UFUR CAPSULE®

Tegafur, Uracil (100mg, 224mg)

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What UFUR Capsule is used for

UFUR capsule is used in remission of symptoms of the following cancers: head and neck, gastric, bowel, liver, gallbladder or bile-duct, pancreatic, lung, breast, bladder, prostatic, and lower part of the womb.

It is used in combination with another medicine containing folinate for bowel cancer.

How UFUR Capsule works

UFUR capsule has two medicines in it. One is called tegafur and the other uracil. Tegafur is a medicine to treat cancer by blocking the cancer cell growth and division (cytostatic). Uracil helps the tegafur to work better. It does this by slowing the rate that tegafur is passed out of the body.

Before you use UFUR Capsule

- When you must not use it
- 1) You are allergic to the ingredients of this product.
- 2) You are taking the antiviral medicine sorivudine. The concomitant use of *UFUR Capsule* with the antiviral medicine sorivudine may cause fatal side effect.
- 3) You are pregnant; trying to get pregnant or think you may be pregnant.
- 4) You are breast-feeding.
- <u>Before you start to use it</u>

Please make sure you have understood the explanation given by your doctor

or pharmacist before taking this medicine. Speak to your doctor / pharmacist if you have one of following conditions:

- 1) Liver problem.
- Bone marrow damage from previous radiotherapy or treatment with other anticancer medicines
- 3) Bone marrow depression
- 4) Liver dysfunction
- 5) Kidney dysfunction
- 6) Infectious diseases
- 7) Infections and bleeding tendencies, gastric/intestinal symptoms such as abdominal pain, diarrhea
- 8) Dehydration
- 9) Sugar intolerance
- 10) Heart disease or a history of heart disease
- 11) On or previously treated with other chemotherapy or radiotherapy

- Elderly and children

Elderly or children have to tell your doctor or pharmacist before taking this medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. This is especially important if you take one of the following medicines:

- Tegafur, gimeracil and oteracil combination product used to treat stomach cancer
- Certain medicines used to thin the blood (coumarin anticoagulants such as warfarin)
- 3) Antiviral medicine Sorivudine.
- 4) Phenytoin, which is used to treat epilepsy
- 5) Other anticancer agents or radiation therapy.

How to use UFUR Capsule

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

General dosage:

UFUR capsule is to be taken 3-6 capsules (equivalent to 300-600mg of tegafur) daily in two to three divided doses. Be sure to follow the dosage instructions.

- When to use it

Use as directed by your doctor or pharmacist.

If you are taking folinate plus *UFUR Capsule* combination therapy, meals will affect the efficacy. Do not use folinate plus *UFUR Capsule* during one hour before or after meal.

- How long to use it

Continue taking *UFUR Capsule* for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

It is suggested to take the medicine

Taking too many tablets may cause signs and symptoms which are similar to the side effects.

pack and this leaflet with you.

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While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *UFUR Capsule*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not breastfeed when taking *UFUR Capsule*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *UFUR Capsule* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

UFUR Capsule may decline your immunity; you should avoid contacting people with infectious disease. And if you have symptoms related to infection, like fever, chills, throat pain, back or abdominal pain, or painful urination, please go to hospital.

Side effects

- 1) Fever
- 2) Jaundice and liver dysfunction
- 3) Dehydration
- 4) Kidney dysfunction
- 5) Anorexia (eating disorder), nausea, vomiting, diarrhea
- 6) Inflammation of the intestinal tract
- 7) Bone marrow depression
- 8) Sickness and dizziness
- 9) Sleepiness, consciousness disturbance
- 10) Urinary incontinence
- 11) Coloration of skin by pigment, growth of keratin on the skin.
- 12) Hypersensitivity: Rash, itching and hives may occur rarely.

- Discontinue intake if abnormalities appear.
- 13) Changes in the "white matter" of the brain (leukoencephalopathy)
- 14) Loss sense of smell (anosmia)
- 15) Scarring of lungs (interstitial pneumonia)
- 16) Restricted blood supply to the heart without the feeling of pain (silent angina or silent ischemia)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems / Side Effects / AEFI).

Storage and Disposal of *UFUR* Capsule

- Storage

Keep out of the reach and sight of children.

Store at 25°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

UFUR Capsule is a white to off-white capsule, imprinted with red characters of UFUR on both of Cap and Body, filled with white to pale yellow granules or fine powder.

- Ingredients

- Active ingredients: Tegafur and uracil
- Inactive ingredients:
 Lactose Hydrous; Povidone K-30;
 Stearic Acid; Magnesium Stearate

- <u>MAL number:</u> MAL09102913AZ

Manufacturer

TTY Biopharm Company Limited 838, Chung Hwa Rd., Sec. 1, Chungli Dist., Taoyuan City, 32069, Taiwan

Product Registration Holder

Pharm-D Sdn. Bhd. (535448-K) No 8B, Jalan 1/137C, Bedford Business Park, Off Jalan Kelang Lama, 58000 Kuala Lumpur, Malaysia

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