PACKAGE LEAFLET: INFORMATION FOR THE USER

Capecitabine Waverley 150mg 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 (see section 4).

What is in this leaflet:

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

Capecitabine Waverley belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. Capecitabine Waverley contains 150 mg 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 tumor tissue than in normal tissue).
Capecitabine Waverley is used in the treatment of colon, rectal, gastric, or breast cancers.
Furthermore, Capecitabine Waverley is used to prevent new occurrence of colon cancer after complete removal of the tumor by surgery.
Capecitabine Waverley may be used either alone or in combination with other medicines.

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

Do not take Capecitabine Waverley:
- 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 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) (complete DPD deficiency)
- 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 Waverley
- if you know that you have a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD)
- if you have a family member who has partial or complete deficiency 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 diarrhoea
- 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.

DPD deficiency: DPD deficiency is a genetic condition that is not usually associated with health problems unless you receive certain medicines. If you have DPD deficiency and take Capecitabine Waverley, you are at an increased risk of severe side effects (listed under section 4 Possible side effects). It is recommended to test you for DPD deficiency before start of treatment. If you have no activity of the enzyme you should not take Capecitabine Waverley. If you have a reduced enzyme activity (partial deficiency) your doctor might prescribe a reduced dose. If you have negative test results for DPD deficiency, severe and life-threatening side effects may still occur.

Children and adolescents
Capecitabine Waverley is not indicated in children and adolescents. Do not give Capecitabine Waverley to children and adolescents.

Other medicines and Capecitabine Waverley
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 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),
- 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.

Capecitabine Waverley with food and drink:
You should take Capecitabine Waverley no later than 30 minutes after meals.

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 Capecitabine Waverley if you are pregnant or think you might be.
You must not breast-feed if you are taking Capecitabine Waverley.

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

Capecitabine Waverley contains anhydrous lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Capecitabine Waverley

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 Waverley should only be prescribed by a doctor experienced in the use of anticancer medicines.

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of Capecitabine Waverley 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.

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 **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.**
- It is important that you take all your medicine as prescribed by your doctor.

Capecitabine Waverley 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 medicines 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).

If you take more Capecitabine Waverley than you should
If you take more Capecitabine Waverley 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.

If you forget to take Capecitabine:
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 stop taking Capecitabine Waverley
There are no side effects caused by stopping treatment with capecitabine. In case you are using coumarin anticoagulants (containing e.g. 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
STOP taking Capecitabine Waverley 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.

- ***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.
- ***Stevens-Johnson syndrome and toxic epidermal necrolysis:*** if you experience a painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membranes (e.g. mouth and lips), in particular if this follows pain in the eyes on exposure to light, infections of the respiratory system (e.g. bronchitis) and/or a high temperature.

If caught early, most of 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.

If severe stomatitis (sores in your mouth and/or throat), mucosal inflammation, diarrhoea, neutropenia (increased risk for infections), or neurotoxicity occurs during the first cycle of treatment a DPD deficiency may be involved (please see Section 2: Warning and precautions).

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

If you develop symptoms that suggest the very serious condition of Stevens-Johnson syndrome, this is a medical emergency and you must receive hospital treatment without delay. It is also important that Capecitabine is stopped and not reintroduced even if the symptoms subside.

In addition to the above, when Capecitabine Waverley 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 Capecitabine Waverley. 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 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

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)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine

United Kingdom
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

5. How to store Capecitabine Waverley

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 outer carton and blister after EXP. The expiry date refers to the last day of that month.

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 Waverley contains
- The active substance is capecitabine.
- Capecitabine Waverley 150 mg film coated tablets
- Each tablet contains 150 mg Capecitabine
- The other ingredients are:
  - Tablet core: anhydrous lactose, croscarmellose sodium, hypromellose, microcrystalline cellulose, magnesium stearate.
  - Tablet coating: hypromellose, titanium dioxide (E171), macrogol/PEG, yellow and red iron oxide (E172), talc.

What Capecitabine Waverley looks like and contents of the pack
Capecitabine Waverley 150 mg film coated tablets
Light peach colored film-coated, biconvex, oblong tablets having plain surface on both sides.
Each pack contains 60 film-coated tablets (6 blisters of 10 tablets).

This leaflet was last revised in 07/2020
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Waverley Pharma Europe Ltd.

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1200022828 V03

PACKAGE LEAFLET: INFORMATION FOR THE USER

Capecitabine Waverley 500mg 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 (see section 4).

What is in this leaflet:

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

Capecitabine Waverley belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. Capecitabine Waverley contains 500 mg 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 tumor tissue than in normal tissue).
Capecitabine Waverley is used in the treatment of colon, rectal, gastric, or breast cancers.
Furthermore, Capecitabine Waverley is used to prevent new occurrence of colon cancer after complete removal of the tumor by surgery.
Capecitabine Waverley may be used either alone or in combination with other medicines

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

Do not take Capecitabine Waverley:
- 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 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) (complete DPD deficiency)
- 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 Waverley
- if you know that you have a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD)
- if you have a family member who has partial or complete deficiency 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 diarrhoea
- 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.

DPD deficiency: DPD deficiency is a genetic condition that is not usually associated with health problems unless you receive certain medicines. If you have DPD deficiency and take Capecitabine Waverley, you are at an increased risk of severe side effects (listed under section 4 Possible side effects). It is recommended to test you for DPD deficiency before start of treatment. If you have no activity of the enzyme you should not take Capecitabine Waverley. If you have a reduced enzyme activity (partial deficiency) your doctor might prescribe a reduced dose. If you have negative test results for DPD deficiency, severe and life-threatening side effects may still occur.

Children and adolescents
Capecitabine Waverley is not indicated in children and adolescents. Do not give Capecitabine Waverley to children and adolescents.

Other medicines and Capecitabine Waverley
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 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),
- 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.

Capecitabine Waverley with food and drink
You should take Capecitabine Waverley no later than 30 minutes after meals.

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 Capecitabine Waverley if you are pregnant or think you might be.
You must not breast-feed if you are taking Capecitabine Waverley.

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

Capecitabine Waverley contains anhydrous lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Capecitabine Waverley

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 Waverley should only be prescribed by a doctor experienced in the use of anticancer medicines

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of Capecitabine Waverley 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.

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 **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.**
- It is important that you take all your medicine as prescribed by your doctor.

Capecitabine Waverley 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 medicines 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).

If you take more Capecitabine Waverley than you should
If you take more Capecitabine **Waverley** 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.

If you forget to take Capecitabine Waverley
Do not take the missed dose at all .Do not take 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 Waverley
There are no side effects caused by stopping treatment with capecitabine. In case you are using coumarin anticoagulants (containing e.g. 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking Capecitabine Waverley 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.
- ***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.
- ***Stevens-Johnson syndrome and toxic epidermal necrolysis:*** if you experience a painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membranes (e.g. mouth and lips), in particular if this follows pain in the eyes on exposure to light, infections of the respiratory system (e.g. bronchitis) and/or a high temperature.

If caught early, most of 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.

If severe stomatitis (sores in your mouth and/or throat), mucosal inflammation, diarrhoea, neutropenia (increased risk for infections), or neurotoxicity occurs during the first cycle of treatment a DPD deficiency may be involved (please see Section 2: Warning and precautions).

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

If you develop symptoms that suggest the very serious condition of Stevens-Johnson syndrome, this is a medical emergency and you must receive hospital treatment without delay. It is also important that Capecitabine is stopped and not reintroduced even if the symptoms subside.

In addition to the above, when Capecitabine Waverley 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 Capecitabine Waverley. 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 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

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)

Reporting of side effects :
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5. How to store Capecitabine Waverley
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 outer carton and blister after EXP. The expiry date refers to the last day of that month.
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 Waverley contains
- The active substance is capecitabine
  Capecitabine Waverley 500 mg film coated tablets
  Each tablet contains 500 mg Capecitabine
- The other ingredients are:
  - Tablet core: anhydrous lactose, croscarmellose sodium, hypromellose, microcrystalline cellulose, magnesium stearate.
  - Tablet coating: hypromellose, titanium dioxide (E171), macrogol/PEG, yellow and red iron oxide (E172), talc.

What Capecitabine Waverley tablets looks like and contents of the pack
Capecitabine Waverley 500 mg film coated tablets
Peach colored film-coated, biconvex, oblong tablets having plain surface on both sides.
Each pack contains 120 film-coated tablets (12 blisters of 10 tablets).

This leaflet was last revised in 07/2020
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Waverley Pharma Europe Ltd.

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