

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## CAPECITABINE DISPERSIBLE TABLETS



Read all of this leaflet carefully before you starts taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

### What is in this leaflet

1. What Xelodace DT 1000 MG Tablets is and what it is used for
2. What you need to know before you take Xelodace DT 1000 MG
3. How to take Xelodace DT 1000 MG Tablets
4. Possible side effects
5. How to store Xelodace DT 1000 MG Tablets

### 1. What Xelodace DT 1000 MG Tablets is and what it is used for

Xelodace DT is a prescription medicine used to treat: A kind of cancer called colon or rectal (colorectal) cancer.

Xelodace DT may be used:

- Alone or in combination with other chemotherapy medicines in people with colon cancer that has spread to lymph nodes in the area close to the colon (Stage III colon cancer), to help prevent your cancer from coming back after you have had surgery.
- Adults with rectal cancer, around the time of your surgery, as a part of chemotherapy and radiation (chemo radiation) treatment when your rectal cancer has spread to nearby tissues (locally advanced), alone or in combination with other chemotherapy medicines, when your colorectal cancer cannot be removed by surgery or has spread to other areas of your body (metastatic).

A kind of cancer called breast cancer. Xelodace DT may be used in people with breast cancer that is advanced or has spread to other parts of the body (metastatic): Alone if you are not able to receive an anthracycline medicine or taxane-containing chemotherapy, or in combination with docetaxel when you have received anthracycline containing chemotherapy and it is no longer working. Kinds of cancer called stomach (gastric), esophageal, or gastroesophageal junction (GEJ) cancer. Xelodace DT may be used in adults:

- In combination with other chemotherapy medicines when your cancer of the stomach, esophagus, or GEJ cannot be removed by surgery or has spread to other parts of the body (metastatic).
- When your cancer of the stomach, esophagus, or GEJ is metastatic adenocarcinoma, and: is HER2-positive, and you have not received treatment with Xelodace DT in combination with other treatments for your metastatic cancer.
- A kind of cancer called pancreatic cancer. Xelodace DT may

be used to treat adults in combination with other chemotherapy medicines, to help prevent your pancreatic cancer from coming back after you have had surgery. It is not known if Xelodace DT is safe and effective in children. Do not take Xelodace DT if you: Have had a severe allergic reaction to fluorouracil or capecitabine. Talk to your healthcare provider before taking Xelodace DT if you are not sure.

### 2. What you need to know before you take Xelodace DT 1000 MG

#### Before taking capecitabine

Some medicines are not suitable for people with certain conditions, and sometimes a medicine may only be used if extra care is taken. For these reasons, before you start taking capecitabine it is important that your doctor knows:

- If you are pregnant or breastfeeding.
- If you have an infection or feel particularly unwell.
- If you have any problems with the way your liver works or how your kidneys work.
- If you have a heart condition or if you have an irregular heartbeat.
- If you have a problem with your nervous system.
- If you have too much sugar in your blood (diabetes mellitus).
- If you have been told by a doctor that the level of any electrolyte (such as calcium, sodium, potassium) in your blood is either too high or too low.
- If you have been told by a doctor that you lack certain enzymes which help remove medicines from your body.
- If you have ever had an allergic reaction to a medicine.
- If you are taking any other medicines. This includes any medicines you are taking which are available to buy without a prescription, as well as herbal and complementary medicines.

**Allergies** Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

#### Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of capecitabine in the paediatric population. Safety and efficacy have not been established.

**Geriatric** Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of capecitabine in the elderly. However, elderly patients are more likely to have unwanted side effects (e.g., stomach problems, severe diarrhoea, nausea or vomiting), which may require caution and an adjustment in the dose for patients receiving capecitabine.

**Breastfeeding** There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

### 3. How to take Xelodace DT 1000 MG Tablets

- Before you start the treatment, read any printed information you have been given by your doctor and the printed manufacturer's leaflet from inside your pack of tablets. These

will give you more information about capecitabine and will provide you with a full list of the side-effects which you may experience from taking it.

- Capecitabine will be prescribed for you by a specialist doctor who is experienced in treating your condition. Your dose will be calculated from your weight and height, so it is important that you take the tablets exactly as your doctor tells you to. There are several strengths of tablet available and your dose may be a combination of the different strengths. It is usual to take the tablets in cycles of two doses every day (morning and evening) for 14 days, followed by a seven-day break. This 21-day cycle is then repeated over a number of months. Your dose will be printed on the label of the pack of tablets to remind you about what the doctor said to you.
- Swallow the tablets whole with a drink of water. Do not cut, crush or chew the tablets.
- You should take the tablet within 30 minutes of eating a meal. It will help you to remember to take your doses regularly if you take them after the same meals each day, usually breakfast and dinner.
- If you forget to take a dose, make sure you remember to take the next dose when it is due and let your doctor know about the missed dose. Do not take two doses at the same time to make up for a missed dose.

#### **What happens if I miss a dose?**

If you miss a dose of capecitabine, do not take an extra dose to make up for the one you missed. Take the next dose at the usual time and speak to someone in your treatment team.

#### **How long will I have to take capecitabine for?**

This will vary from person to person.

People with secondary breast cancer will usually keep taking capecitabine until it's no longer helping control the cancer or they have significant side effects. If you have primary breast cancer your treatment team will talk to you about what's best for you.

#### **4. Possible side effects**

Side effects that you should report to your doctor or health care professional as soon as possible:

- Allergic reactions (skin rash, itching or hives; swelling of the face, lips, or tongue)
- Diarrhoea
- Dizziness
- Infection (fever, chills, cough, sore throat, pain or trouble passing urine)
- Low red blood cell counts (trouble breathing; feeling faint; lightheaded, falls; unusually weak or tired)
- Kidney injury (trouble passing urine or change in the amount of urine)
- Light-colour stool
- Liver injury (dark yellow or brown urine; general ill feeling or flu-like symptoms; loss of appetite, right upper belly pain; unusually weak or tired, yellowing of the eyes or skin)
- mouth sores
- nausea or vomiting
- pain or tightness in the chest, neck, back, or arms
- redness, blistering, peeling, bleeding, or swelling of the skin on the palms of your hands or soles of your feet
- redness, blistering, peeling, or loosening of the skin, including inside the mouth
- unusual bruising or bleeding

Side effects that usually do not require medical attention (report to your doctor or health care professional if they

continue or are bothersome):

- Changes in vision
- Constipation
- Loss of appetite
- Mouth sores
- Pain, tingling, numbness in the hands or feet
- Stomach pain

**The following side effects are common (occurring in greater than 30%) for patients taking capecitabine:**

[Low white blood cell count](#)

- (This can put you at increased risk for infection) [Low red blood cell count \(anaemia\)](#)

[Hand-foot syndrome](#)

- (Palmar-plantar erythrodysesthesia or PPE) - skin rash, swelling, redness, pain and/or peeling of the skin on the palms of hands and soles of feet. Usually mild, has started as early as 2 weeks after start of treatment. May require reductions in the dose of the medication)

[Diarrhea](#)

- [Elevated liver enzymes](#)
- (Increased bilirubin levels) (see liver problems)
- [Nausea and vomiting](#)
- [Rash & itching](#)
- [Abdominal pain](#)

**These side effects are less common side effects (occurring in about 10-29%) of patients receiving capecitabine:**

- [Low platelet count](#)
- Back, muscle, joint, bone pain (see [pain](#))
- [Headache](#)
- GI Motility disorder

Not all side effects are listed above. Some that are rare (occurring in less than 10% of patients) are not listed here. However, you should always inform your health care provider if you experience any unusual symptoms.

#### **5. How to store Xelodace DT 1000 MG Tablets**

- Keep all medicines out of the reach and sight of children.
- Store in a cool, dry place, away from direct heat and light.

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