XULOX FILM COATED TABLET 500MG

Capecitabine 500mg

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What XULOX is used for

XULOX is used in the treatment of breast, colon, rectal and gastric cancer. XULOX may also be used to prevent new occurrence of colon cancer after complete removal of the tumour by surgery.
XULOX may be used either alone or in combination with other medicines.

How XULOX works

XULOX belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. XULOX contains capecitabine, which itself is not a cytostatic medicine. Only after being absorbed by the body is it changed into an active anti-cancer medicine (more in tumour tissue than in normal tissue).

Before you use XULOX

- *When you must not use it*

Do not take this medicine if:

- you are allergic to capecitabine or any of the other ingredients of this medicine (listed in the Product Description). You must inform your doctor if you know that you have an allergy or over-reaction to this medicine.
- if you previously have had severe reactions to fluoropyrimidine therapy (a group of anticancer medicines such as fluorouracil),
- if you are pregnant or breast-feeding,
- if you have severely low levels of white cells or platelets in the blood (leucopenia, neutropenia or thrombocytopenia),
- if you have severe liver or kidney problems,
- if you know that you do not have any activity of the enzyme dihydropyrimidine dehydrogenase (DPD),
- if you are being treated now or have been treated in the last 4 weeks with brivudine as part of herpes zoster (chickenpox or shingles) therapy.

Children and adolescents

XULOX is not indicated in children and adolescents. Do not give XULOX to children and adolescents.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You must not take XULOX if you are pregnant or think you might be.

- *Before you start to use it*

Talk to your doctor or pharmacist before taking XULOX:

- if you know that you have a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD),
- if you have liver or kidney diseases,
- if you have or had heart problems (for example an irregular heartbeat or pains to the chest, jaw and back brought on by physical effort and due to problems with the blood flow to the heart),
- if you have brain diseases (for example, cancer that has spread to the brain, or nerve damage (neuropathy)),
- if you have calcium imbalances (seen in blood tests),
- if you have diabetes,
- if you cannot keep food or water in your body because of severe nausea and vomiting,
- if you have diarrhea,
- if you are or become dehydrated,
- if you have imbalances of ions in your blood (electrolyte imbalances, seen in tests),
- if you have a history of eye problems as you may need extra monitoring of your eyes,
- if you have a severe skin reaction.

XULOX contains lactose anhydrous

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

- *Taking other medicines*

Before starting treatment, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is extremely important, as taking more than one medicine at the same time can strengthen or weaken the effect of the medicines.

You must not take brivudine (an anti-viral medicines for treatment of shingles or chickenpox) at the same time as capecitabine treatment (including during any rest periods when you are not taking any capecitabine tablets).

If you have taken brivudine you must wait for at least 4 weeks after stopping brivudine before starting to take capecitabine. See also section "*When you must not use it*".

Also, you need be particularly, careful if you are taking any of the following:

- gout medicine (allopurinol),
- blood-thinning medicines (coumarin, warfarin),
- medicines for seizures or tremors (phenytoin),
- interferon alpha,
- radiotherapy and certain medicines used to treat cancer (folinic acid, oxaliplatin, bevacizumab, cisplatin, irinotecan),
- medicines used to treat folic acid deficiency.

How to use XULOX

- *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

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understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of XULOX is based on your body surface area. This is calculated from your height and weight. The usual dose for adults is 1250 mg/m^2 of body surface area taken two times daily (morning and evening). Two examples are provided here: A person whosebody weight is 64 kg and height is 1.64 m has a body surface area of 1.7 m^2 and should take 4 tablets of 500 mg and 1 tablet of 150 mg two times daily. A person whose body weight is 80 kg and height is 1.80 m has a body surface area of 2.00 m^2 and should take 5 tablets of 500 mg two times daily.

Your doctor will tell you what dose you need to take, when to take it and for how long you need to take it.

- *When to use it*
  - Use as directed by your doctor or pharmacist.
  - You should take XULOX no later than 30 minutes after meals.
  - Take the tablets **morning and evening** as prescribed by your doctor.
  - Take the tablets within **30 minutes after the end of a meal** (breakfast and dinner) **and swallow whole with water. Do not crush or cut tablets. If you cannot swallow XULOX tablets whole, tell your healthcare provider**.
  - It is important that you take all your medicine as prescribed by your doctor.

- *How long to take it*
  - Use XULOX tablet for the duration that the doctor recommends.
  - XULOX tablets are usually taken for 14 days followed by a 7-days rest period (when no tablets are taken). This 21-days period is one treatment cycle.
  - In combination with other medicines the usual dose for adults may be less than 1250 mg/m^2 of body surface area, and you may need to take the tablets over a different time period (e.g. every day, with no rest period).
  - There are no side effects caused by stopping treatment with capecitabine. In case you are using coumarin anticoagulants (containing eg, phenprocoumon), stopping capecitabine might require that your doctor adjusts your anticoagulant dose.
  - If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- *If you forget to use it*

Do not take the missed dose at all.
Do not take a double dose to make up for a forgotten dose. Instead, continue your regular dosing schedule and check with your doctor.

- *If you use too much (overdose)*

If you take more XULOX than you should, contact your doctor as soon as possible before taking the next dose.

You might get the following side effects if you take a lot more capecitabine than you should: feeling or being sick, diarrhoea, inflammation or ulceration of the gut or mouth, pain or bleeding from the intestine or stomach, or bone marrow depression (reduction in certain kinds of blood cells). Tell your doctor immediately if you experience any of these symptoms.

While you are using it

- *Things you must do*

DPD deficiency
DPD deficiency is a rare condition present at birth that is not usually associated with health problems unless you receive certain medicines. If you have unrecognised DPD deficiency and take XULOX, you are at an increased risk of acute early-onset of severe forms of the side effects listed under section "Side effects". Contact your doctor immediately if you are concerned about any of the side effects or if you notice any additional side effects not listed in the leaflet (see section "Side effects").

Pregnancy and breast-feeding
If you are a woman who could become pregnant you should use effective contraception during treatment with XULOX and for 6 months after the last dose. If you are a male patient and your female partner could become pregnant, you should use effective contraception during treatment with XULOX and for 3 months after the last dose.

- *Things you must not do*

Do not stop using the medicine unless advised by your doctor.
Do not use any new medicines without consulting your doctor or pharmacist. Do not give XULOX to anyone else, even if they have the same symptoms or conditions as you.

Pregnancy and breast-feeding
You must not breast-feed if you are taking XULOX and for 2 weeks after the last dose.

- *Things to be careful of*

Driving and using machines
XULOX may make you feel dizzy, nauseous or tired. It is therefore possible that Xeloda could affect your ability to drive a car or operate machines.

Side effects
Like all medicines, XULOX may cause side effects, although not everybody gets them.

STOP taking XULOX immediately and contact your doctor if any of these symptoms occur:
- Diarrhoea: if you have an increase of 4 or more bowel movements compared to your normal bowel movements each day or any diarrhoea at night.
- Vomiting: if you vomit more than once in a 24-hour time period.
- Nausea: if you lose your appetite, and the amount of food you eat each day is much less than usual.
- Stomatitis: if you have pain, redness, swelling or sores in your mouth and/or throat.

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- Hand-and-foot skin-reaction: if you have pain, swelling, redness or tingling of hands and/or feet
- Fever: if you have a temperature of 38°C or greater.
- Infection: if you experience signs of infection caused by bacteria or virus, or other organisms.
- Chest pain: if you experience pain localised to the centre of the chest, especially if it occurs during exercise.
- Steven-Johnson syndrome: if you experience painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membrane (e.g. mouth and lips), in particular if you had before light sensitivity, infections of the respiratory system (e.g. bronchitis) and/or fever.
- DPD Deficiency: if you have a known DPD deficiency, you are at an increased risk of acute early-onset of toxicity and severe, life-threatening, or fatal adverse reactions caused by XULOX (e.g. stomatitis, mucosal inflammation, diarrhoea, neutropenia and – neurotoxicity). *Angioedema*: Seekmedical attention straight away if you notice any of the following symptoms,
  - you may need urgent medical treatment: Swelling mainly of the face, lips, tongue or throat which makes it difficult to swallow or breathe, itching and rashes. This could be a sign of angioedema.

If caught early, these side effects usually improve within 2 to 3 days after treatment discontinuation. If these side effects continue, however, contact your doctor immediately.

Your doctor may instruct you to restart treatment at a lower dose.

Hand and foot skin-reaction can lead to loss of fingerprint, which could impact your identification by fingerprint scan.

In addition to the above, when XULOX is used alone, very common side effects, which may affect more than 1 in 10 people are:
- abdominal pain
- rash, dry or itchy skin
- tiredness
- loss of appetite (anorexia)

These side effects can become severe; therefore, it is important that you always contact your doctor immediately when you start to experience a side effect. Your doctor may instruct you to decrease the dose and/or temporarily discontinue treatment with XULOX. This will help reduce the likelihood that the side effect continues or becomes severe.

Other side effects are:
Common side effects (may affect up to 1 in 10 people) include:
- decreases in the number of white blood cells or red blood cells (seen in tests).
- dehydration, weight loss
- sleeplessness (insomnia), depression
- headache, sleepiness, dizziness, abnormal sensation in the skin (numbness or tingling sensation), taste changes
- eye irritation, increased tears, eye redness (conjunctivitis)
- inflammation of the veins (thrombophlebitis),
- Shortness of breath, nose bleeds, cough, runny nose.
- cold sores or other herpes infections.
- infections of the lungs or respiratory system (e.g. pneumonia or bronchitis).
- bleeding from the gut, constipation, pain in upper abdomen, indigestion, excess wind, dry mouth.
- skin rash, hair loss (alopecia), skin reddening, dry skin, itching (pruritus), skin discolouration, skin loss, skin inflammation, nail disorder.
- pain in the joints, or in the limbs (extremities), chest or back
- fever, swelling in the limbs, feeling ill.
- problems with liver function (seen in blood tests) and increased blood bilirubin (excreted by the liver).

Uncommon side effects (may affect up to 1 in 100 people) include:
- blood infection, urinary tract infection, infection of the skin, infections in the nose and throat, fungal infections (including those of the mouth), influenza, gastroenteritis, tooth abscess,
- lumps under the skin (lipoma),
- decreases in blood cells including platelets, thinning of blood (seen in tests)
- Allergy,
- diabetes, decrease in blood potassium, malnutrition, increased blood triglycerides,
- confusional state, panic attacks, depressed mood, decreased libido,
- difficulty speaking, impaired memory, loss of movement coordination, balance disorder, fainting, nerve damage (neuropathy) and problems with sensation,
- blurred or double vision,
- vertigo, ear pain,
- irregular heartbeat and palpitations (arrhythmias), chest pain and heart attack (infarction),
- blood clots in the deep veins, high or low blood pressure, hot flushes, cold limbs (extremities), purple spots on the skin
- blood clots in the veins in the lung (pulmonary embolism), collapsed lung, coughing up blood, asthma, shortness of breath on exertion,
- bowel obstruction, collection of fluid in the abdomen, inflammation of the small or large intestine, the stomach or the oesophagus, pain in the lower abdomen, abdominal discomfort, heartburn (reflux of food from the stomach), blood in the stool,
- jaundice (yellowing of skin and eyes),
- skin ulcer and blister, reaction of the skin with sunlight, reddening of palms, swelling or pain of the face,
- joint swelling or stiffness, bone pain, muscle weakness or stiffness,
- fluid collection in the kidneys, increased frequency of urination during the night, incontinence, blood in the urine,
  increase in blood creatinine (sign of kidney dysfunction),
- unusual bleeding from the vagina,
- swelling (oedema), chills and rigors.

Some of these side effects are more common when capecitabine is used with other medicines for the treatment

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of cancer. Other side-effects seen in this setting are the following:

Common side effects (may affect up to 1 in 10 people) include:

- decrease in blood sodium, magnesium or calcium, increase in blood sugar,
- nerve pain,
- ringing or buzzing in the ears (tinnitus), loss of hearing,
- vein inflammation,
- hiccups, change in voice,
- pain or altered/abnormal sensation in the mouth, pain in the jaw,
- sweating, night sweats,
- muscle spasm,
- difficulty in urination, blood or protein in the urine,
- bruising or reaction at the injection site (caused by medicines given by injection at the same time).

Rare side effects (may affect up to 1 in 1,000 people) include:

- narrowing or blockage of tear duct (lacrimal duct stenosis),
- liver failure,
- inflammation leading to dysfunction or obstruction in bile secretion (cholestatic hepatitis),
- specific changes in the electrocardiogram (QT prolongation),
- certain types of arrhythmia (including ventricular fibrillation, torsade de pointes, and bradycardia),
- eye inflammation causing eye pain and possibly eyesight problems,
- inflammation of the skin causing red scaly patches due to an immune system illness,
- swelling mainly of the face, lip, tongue or throat, itching and rashes(angioedema).

Very rare side effects (may affect up to 1 in 10,000 people) include:

- severe skin reaction such as skin rash, ulceration and blistering which may involve ulcers of the mouth, nose, genitalia, hands, feet and eyes (red and swollen eyes)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of XULOX

- Storage

  Keep out of the reach and sight of children.

  Store below 30°C.

  Do not use this product after the expiry date, shown on the pack and blisters.

- *Disposal*

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

Product Description

- *What it looks like*

  Dark pink colored, capsule shaped biconvex film coated tablet debossed with CAP on one side and 500 on other side

- *Ingredients*

  - *Active ingredient*

    Capecitabine

  - *Inactive ingredients*

    Lactose Anhydrous (Super tab 21 AN), Microcrystalline Cellulose (Avicel PH 101), Croscarmellose Sodium (Ac di sol), Hydroxy propyl methyl cellulose (Hypromellose 606), Microcrystalline Cellulose (Avicel PH 102), Magnesium Stearate, Opadry Pink 03A84598, Purified Water.

MAL number

MAL22016012AZ

Manufacturer

Shilpa Medicare Limited,
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Product Registration Holder

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