usual after minor cuts or scrapes, bleeding gums or nose bleeds, rash of small reddish-purple spots on your skin, blood in your stool, urine or vomit

- passing little or no urine, drowsiness, nausea, vomiting, poor appetite, headache, weakness, fever, diarrhoea, irritable

- nausea, vomiting, diarrhoea, abdominal pain, loss of appetite with yellowing of the skin and eyes, bleeding, fatigue, weakness, or confusion
• burning, stinging, pain, redness or swelling at the injection site
• Fatigue, fluid on the ankles or abdomen, shortness of breath, dry or moist cough

These are serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following signs of a sudden life-threatening allergic reaction:
• chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

Tell your doctor if you notice any of these effects, or if you experience any other effects while being given Mitomycin-C Kyowa.

What is in Mitomycin-C Kyowa

The Active ingredient in Mitomycin-C Kyowa is mitomycin.
Each vial contains either 2mg, 10mg or 20mg mitomycin.
The In-active ingredient in Mitomycin-C Kyowa is sodium chloride.
Before being given to you the Mitomycin-C Kyowa will have been dissolved in sterile water and added to an intravenous fluid.

Who makes Mitomycin-C Kyowa

Mitomycin-C Kyowa is made in Japan by
Kyowa Hakko Kogyo Co., Ltd

Mitomycin-C Kyowa is distributed in Australia by
Bristol Laboratories a division of
Bristol-Myers Squibb Australia Pty Ltd

Registration Numbers:
Mitomycin-C Kyowa 2mg AUST R 19717
Mitomycin-C Kyowa 10mg AUST R 19716
Mitomycin-C Kyowa 20mg AUST R 19739

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