

Package leaflet: Information for the user

Capecitabine Dexcel 150 mg film-coated tablets

Capecitabine Dexcel 500 mg film-coated tablets

capecitabine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Capecitabine Dexcel is and what it is used for
2. What you need to know before you take Capecitabine Dexcel
3. How to take Capecitabine Dexcel
4. Possible side effects
5. How to store Capecitabine Dexcel
6. Contents of the pack and other information

1. What Capecitabine Dexcel is and what it is used for

Capecitabine Dexcel belongs to the group of medicines called "cytostatic agents", which stop the growth of cancer cells. Capecitabine Dexcel contains 150 mg capecitabine, which itself is not a cytostatic agent. Only after being absorbed by the body is it changed into an active anti-cancer agent (more in tumour tissue than in normal tissue).

Capecitabine Dexcel belongs to the group of medicines called "cytostatic agents", which stop the growth of cancer cells. Capecitabine Dexcel contains 500 mg capecitabine, which itself is not a cytostatic agent. Only after being absorbed by the body is it changed into an active anti-cancer agent (more in tumour tissue than in normal tissue).

Capecitabine Dexcel is prescribed by doctors for the treatment of colon, rectal, gastric, or breast cancers. Furthermore, Capecitabine Dexcel is prescribed by doctors to prevent new occurrence of colon cancer after complete removal of the tumour by surgery.

Capecitabine Dexcel may be used either alone or in combination with other agents.

2. What you need to know before you take Capecitabine Dexcel

Do not take Capecitabine Dexcel:

- if you are allergic to capecitabine or any of the other ingredients of this medicine (listed in section 6). You must inform your doctor if you know that you have an allergy or over-reaction to Capecitabine Dexcel,
- if you are pregnant or nursing,
- if you have blood disorders,
- if you have liver ailments or kidney problems,
- if you have a known deficiency for the enzyme dihydropyrimidine dehydrogenase (DPD), or

- if you are being treated now or have been treated in the last 4 weeks with brivudine, sorivudine or similar classes of substance as part of herpes zoster (chickenpox or shingles) therapy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Capecitabine Dexcel if you

- have liver or kidney diseases
- have or had other illnesses, such as heart problems or chest pain
- have brain diseases
- have calcium imbalances
- have diabetes

Other medicines and Capecitabine Dexcel

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

- gout medicines (allopurinol),
- blood-thinning medicines (coumarin, warfarin),
- certain anti-viral medicines (sorivudine and brivudine) or
- medicines for seizures or tremors (phenytoin).

Capecitabine Dexcel with food and drink

You should take Capecitabine Dexcel no later than 30 minutes after meals.

Pregnancy, breast-feeding and fertility

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 should not take Capecitabine Dexcel if you are pregnant or think you might be. You should not breast-feed if you are taking Capecitabine Dexcel.

Driving and using machines

Capecitabine Dexcel may make you feel dizzy, nauseous or tired. It is therefore possible that Capecitabine Dexcel could affect your ability to drive a car or operate machinery.

3. How to take Capecitabine Dexcel

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Capecitabine Dexcel tablets should be **swallowed with water**.

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of Capecitabine Dexcel is based on your body surface area. This is calculated from your height and weight. The usual dose for adults is 1250 mg/m² of body surface area taken two times daily (morning and evening). Two examples are provided here: A person whose body weight is 64 kg and height is 1.64 m has a body surface area of 1.7 m² 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 m² and should take 5 tablets of 500 mg two times daily.

Capecitabine Dexcel tablets are usually taken for 14 days followed by a 7 day rest period (when no tablets are taken). This 21 day period is one treatment cycle.

In combination with other agents the usual dose for adults may be less than 1250 mg/m² 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).

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

Your doctor may want you to take a combination of 150 mg and 500 mg tablets for each dose.

- Take the tablets in the combination prescribed by your doctor for your morning and evening doses.
- Take the tablets within 30 minutes after the end of a meal (breakfast and dinner).
- It is important that you take all your medication as prescribed by your doctor.

If you take more Capecitabine Dexcel than you should, contact your doctor before taking the next dose.

If you forget to take Capecitabine Dexcel:

Do not take the missed dose at all and do not double the next one. 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 stop taking Capecitabine Dexcel

There are no side-effects caused by stopping treatment with Capecitabine Dexcel. In case you are using coumarin anticoagulants (e.g. phenprocoumon), stopping Capecitabine Dexcel 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. When Capecitabine Dexcel is used alone, very common side effects which may affect more than 1 in 10 people are:

- diarrhoea, nausea, vomiting, stomatitis (sores in mouth and throat) and abdominal pain
- hand-and-foot skin-reaction (palms of the hands or soles of the feet tingle, become numb, painful, swollen or red), 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 Capecitabine Dexcel. This will help reduce the likelihood that the side effect continues or becomes severe.

STOP taking Capecitabine Dexcel 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.
- **Hand-and-foot skin-reaction:** if you have pain, swelling, and redness of hands and/or feet
- **Fever or Infection:** if you have a temperature of 38°C or greater, or other signs of infection.
- **Chest pain:** if you experience pain localised to the centre of the chest, especially if it occurs during exercise.

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.

Other common and usually mild side-effects which may affect up to 1 in 10 people have been seen: decreases in the number of white blood cells or red blood cells, skin rashes, slight hair loss, weariness, fever, weakness, drowsiness, headache, numbness or tingling sensations, taste changes, dizziness, sleeplessness, swelling in the legs, constipation, dehydration, cold sores, inflammation of the nose and throat, chest infection, depression, problems with the eyes, inflammation of the veins (thrombophlebitis), shortness of breath, nose bleeds, cough, runny nose, bleeding from the gut, heartburn, excess wind, dry mouth, skin discolouration, nail disorder, pain in the joints, chest or back and loss of weight.

If you are concerned about these or any other unexpected effect(s), talk to your doctor. If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Capecitabine Dexcel

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton after <EXP>. The expiry date refers to the last day of that month.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements for cytotoxic agents.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Capecitabine Dexcel contains

Capecitabine Dexcel 150 mg film-coated tablets:

- The active substance is capecitabine. Each film-coated tablet contains 150 mg capecitabine.

Capecitabine Dexcel 500 mg film-coated tablets:

- The active substance is capecitabine. Each film-coated tablet contains 500 mg capecitabine.
- The other ingredients are:
 - Tablet core: Croscarmellose Sodium, Microcrystalline Cellulose, Hypromellose, Silica colloidal anhydrous, Magnesium Stearate,
 - Tablet coating: Hypromellose, Titanium Dioxide (E171), Talc, Macrogol 400, Red Iron Oxide (E172), Yellow Iron Oxide (E172)

What Capecitabine Dexcel looks like and contents of the pack

Capecitabine Dexcel 150 mg film-coated tablets:

Light-peach oval film-coated tablets embossed with “150” on one side. Of approximate dimensions 11.4 mm x 5.9 mm.

Capecitabine Dexcel 150 mg film-coated tablet pack contains 60 film-coated tablets.

Capecitabine Dexcel 500 mg film-coated tablets:

Peach, oblong capsule-shaped, film-coated tablets embossed with “500” on one side. Of approximate dimensions 17.1 mm x 8.1 mm.

Capecitabine Dexcel 500 mg film-coated tablet pack contains 120 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following names:

This leaflet was last revised in 28 November 2012 <To be completed nationally>