

INTACAPE 500MG TABLETS

Capecitabine Tablets (500 mg)

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What INTACAPE is used for

INTACAPE is a prescription medicine used to treat people with:

- breast cancer that has spread to other parts of the body (metastatic) together with another medicine called docetaxel after treatment with certain other anticancer medicines have not worked.
- breast cancer that has spread to other parts of the body and has not improved after treatment with taxanes and anthracyclines, or who cannot receive any more treatment with certain anti-cancer medicines.
- After surgery of stage III cancer of the colon (Dukes' C stage).
- cancer of the colon or rectum (colorectal) that has spread to other parts of the body (metastatic).
- As 1st line treatment for patients with cancer of the foodpipe (esophagus) or stomach in combination with drugs belonging to the class platinums.

It is not known if INTACAPE is safe and effective in children.

How INTACAPE works

INTACAPE belongs to the group of medicines called "cytostatic medicines", which stop the growth of cancer cells. INTACAPE 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 INTACAPE

When you must not take it

Do not take INTACAPE if you:

- have severe kidney problems.
- are allergic to capecitabine, 5-fluorouracil, or any of the ingredients in INTACAPE. See the end of this leaflet for a complete list of ingredients in INTACAPE.

- Talk to your doctor before taking INTACAPE if you are not sure if you have any of the conditions listed above.

Before you start to take it

Before you take INTACAPE, tell your doctor if you:

- have had heart problems.
- have kidney or liver problems.
- have been told that you lack the enzyme DPD (dihydropyrimidine dehydrogenase)
- have any other medical conditions.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. INTACAPE may affect the way other medicines work, and other medicines may affect the way INTACAPE works. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new 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 need to be particularly careful if you are taking any of the following:

- blood-thinning medicines (coumarin, warfarin),
- certain anti-viral medicines (sorivudine and brivudine),
- medicines for seizures or tremors (phenytoin)
- radiotherapy and certain medicines used to treat cancer (folinic acid, oxaliplatin, bevacizumab)
- Antacids

How to use INTACAPE

How much to use

Take INTACAPE exactly as your doctor tells you to take it.

Your doctor will tell you how much INTACAPE to take and when to take it.

When to use it

Take INTACAPE 2 times a day, 1 time in the morning and 1 time in the evening.

Take INTACAPE within 30 minutes after finishing a meal. Swallow INTACAPE tablets whole with water. Do not crush or cut INTACAPE tablets.

How long to use it

If you have side effects with INTACAPE, if needed your doctor may decide to:

- change your dose of INTACAPE
- treat you with INTACAPE less often
- tell you to stop taking INTACAPE until certain side effects get better or go away
- stop your treatment with INTACAPE if you have certain side effects and they are severe

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

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schedule and check with your doctor.

If you use too much (overdose)

If you take too much INTACAPE, call your doctor or go to the nearest emergency room right away.

While you are using INTACAPE

Things you must do

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

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

INTACAPE 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.

Things you must not do

Do not take INTACAPE:

- if you are allergic to capecitabine or any of the other ingredients of this medicine. 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 an unexpected reactions to fluoropyrimidine therapy (a group of anticancer medicines such as fluorouracil), hypersensitivity to fluorouracil
- if you know that you have DPD deficiency
- if you are pregnant or breast-feeding

If any of the agents in the combination regimen is contraindicated, that agent should not be used.

Things to be careful of

Talk to your doctor or pharmacist before taking INTACAPE

- if you have diarrhea if you are or become dehydrated
- If you are dehydrated because of severe nausea and vomiting
- 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 a partial deficiency in the activity of the enzyme (DPD)
- if you have a pain, swelling, redness or tingling of hands and/or feet (Hand-and-foot skin-reaction)
- if you have liver or kidney diseases

Side effects

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

The most common side effects of INTACAPE include:

- diarrhoea
- nausea
- vomiting
- stomach area (abdominal) pain
- hand-foot syndrome
- tiredness
- weakness
- loss of appetite for food
- irregular heartbeat and palpitations, chest pain, heart problems
- 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)
- blood clots in the veins

These are not all the possible side effects of INTACAPE. For more

information, ask your doctor or pharmacist.

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 INTACAPE

Storage

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date, which is stated on the carton.

Do not store above 30°C.

Disposal

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 to protect the environment.

Product description

What it looks like

Peach coloured, oblong shaped, biconvex, film coated tablets, debossed with '500' on one side and plain on other side

Ingredients

Active ingredient:
Capecitabine

Inactive ingredient:

Anhydrous Lactose
Microcrystalline Cellulose
Croscarmellose Sodium
Hydroxypropylmethylcellulose E5
Magnesium Stearate
Hydroxypropylmethylcellulose 6cps
Purified Talc
Titanium Dioxide
Ferric oxide red
Ferric oxide yellow

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Manufacturer:

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Product Registration Holder:

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