APPROVED PATIENT INFORMATION LEAFLET (Clean copy)

S4

REBUTRIX 150 mg (film coated tablet)

REBUTRIX 500 mg (film coated tablet)

(Capecitabine)

(Contains Sugar: Lactose Monohydrate)

Read all of this leaflet carefully before you start taking REBUTRIX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **REBUTRIX** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. WHAT REBUTRIX IS AND WHAT IS USED FOR

REBUTRIX contain a medicine called capecitabine.

This belongs to a class of cytostatic medicines (medicines that inhibits cell growth).

REBUTRIX used in the treatment of cancers especially breast cancer, colorectal cancer and gastric cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE REBUTRIX

Do not take REBUTRIX:

- If you have ever had an allergic reaction to **REBUTRIX** or any ingredient of the **REBUTRIX**.

- If you have a history of severe unexpected reactions with fluoropyrimidine therapy (this is also an anticancer medicine).
- If you have ever had any hypersensitivity reactions to fluorouracil (capecitabine metabolite).
- If you are dihydropyrimidine dehydrogenase deficient (DPD is a certain type of metabolic disorder).
- If you have any type of blood disorder like leukopaenia (abnormal lowering of the white blood cell count), neutropenia (abnormally low concentration of neutrophils (a type of white blood cell)), or thrombocytopenia (a condition in which you have a low blood platelet count).
- If you have severe liver problems.
- If you have severe kidney problems.
- If you are being treated with sorivudine now or in the last 4 weeks or its analogues like brivudine (these are antiviral medicines).
- If you are pregnant or planning to become pregnant or breastfeeding.

Warnings and precautions

Take special care with **REBUTRIX** by telling your doctor**:**

- If you are taking blood thinning medicine such as warfarin.
- If you have diarrhoea.
- If you are or become dehydrated because of severe nausea and vomiting.
- If you have heart problems.
- If you have liver problems.
- If you have kidney problems.\
- If you have numbness and changes in sensation, redness, pain or swelling of your hands and feet as **REBUTRIX** can also cause “hand and foot syndrome.”

Taking other medicines with REBUTRIX:

Always tell your healthcare professional if you are taking any other medicine (This included complementary and traditional medicines).

REBUTRIX may have an effect on other medicines or other medicines may have an effect on **REBUTRIX**.

- Blood clotting and bleeding parameters may be changed when **REBUTRIX** is given with warfarin or phenoprocoumon.
- Phenytoin plasma concentrations and toxicity symptoms are increased when **REBUTRIX** is given with phenytoin (used to treat epilepsy).
- Plasma concentration of **REBUTRIX** is increased when **REBUTRIX** is given with antacids (antacids are medicines which neutralises the stomach acidity).
- Dose should be reduced when **REBUTRIX** is given with folinic acid (decrease the toxic effects of methotrexate and pyrimethamine) or interferon alfa (medicine used to treat viral infections and cancers).
- If you are currently being treated or have had a previous history with radiotherapy, you may be more likely to experiencing side effects.
- A possible life-threatening interaction exists between REBUTRIX and sirovudine or its chemically related analogues such as brivudine therefore these medicines should not be administered together.

Taking REBUTRIX with food and drink:

REBUTRIX should be swallowed with water within 30 minutes after a meal.

Pregnancy and breastfeeding:

If your pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **REBUTRIX.**

REBUTRIX is not recommended during pregnancy or breastfeeding, (see 'Do not take **REBUTRIX**, as **REBUTRIX** may be harmful to the baby. Your doctor may prescribe an effective method of contraception during treatment and for 6 months after the last dose of **REBUTRIX**.

Driving and using machinery:

Since **REBUTRIX** may cause dizziness (a feeling that you are about to fall), tiredness and vision problems, this may influence your ability to drive, use machinery or perform any other tasks that require concentration.

REBUTRIX contains lactose:

REBUTRIX contains lactose, which is a type of sugar. 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 REBUTRIX

Do not share medicines prescribed for you with any other person.

Always take **REBUTRIX** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose may vary depending on the type and severity of your cancer, your age and your body surface area.

REBUTRIX should be swallowed with a glass of water within 30 minutes after a meal.

Your doctor will tell you how long your treatment with **REBUTRIX** will last. Do not stop treatment early because this may cause reoccurrence of your condition. If you have the impression that the effect of **REBUTRIX** is too strong or too weak, tell your doctor or pharmacist.

If you take more REBUTRIX than you should:

If you take more than your required dose you may experience nausea, vomiting, diarrhoea (frequent and watery bowel movements), mucositis (inflammation of mucous membrane), gastrointestinal irritation, bleeding and bone marrow depression.

Symptomatic and supportive measures should be provided.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take REBUTRIX:

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBILE SIDE EFFECTS

Not all side effects reported for **REBUTRIX** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

REBUTRIX can have side effects:

If any of the following happens, stop taking **REBUTRIX** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth and throat, which may cause difficulty in breathing,
- pruritus (an intense itching sensation),
- skin discoloration,
- skin ulceration or blistering of the skin, mouth, eyes or genitals as this may be due to a serious allergic reaction known as Stevens-Johnson Syndrome.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **REBUTRIX**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreases in the amount of red blood cells, white blood cells and platelets (seen in blood tests)
- loss of appetite
- abdominal or stomach pain,
- diarrhoea (frequent and watery bowel movements) moderate or severe,
- stomatitis (sores in mouth and throat),
- constipation (difficult evacuation of the bowels) mild or moderate,
- nausea,
- unusual tiredness,

- vomiting,
- hyperbilirubinaemia (high amounts of bile pigment (bilirubin) in the blood),
- dermatitis (inflammation of the skin),
- hand and foot syndrome (redness, swelling, and pain on the palms of the hands and/or the soles of the feet).

Less frequent side effects:

- encephalopathy (brain related disease or disorder),
- fungal infection,
- infection,
- keratoconjunctivitis (inflammation of the crania and conjunctiva),
- sepsis (presence of pus-forming bacteria or their toxins in the blood or tissues),
- viral infection,
- influenza like illness,
- irritability,
- coagulation disorder (blood clotting disorder),
- leukopenia (abnormal lowering of the white blood cell count),
- lymphedema (lymph accumulating in the tissues),
- hypokalemia (low level of potassium in the circulating blood),
- hypomagnesemia (lower serum magnesium concentration),
- hypertriglyceridemia (higher blood levels of triglycerides),
- dehydration (depletion of bodily fluids),
- loss of consciousness,
- dizziness (a feeling that you are about to fall),
- insomnia (chronic sleeplessness),
- confusion,
- depression,
- ataxia (inability to coordinate voluntary muscle movements),
- headache,

- paresthesia (abnormal skin sensations),
- impaired balance,
- tremor (involuntary vibration),
- conjunctivitis (inflammation of the conjunctiva of the eye),
- eye irritation,
- angina pectoris - heart condition marked by chest pain),
- atrial fibrillation,
- bradycardia (abnormally slow heartbeat),
- cardiomyopathy (heart muscle disorder),
- cardiotoxicity (damage to the heart muscle),
- extrasystoles (a heartbeat outside the normal rhythm),
- myocarditis (inflammation of the myocardia of the heart),
- pericardial effusion (fluid around the heart),
- tachycardia (abnormally higher heart beat),
- ventricular extrasystoles (extra, abnormal heartbeats that begin in one of ventricles),
- cerebrovascular accident,
- hypotension (abnormally low blood pressure),
- hypertension (abnormally high blood pressure),
- phlebitis (inflammation of a vein (usually in the legs)),
- thrombophlebitis (conjunction with the formation of a blood clot),
- deep vein thrombosis,
- hot flushes (sudden brief sensation of heat),
- bronchitis (inflammation of bronchus),
- bronchopneumonia (acute inflammation of the walls of the bronchioles),
- bronchospasm (spasm of the bronchi that makes exhalation difficult and noisy),
- dyspnea (difficult or laboured respiration),
- respiratory distress,
- dysarthria (impaired speech ability),

- epistaxis (bleeding from the nostril, nasal cavity, or nasopharynx),
- hemoptysis (coughing up of blood or blood-stained mucus from the bronchi, larynx, trachea, or lungs),
- pneumonia (inflammation of the lung parenchyma),
- pulmonary embolism (blockage of the pulmonary artery),
- asthma (inflammation and narrowing of the airways),
- cough,
- hoarseness (a throaty harshness),
- laryngitis (inflammation of larynx),
- dysphasia (language disorder marked by deficiency in the generation of speech),
- gastric ulcer,
- gastrointestinal hemorrhage (bleeding in the gastrointestinal tract),
- gastrointestinal tract toxicity,
- hemorrhage (bleeding),
- ileus (blockage of the intestine (especially the ileum)),
- dyspepsia (digestive function disorder),
- abdominal distension (air (gas) or fluid, accumulate in the abdomen),
- abnormal coordination,
- ascites (accumulation of serous fluid in peritoneal cavity),
- gastroenteritis (inflammation of the stomach and intestines),
- gastrointestinal mobility disorder,
- cholestatic hepatitis (blockage of the bile ducts outside of the liver),
- hepatic fibrosis or hepatitis (inflammation of the liver),
- photosensitivity (sensitivity to light),
- radiation recall syndrome (severe skin reaction that occurs when certain chemotherapy drugs are administered during or soon after radiation treatment),
- nail disorder,
- sweating increased,

- bone marrow depression,
- arthralgia (pain in a joint),
- back pain,
- arthritis (Inflammation of one or more joints),
- bone pain,
- difficulty in walking,
- fibrosis (development of excess fibrous connective tissue in an organ),
- muscle weakness,
- renal impairment (kidney problems),
- proctalgia (condition in which the kidneys lose the ability to remove waste and balance fluids),
- collapse,
- fever,
- pyrexia (raised body temperature – fever),
- thirst (a feeling of needing or wanting to drink something),
- increased weight.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: http:///www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **REBUTRIX.**

5. HOW TO STORE REBUTRIX

Store at or below 30 °C.

Keep the blisters in the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What REBUTRIX contains

The active substance is Capecitabine.

REBUTRIX 150 mg:

Each film coated tablet contains capecitabine 150 mg. Contains sugar: 19.99 mg lactose.

REBUTRIX 500 mg:

Each film coated tablet contains capecitabine 500 mg. Contains sugar: 66.65 mg of lactose.

The other ingredients of **REBUTRIX** are cellulose microcrystalline, croscarmellose sodium, ferric oxide red, ferric oxide yellow, hypromellose, magnesium stearate, talc and titanium dioxide.

What REBUTRIX looks like and contents of the pack

REBUTRIX 150 mg:

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

REBUTRIX 500 mg:

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

Blister pack:

Tablets are packed in clear 250 micrometer PVC film coated with 90 g/m^2 PVdC as the forming material and 25 micrometer aluminium foil with 7 g/m^2 heat seal lacquer as the lidding material.

For 150 mg:

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

For 500 mg:

Pack size: 120's – Each carton contains 12 blisters of 10 tablets each.

Holder of Registration

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