

INTACAPE 150 (Capecitabine Tablets USP 150 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 platinum.

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 use 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.
- if you have known dihydropyrimidine dehydrogenase (DPD) deficiency
- you are taking a medicine containing sorivudine or brivudine. Taking sorivudine or brivudine at the same time as INTACAPE is potentially fatal.
- The package is torn or shows signs of tampering.
- The expiry date (EXP) printed on the pack has passed.
- If you take this medicine after the expiry date has passed, it may not work as well.
- 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 use it

Talk to your doctor before taking INTACAPE, if you

- know that you have a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD)
- have liver or kidney diseases
- have or had heart problems (for example an irregular heart beat) or pains to the chest, jaw and back, brought on by physical effort and due to problems with the blood flow to the heart
- have brain diseases (for example cancer that has

spread to the brain) or nerve damage (neuropathy)

- have calcium imbalances (seen in blood tests)
- have diabetes
- cannot keep your food or water in your body because of severe nausea and vomiting
- have diarrhoea
- are or become dehydrated
- have imbalances of ions in your blood (electrolyte imbalances, seen in test)
- have a history of eye problems as you may need extra monitoring of your eyes
- have severe skin reaction

DPD deficiency: DPD deficiency is a rare condition present at birth that is not usually associated with health problems unless you receive certain medicines. If you have an unrecognised DPD deficiency and take INTACAPE, you are at an increased risk of acute early-onset of severe forms of the side effects listed under *section side effects*. Contact your doctor immediately if you are concerned about any of the side effects or if you notice any additional side effects not listed in the leaflet.

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, medicines used to treat heartburn or indigestion

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. Your doctor will calculate the dose based on your height and weight.

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 schedule and check with your doctor.

If you use too much (overdose)

You might get the following side effects if you take a lot more capecitabine than you should: nausea, vomiting, diarrhoea, inflammation or ulceration of the gut or mouth, pain or bleeding from the intestine or stomach, or reduction in certain kinds of blood cells. Tell your doctor immediately

if you experience any of these symptoms.

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

While you are using it

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.

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 reaction 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
- 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.

Side effects

INTACAPE helps most people with cancers of the bowel, breast, stomach or oesophagus (food pipe), but it may cause unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- loss of appetite, weight loss
- hand and foot syndrome
- diarrhea
- vomiting
- nausea (feeling like you want to vomit)

- stomach area (abdominal) pain
- fatigue (tiredness), weakness or weariness
- increased amounts of red blood cell breakdown products (bilirubin) in your blood

Some of these side effects are more common when capecitabine is used with other medicines for the treatment of cancer.

- heart problems
- loss of too much body fluid (dehydration) and kidney failure.
- serious skin and mouth reactions.
- decrease in white blood cells, platelets, and red blood cell counts.
- nervous system disorder

These are the more common side effects of INTACAPE. Your doctor may advise to change the dose of INTACAPE that you are taking if you experience any of the above side effects.

Tell your doctor immediately if you experience any of the following side effects:

- nausea that reduced your appetite significantly
- vomiting (more than once within 24 hours)
- severe diarrhoea with more than 4 bowel movements each day
- pain, redness and/or swelling that affects your daily activities significantly
- pain, redness, swelling or ulcers in the mouth and/or throat
- if you have pain, swelling, redness or tingling of hands and/or feet
- if you have a temperature of 38°C or greater.
- if you experience signs of infection caused by bacteria or virus, or other organisms.
- chest pain
- if you experience painful red or purplish rash that spreads and blisters and/or other

lesions begin to appear in the mucous membrane (e.g. mouth and lips), in particular if you had before light sensitivity, infections of the respiratory system (e.g. bronchitis) and/or fever

You need to stop taking INTACAPE if you experience the above side effects. Your doctor will treat your side effects before they start you on INTACAPE again.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

These side effects may differ when taking INTACAPE in combination with a chemotherapy medicine.

Please consult with your doctor on possible side effects that may occur when taking INTACAPE in combination with a chemotherapy medicine.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my (Consumer → Reporting → 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

Light peach coloured, oblong shaped, biconvex, film coated tablets, debossed with '150' on one side and plain on other side

Ingredients

Active ingredient:

Capecitabine

Inactive ingredient:

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

MAL number:

Manufacturer

Intas Pharmaceuticals Limited.
Plot Numbers 457-458 &
191/218P,
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Product

Registration Holder

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