CAPECITABINE-DRLA

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking CAPECITABINE-DRLA?

CAPECITABINE-DRLA contains the active ingredient capecitabine. CAPECITABINE-DRLA is used to treat cancer of bowel and rectum (colorectal), breast cancer, cancer of the stomach and food pipe (oesophagus).

For more information, see Section 1. Why am I taking CAPECITABINE-DRLA? in the full CMI.

2. What should I know before I take CAPECITABINE-DRLA?

Do not take if you have ever had an allergic reaction to CAPECITABINE-DRLA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take CAPECITABINE-DRLA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CAPECITABINE-DRLA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take CAPECITABINE-DRLA?

- Take your medicine two times each day (morning and evening).
- Swallow the tablets whole with a full glass of water. Do not chew the tablets.

More instructions can be found in Section 4. How do I take CAPECITABINE-DRLA? in

the full CMI.

5. What should I know while taking CAPECITABINE-DRLA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking • CAPECITABINE-DRLA. If you become pregnant while taking this medicine, tell • your doctor immediately. Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.
Things you should not do	• Do not take CAPECITABINE-DRLA to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how CAPECITABINE-DRLA affects you.
Looking after your medicine	• Keep below 25°C. • Keep your tablets in the pack until it is time to take them.

For more information, see Section 5. What should I know while taking CAPECITABINE-DRLA? in the full CMI.

6. Are there any side effects?

Less serious side effects are stomach problems; fatigue; skin problems; fever; headache; dizziness; hair loss; eye problems; dehydration; sore mouth and throat; breathing problems; redness or swelling of hands and/or feet; changes in taste; muscle and joint pain; difficulty in sleeping. Serious side effects are severe diarrhoea; nausea; vomiting; pain redness and swelling of hand and/or feet; passing little or no urine; breathing problem; chest pain, irregular heartbeat; confusion; memory loss; blurred vision, weakness; liver problems, blood in faeces, severe blisters and bleeding on face and genitals; severe skin reactions. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CAPECITABINE-DRLA

Active ingredient(s): *capecitabine*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CAPECITABINE-DRLA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking CAPECITABINE-DRLA.**

Where to find information in this leaflet:

1. Why am I taking CAPECITABINE-DRLA?
2. What should I know before I take CAPECITABINE-DRLA?
3. What if I am taking other medicines?
4. How do I take CAPECITABINE-DRLA?
5. What should I know while taking CAPECITABINE-DRLA?
6. Are there any side effects?
7. Product details

1. Why am I taking CAPECITABINE-DRLA?

CAPECITABINE-DRLA contains the active ingredient capecitabine. CAPECITABINE-DRLA belongs to a group of medicines called anti-neoplastic medicines. Within this group, CAPECITABINE-DRLA belongs to a class of medicines called fluoropyrimidine analogues.

The active ingredient, capecitabine, is converted in the body by the liver and cancer cells to a medicine called 5-fluorouracil (also called 5-FU). It is 5-FU that works to kill or stop the growth of cancer cells.

CAPECITABINE-DRLA is used to treat:

- cancer of the bowel and rectum (colorectal)
- breast cancer
- cancer of the stomach and food pipe (oesophagus)

CAPECITABINE-DRLA may be prescribed alone or in combination with other medicines used to treat cancer, such as chemotherapy medicines.

Ask your doctor if you have any questions about why CAPECITABINE-DRLA has been prescribed for you.

Your doctor may have prescribed it for another reason. CAPECITABINE-DRLA is only available with a doctor's prescription. CAPECITABINE-DRLA is not addictive.

2. What should I know before I take CAPECITABINE-DRLA?

Warnings

Do not take CAPECITABINE-DRLA if:

- you are allergic to:
  - any medicine containing capecitabine
  - fluorouracil (also called 5-FU), a medicine used to treat cancer
  - other fluoropyrimidine medicines
  - any of the ingredients listed at the end of this leaflet

  Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin

  Always check the ingredients to make sure you can take this medicine.
- have or have had any of the following:
  - severe kidney disease
  - known dihydropyrimidine dehydrogenase (DPD) deficiency
- you are taking any medicines containing the following:
  - sorivudine
  - brivudine

  These medicines are usually used to treat viral infections such a shingles, chicken pox, or cold sores (herpes simplex 1). Taking these medicines at the same time as CAPECITABINE-DRLA is potentially fatal.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

  If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have or have had any of the following medical conditions:
  - heart disease, coronary artery disease
  - kidney disease
  - liver disease
- are dehydrated. Some signs of dehydration include:
  - dry skin
  - dark coloured urine
  - thirst
  - weakness or fatigue
  - loss of appetite
- take any medicines for any other condition

If you have not told your doctor about any of the above, tell them before you start taking CAPECITABINE-DRLA.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy. Your doctor may advise you to avoid becoming pregnant while taking this medicine.

Do not breastfeed if you are taking this medicine.

It is not known whether CAPECITABINE-DRLA and 5-FU pass into breast milk. Your doctor will discuss with you the risks and benefits involved.

Use in children

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with CAPECITABINE-DRLA and affect how it works. These include:

- warfarin, a medicine used to prevent blood clots and to thin the blood
- phenytoin, a medicine used to treat seizures, epilepsy and heart irregularities
- leucovorin, also called folinic acid, a medicine used to treat folic acid deficient anaemias
- antacids, medicines used to treat heart burn or indigestion

These medicines may be affected by CAPECITABINE-DRLA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CAPECITABINE-DRLA.

4. How do I take CAPECITABINE-DRLA?

How much to take

- Take CAPECITABINE-DRLA exactly as your doctor has told you to.
- CAPECITABINE-DRLA may be given with or without chemotherapy.
- Your doctor will tell you how many CAPECITABINE-DRLA tablets to take each day and how often to take them. Your doctor will calculate your dose based on your height and weight.
- Your doctor may vary your dose depending on the nature of your illness and your response to CAPECITABINE-DRLA.

Use in elderly patients:

The same dose is recommended for elderly patients given CAPECITABINE-DRLA alone.

A lower dose may be given to elderly patients taking CAPECITABINE-DRLA in combination with other medicines to treat cancer.

When to take CAPECITABINE-DRLA

- Take your medicine two times each day (morning and evening).

  Taking it at the same times each day will have the best effect. It will also help you remember when to take it.
- Take your medicine with food.
- You should take CAPECITABINE-DRLA no later than 30 minutes after food.
- When you take CAPECITABINE-DRLA in combination with chemotherapy, your doctor will advise which days of your treatment cycle you should take CAPECITABINE-DRLA.

How to take CAPECITABINE-DRLA

- Swallow the tablets whole with a full glass of water.
- Do not chew the tablets.

How long to take CAPECITABINE-DRLA

- Continue taking your medicine for as long as your doctor tells you.

  The duration of treatment with CAPECITABINE-DRLA varies, depending on the nature of your illness and your individual response to treatment.
- Your CAPECITABINE-DRLA therapy is made up of a series of treatment cycles which usually last for 21 days. Your doctor will advise you how many cycles of treatment you will have and whether there are any rest days in the cycle.

  In most cases, your treatment cycle will consist of intermittent CAPECITABINE-DRLA therapy, where you will take CAPECITABINE-DRLA for 14 days, followed by a rest period of 7 days. During the rest period, you will not take any CAPECITABINE-DRLA.

  Alternatively, your treatment cycle may be continuous, which involves 21 days of CAPECITABINE-DRLA treatment with no rest period.

If you forget to take CAPECITABINE-DRLA

Skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much CAPECITABINE-DRLA

If you think that you or anyone else has taken too much CAPECITABINE-DRLA, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre **(13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Some signs of an overdose may include nausea, vomiting, diarrhoea or gastrointestinal irritation and bleeding.

5. What should I know while taking CAPECITABINE-DRLA?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CAPECITABINE-DRLA.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking CAPECITABINE-DRLA.
- If you become pregnant while taking CAPECITABINE-DRLA, tell your doctor immediately.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

  Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you develop:

- diarrhoea (more than 4 bowel movements each day)
- nausea (feeling like you want to vomit) and it has affected your appetite significantly
- vomiting, and vomit more than once in a 24-hour period
- redness or swelling of your hands and/or feet that affects your normal activities, also called hand-foot syndrome
- pain, redness, swelling, sores or ulcers in the mouth

CAPECITABINE-DRLA can sometimes cause the above problems in some people. Your doctor may stop your treatment and treat these issues before starting you on CAPECITABINE-DRLA again.

Remind any doctor, dentist or pharmacist you visit that you are taking CAPECITABINE-DRLA.

Things you should not do

- Do not take CAPECITABINE-DRLA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

- Ensure that you remain well hydrated by drinking adequate amounts of water each day.

Driving or using taking machines

Be careful before you drive or use any machines or tools until you know how CAPECITABINE-DRLA affects you.

Looking after your medicine

- Keep below 25°C.
- Keep your tablets in the pack until it is time to take them.

  If you take the tablets out of the pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a- half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take CAPECITABINE-DRLA or it is out of date, take it to any pharmacy for safe disposal.

Do not take CAPECITABINE-DRLA after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CAPECITABINE-DRLA.

CAPECITABINE-DRLA helps most people with cancer, but it may have unwanted side effects in a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• diarrhoea • vomiting • nausea (feeling like you want to vomit) • fatigue (tiredness) or weariness • skin rashes, dry, itchy or red skin	**Speak to your doctor if you have any of these less serious side effects and**

Less serious side effects	What to do
• pain in your abdomen (gut) • fever, or increased temperature • constipation • headache • dizziness • loss of appetite, weight loss • hair loss • increased eye watering or irritation, conjunctivitis (itchy eyes and crusty eyelids) • indigestion or wind (gas) • dry mouth, thirst, dehydration, dark coloured urine • sore mouth, mouth ulcers, cold sores • nail disorders • sore throat, cough, nose bleeds • shortness of breath, difficulty in breathing or tightening of the chest • redness or swelling of your hands and/or feet • tingling or numbness of the hands or feet • altered sense of taste • muscle and joint pain • difficulty sleeping.	**they worry you.** Your doctor may change your dose of CAPECITABINE-DRLA if you experience any of the above side effects.

Serious side effects

Serious side effects	What to do
• severe diarrhoea with more than 4 bowel movements each day • nausea that has significantly reduced your appetite • vomiting more than once in a 24-hour period • pain, redness and/or swelling of your hands and/or feet that has affected your normal activities (hand-foot syndrome) • pain, redness, swelling or ulcers in the mouth (stomatitis) • passing little or no urine (this could be a sign of kidney disease) • drowsiness • breathlessness.	**Tell your doctor as soon as possible if you notice any of these side effects.** You may need to stop taking CAPECITABINE-DRLA and be treated for these side effects by your doctor, before starting CAPECITABINE-DRLA again.
• chest pain • irregular heartbeat • shortness of breath • one or a combination of the following: o confusion o disorientation or memory loss	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
o changes in the way you move, walk or talk o poor balance or lack of coordination o decreased strength or progressive weakness in your body o blurred or loss of vision • numbness or weakness of arms and/or legs • signs of infection such as swelling, redness, and increased temperature • signs of liver disease such as yellowing of the skin and eyes • blood in the faeces • severe blisters and bleeding in the lips, eyes, mouth, nose, or genitals • severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin, accompanied by fever and chills, aching muscles and generally feeling unwell.	

These side effects may differ when taking CAPECITABINE-DRLA in combination with a chemotherapy medicine.

Ask your doctor for possible side effects that may be caused by taking CAPECITABINE-DRLA with a chemotherapy medicine.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CAPECITABINE-DRLA contains

Active ingredient (main ingredient)	capecitabine
Other ingredients	croscarmellose sodium hypromellose

(inactive ingredients)	iron oxide red iron oxide yellow lactose magnesium stearate microcrystalline cellulose purified talc titanium dioxide
Potential allergens	sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What CAPECITABINE-DRLA looks like

Availability

Capecitabine-DRLA tablets are available in two strengths, 150 mg and 500 mg.

Capecitabine-DRLA tablets come in blister packs in the following pack sizes:

- 150 mg - 60 tablets
- 500 mg - 120 tablets

What Capecitabine-DRLA looks like

- 150 mg: Light peach film- coated tablet of biconvex, oblong shape with the marking “150” on one side and “RDY” on other side (AUST R 200935).
- 500 mg: Peach, film-coated tablet of biconvex, oblong shape with the marking “500” on one side and “RDY” on the other side (AUST R 200933).

Who distributes CAPECITABINE-DRLA

Sponsor

Dr Reddy’s Laboratories (Australia) Pty Ltd

Suite 3.03, Level 3, 390 St Kilda Road, Melbourne

VIC 3004

Tel: 1800 733 397

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