Package leaflet: Information for the user

Capecitabine Actavis 150 mg film-coated tablets
Capecitabine Actavis 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 Actavis is and what it is used for
2. What you need to know before you take Capecitabine Actavis
3. How to take Capecitabine Actavis
4. Possible side effects
5. How to store Capecitabine Actavis
6. Contents of pack and other information

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

Capecitabine Actavis belongs to the group of medicines called "cytostatic agents", which stop the growth of cancer cells. Capecitabine Actavis contains 150 mg or 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 Actavis is prescribed by doctors for the treatment of colon, rectal, gastric, or breast cancers.
Furthermore, Capecitabine Actavis is prescribed by doctors to prevent new occurrence of colon cancer after complete removal of the tumour by surgery.

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

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

Do not take Capecitabine Actavis:
- if you are allergic to capecitabine, fluorouracil 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 Actavis or to fluoropyrimidine therapy,
- 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:
Before treatment with Capecitabine Actavis, make sure your doctor knows 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 Actavis:
Before starting treatment, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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 Actavis with food, drink and alcohol:
You should take Capecitabine Actavis no later than 30 minutes after meals.

Pregnancy, breast-feeding and fertility
Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. You should not take Capecitabine Actavis if you are pregnant or think you might be. You should not breast-feed if you are taking Capecitabine Actavis. Ask your doctor or pharmacist for advice before taking any medicine.

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

Capecitabine Actavis contains lactose monohydrate:
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Capecitabine Actavis

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

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of Capecitabine Actavis 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 Actavis 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 Actavis than you should,** contact your doctor before taking the next dose.

**If you forget to take Capecitabine Actavis:** do **not** take the missed dose at all and do **not** double the next one. Instead, continue your regular dosing schedule and check with your doctor.

**If you stop taking Capecitabine Actavis:**
There are no side-effects caused by stopping treatment with Capecitabine Actavis. In case you are using coumarin anticoagulants (e.g. Marcumar), stopping Capecitabine Actavis 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 Actavis is used alone, the most common side effects which may affect more than 1 person in 10 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 Actavis. This will help reduce the likelihood that the side effect continues or becomes severe.

**STOP** taking Capecitabine Actavis 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 less common and usually mild side-effects which may affect between 1 and 10 people in 100 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 discoloration, 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 any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Capecitabine Actavis

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the outer carton, label and blister, after EXP.

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 Actavis contains

- The active substance is capecitabine (150 mg or 500 mg per film-coated tablet).
- The other ingredients are:
  - Tablet core: lactose monohydrate, microcrystalline cellulose, hypromellose, croscarmellose sodium, magnesium stearate.
  - Tablet coating: hypromellose, titanium dioxide (E171), macrogol 6000, red iron oxide (E172).

What Capecitabine Actavis looks like and contents of the pack

Pink coloured, capsule shaped, biconvex, film coated tablets, debossed with “150” or “500” on one side and plain on other side.

Capecitabine Actavis 150 mg film-coated tablet pack contains 60 film-coated tablets.
Capecitabine Actavis 500 mg film-coated tablet pack contains 120 film-coated tablets.

Marketing Authorisation Holder

Actavis Group PTC ehf,
Reykjavikurvegi 76-78,
220 Hafnarfjordur,
Iceland

Manufacturer

Actavis Nordic A/S
Ørnegårdsvej 16,
This medicinal product is authorised in the Member States of the EEA under the following names:

**Belgium**  Capécitabine Actavis 150 / 500 mg comprimés pelliculés
Capecitabine Actavis 150 / 500 mg filmomhulde tabletten
Capecitabin Actavis 150 / 500 mg Filmtabletten

**Austria**  Capecitabin Actavis 150 / 500 mg Filmtabletten

**Bulgaria**  Capecitabine Actavis 150 / 500 mg film-coated tablets

**Czech Republic**  Capecitabin Actavis 150 / 500 mg

**Germany**  Capecitabin-Actavis 150 / 500 mg Tabletten

**Denmark**  Capecitabin Actavis

**Estonia**  Capecitabine Actavis

**Spain**  Capecitabina Actavis 150 / 500 mg comprimidos recubiertos con película EFG

**Finland**  Capecitabin Actavis 150 / 500 mg tabletti, kalvopäälysteineen

**France**  Capecitabine Actavis 150 / 500 mg, comprimé pelliculé

**Hungary**  Capecitabin Actavis 150 / 500 mg filmtabletta

**Ireland**  Capecitabine Actavis 150 / 500 mg Film-coated Tablets

**Iceland**  Capecitabine Actavis

**Italy**  Capecitabine Actavis

**Lithuania**  Capecitabina Actavis 150 / 500 mg plèvele dengtos tabletés

**Luxembourg**  Capécitabine Actavis 150 / 500 mg comprimés pelliculés

**Latvia**  Capecitabine Actavis 150 / 500 mg apvalkotās tabletes

**Netherlands**  Capecitabine Actavis 150 / 500 mg filmomhulde tabletten

**Norway**  Capecitabin Actavis 150 / 500 mg tabletter, filmdrasjerete

**Poland**  Capecitabine Actavis

**Portugal**  Capecitabina Actavis

**Romania**  Capecitabina Actavis 150 / 500 mg comprimate filmate

**Sweden**  Capecitabin Actavis

**Slovakia**  Capecitabín Actavis

**UK**  Capecitabine Actavis 150 / 500 mg Film-coated Tablets

**This leaflet was last revised in April 2012**