# TANGITARE (Regorafenib film-coated tablets 40mg)

Regorafenib (40mg)

**What is in this leaflet**



Read this Consumer Medication Information leaflet before you start taking TANGITARE and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

## 1. What TANGITARE is used for

TANGITARE is a prescription medicine used to treat people with:

- colon or rectal cancer that has spread to other parts of the body and for which they have received previous treatment with certain chemotherapy medicines
- a rare stomach, bowel, or esophagus cancer called GIST (gastrointestinal stromal tumors) that cannot be treated with surgery or that has spread to other parts of the body and for which they have received previous treatment with certain medicines
- a type of liver cancer called hepatocellular carcinoma (HCC) in people who have been previously treated with sorafenib

It is not known if TANGITARE is safe and effective in children less than 18 years of age.

## 2. How TANGITARE works

TANGITARE works by slowing down the growth and spread of cancer cells and cutting off the blood supply that keeps cancer cells growing.

## 3. Before you use TANGITARE

*What is the most important information I should know about TANGITARE*

TANGITARE can cause serious side effects, including:

**Liver problems.** TANGITARE can cause liver problems which can be serious and sometimes lead to death. Your healthcare provider will do blood tests to check your liver function before you start taking TANGITARE and during your treatment with TANGITARE to check for liver problems. Tell your healthcare provider right away if you get any of these symptoms of liver problems during treatment:

- yellowing of your skin or the white part of your eyes (jaundice)
- nausea or vomiting
- dark "tea-colored" urine
- change in sleep pattern

Before taking TANGITARE, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems in addition to liver cancer
- have bleeding problems
- have high blood pressure
- have heart problems or chest pain
- plan to have any surgical procedures or have had recent surgery.
- are pregnant or plan to become pregnant. TANGITARE can harm your unborn baby.
    - Females should use effective birth control during treatment with TANGITARE and for 2 months after your final dose of TANGITARE. Tell your healthcare provider right away if you become pregnant during treatment with TANGITARE or within 2 months after your final dose of TANGITARE.
    - Males with female partners who can become pregnant should use effective birth control during treatment with TANGITARE and for 2 months after your final dose of TANGITARE
- are breastfeeding or plan to breastfeed. It is not known if TANGITARE passes into your breast milk. Do not breastfeed during treatment with TANGITARE and for 2 weeks after your final dose of TANGITARE

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins and herbal supplements. TANGITARE may affect the way other medicines work, and other medicines may affect how TANGITARE works.

## 4. How to use TANGITARE

- Take TANGITARE exactly as your healthcare provider tells you.
- You will usually take TANGITARE 1 time a day for 21 days (3 weeks) and then stop for 7 days (1 week). This is 1 cycle of treatment. Repeat this cycle for as long as your healthcare provider tells you to.
- Swallow TANGITARE tablets whole with water following a low-fat meal.
- Take TANGITARE at the same time each day following a low-fat meal that contains less than 600 calories and less than 30% fat.
- If you miss a dose, take it as soon as you remember on that day. Do not take two doses on the same day to make up for a missed dose.
- If you take too much TANGITARE call your healthcare provider or go to the nearest emergency room right away.

## 5. While you are using it

- Avoid drinking grapefruit juice and taking St. John's Wort during treatment with TANGITARE. These can affect the way TANGITARE works.

## 6. Side effects

**TANGITARE can cause serious side effects including:**

See "*What is the most important information I should know about TANGITARE*"

**Infection.** TANGITARE may lead to a higher risk of infections especially of the

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urinary tract, nose, throat and lung. TANGITARE may also lead to a higher risk of fungal infections of the mucous membrane, skin or the body. Tell your healthcare provider right away if you get:

- fever
- severe cough with or without an increase in mucus (sputum) production
- severe sore throat
- shortness of breath
- burning or pain when urinating
- unusual vaginal discharge or irritation
- redness, swelling or pain in any part of the body
- **severe bleeding.** TANGITARE can cause bleeding which can be serious and sometimes lead to death. Tell your healthcare provider if you have any signs of bleeding during treatment with TANGITARE including:
  - vomiting blood or if your vomit looks like coffee- grounds
  - pink or brown urine
  - red or black (looks like tar) stools
  - coughing up blood or blood clots
  - menstrual bleeding that is heavier than normal
  - unusual vaginal bleeding
  - nose bleeds that happen often
  - bruising
  - lightheadedness
- **a tear in your stomach or intestinal wall (bowel perforation).** TANGITARE may cause a tear in your stomach or intestinal wall (bowel perforation) that can be serious and sometimes lead to death. Tell your healthcare provider right away if you get:
  - severe pain in your stomach-area (abdomen)
  - swelling of the abdomen
  - fever
  - chills
  - nausea
  - vomiting
  - dehydration
- **a skin problem called hand-foot skin reaction and severe skin rash**. Hand-foot skin reactions are common and sometimes can be severe. Tell your healthcare provider right away if you get redness, pain, blisters, bleeding, or swelling on the palms of your hands or soles of your feet, or a severe rash.
- **high blood pressure.** Your blood pressure should be checked every week for the first 6 weeks of starting TANGITARE. Your blood pressure should be checked regularly and any high blood pressure should be treated during treatment with TANGITARE. Tell your healthcare provider if you have severe headaches, lightheadedness, or changes in your vision.
- **decreased blood flow to the heart and heart attack.** Get emergency help right away if you get symptoms such as chest pain, shortness of breath, feel dizzy or feel like passing out.
- **a condition called Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** Call your healthcare provider right away if you get: severe headaches, seizure, confusion, change in vision, or problems thinking.
- **wound healing problems.** If you need to have a surgical procedure, tell your healthcare provider that you are taking TANGITARE. You should stop taking TANGITARE at least 2 weeks before any planned surgery.

**The most common side effects of TANGITARE include:**

- pain, including stomach-area(abdomen)
- tiredness, weakness, fatigue
- frequent or loose bowel movements (diarrhea)
- decreased appetite
- infection
- voice changes or hoarseness
- increase in certain liver function test
- fever
- swelling, pain and redness of the lining in your mouth, throat, stomach and bowel (mucositis)
- weight loss

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with TANGITARE if you have certain side effects.

These are not all of the possible side effects of TANGITARE.
Call your doctor for medical advice about side effects.

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 Vaccine (AEFI)].

**7. Storage and Disposal of TANGITARE**

- Store below 30°C.
- Store in the original package in order to protect from moisture.
- "Keep the bottle tightly closed after first opening. Once the bottle is opened the medicinal product
- has shown to be stable for 4 weeks. Thereafter, the product is to be discarded".

**Keep TANGITARE and all medicines out of the reach of children.**
**General information about TANGITARE.**
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TANGITARE for a condition for which it was not prescribed. Do not give TANGITARE to other people even if they have the same symptoms you have. It may harm them.
This leaflet summarizes the most important information about TANGITARE. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TANGITARE this is written for health professionals.

**8. Product Description**
*What TANGITARE looks like*
TANGITARE is a Light pink oval, biconvex, film-coated tablet debossed with “40” on one side and plain on other.

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They are supplied in bottle of 28 tablets.

**Ingredients**
**Active ingredient:** regorafenib (As Monohydrate)

**Inactive ingredients:** Microcrystalline cellulose, Croscarmellose sodium, Povidone, Ethanol Anhydrous, Acetone, Magnesium stearate, Colloidal Silicon Dioxide, Opadry Pink 20B540009-CN

**MAL No.**
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**9. Manufacturer**
Aizant Drug Research Solutions Private Limited.,
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Apparel Park Road Dulapally,
Dundigal Gandimaisamma,
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**10. Date of revision**
10/07/2025

**11. Serial number:**
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