

YULAREB FILM-COATED TABLETS

Abemaciclib (50 mg, 100 mg and 150 mg)

What is in this leaflet

1. What Yulareb is used for
2. How Yulareb works
3. Before you use Yulareb
4. How to use Yulareb
5. While you are using Yulareb
6. Side effects
7. Storage and Disposal of Yulareb
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Yulareb is used for

Yulareb is a prescription medicine used:

- in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer with a high risk of coming back as determined by your doctor.
- in combination with an aromatase inhibitor as the first endocrine-based therapy to treat adult patients, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has worsened or that has spread to other parts of the body (metastatic).
- in combination with fulvestrant to treat adult with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has worsened or that has spread to other parts of the body (metastatic) and whose disease has progressed after endocrine therapy.

When Yulareb is used in combination with fulvestrant, tamoxifen, or an aromatase inhibitor, also read the Patient Information for the prescribed product. Ask your doctor or pharmacist if you are not sure.

How Yulareb works

Yulareb contains the active substance abemaciclib. It belongs to a group of medicines called cyclin-dependent kinases 4 and 6 (CDK4 and CDK6) inhibitors. A kinase is a type of protein in the body that helps control cell division. Yulareb works by interfering with the kinase and stopping cancer cells from dividing and growing.

Before you use Yulareb

- When you must not use it

Do not take Yulareb:

- if you are allergic to abemaciclib or any of the other ingredients of this medicine (see section **Product description**).

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

Pregnancy and breast-feeding

Yulareb can harm your unborn baby.

Females who are able to become pregnant:

- Your doctor will do a pregnancy test before you start treatment with Yulareb.
- You should use effective birth control (contraception) during treatment with Yulareb and for 3 weeks after the last dose of Yulareb.
- Tell your doctor or pharmacist right away if you become pregnant or think you are pregnant during treatment with Yulareb.

It is not known if Yulareb passes into your breast milk. Do not breastfeed during treatment with Yulareb and for at least 3 weeks after the last dose of Yulareb.

- Before you start to use it

Tell your doctor or pharmacist about all your medical conditions, including if you:

- have fever, chills, or any other signs of an infection.
- have a history of blood clots in your veins.
- have lung or breathing problems.
- have liver or kidney problems.
- are pregnant or plan to become pregnant. Yulareb can harm your unborn baby.

- Taking other medicines

Tell your doctor or pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Yulareb may affect the way other medicines work, and other medicines may affect how Yulareb works, causing serious side effects.

Avoid taking ketoconazole during treatment with Yulareb. Tell your doctor or pharmacist if you take a medicine that

contains ketoconazole. Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

Avoid grapefruit and products that contain grapefruit during treatment with Yulareb. Grapefruit may increase the amount of Yulareb in your blood.

How to use Yulareb

- How much to use

Take Yulareb exactly as your doctor or pharmacist tells you. Your doctor or pharmacist may change your dose if needed.

- When to use it

Yulareb may be taken with or without food. Swallow Yulareb tablets whole. Do not chew, crush, or split the tablets before swallowing. Do not take Yulareb tablets if they are broken, cracked or damaged. Take your doses of Yulareb at about the same time every day.

- How long to use it

Do not stop taking Yulareb or change the dose without talking to your doctor or pharmacist.

- If you forget to use it

If you vomit or miss a dose of Yulareb, take your next dose at your regular time. Do not take 2 doses of Yulareb at the same time to make up for the missed dose.

- If you use too much (overdose)

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

While you are using Yulareb

- Things you must do

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

Do not use Yulareb for a condition for which it was not prescribed. Do not give Yulareb to other people, even if they have the same symptoms you have. It may harm them.

- Things to be careful of

Yulareb may cause fertility problems in males. This may affect your ability to

father a child. Talk to your doctor or pharmacist if this is a concern for you.

Side effects

Yulareb may cause serious side effects, including:

- Diarrhea. Diarrhea is common with Yulareb treatment and may sometimes be severe. Diarrhea may cause you to develop dehydration or an infection. The most common time to develop diarrhea is during the first month of Yulareb treatment. If you develop diarrhea during treatment with Yulareb, your doctor may tell you to temporarily stop taking Yulareb, stop your treatment, or decrease your dose.

- If you have any loose stools, start taking an antidiarrheal medicine (such as loperamide), drink more fluids, and tell your doctor right away.

- Low white blood cell counts (neutropenia). Low white blood cell counts are common during treatment with Yulareb and may cause serious infections that can lead to death. Your doctor should check your white blood cell counts before and during treatment. If you develop low white blood cell counts during treatment with Yulareb, your doctor may tell you to temporarily stop taking Yulareb, decrease your dose, or wait before starting your next month of treatment. Tell your doctor right away if you have signs and symptoms of low white blood cell counts or infections, such as fever and chills.

- Lung problems (interstitial lung disease (ILD) or pneumonitis). Yulareb may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. If you develop lung problems during treatment with Yulareb, your doctor may tell you to temporarily stop taking Yulareb, decrease your dose, or stop your treatment. Tell your doctor right away if you have any new or worsening symptoms, including:

- Trouble breathing or shortness of breath
 - Cough with or without mucus
 - Chest pain

- Liver problems. Yulareb can cause serious liver problems. Your doctor should do blood tests to check your liver before and during treatment with Yulareb. If you develop liver problems during treatment with Yulareb, your

doctor may reduce your dose or stop your treatment. Tell your doctor right away if you have any of the following signs and symptoms of liver problems:

- Feeling very tired
- Pain on the upper right side of your stomach area (abdomen)
- Loss of appetite
- Bleeding or bruising more easily than normal

- Blood clots in your veins, or in the arteries of your lungs. Yulareb may cause serious blood clots that have led to death. If you develop blood clots during treatment with Yulareb, your doctor may tell you to temporarily stop taking Yulareb. Tell your doctor right away if you get any of the following signs and symptoms of a blood clot:

- Pain of swelling in your arms or legs
 - Shortness of breath
 - Chest pain
 - Rapid breathing
 - Rapid heart rate

The most common side effects of Yulareb include:

- Nausea
- Infections
- Low red blood cell counts (anemia)
- Decreased appetite
- Headache
- Hair thinning or hair loss (alopecia)
- Abdominal pain
- Tiredness
- Low white blood cell counts (leukopenia)
- Vomiting
- Low platelet count (thrombocytopenia)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 Yulareb

- Storage

Keep this medicine out of the sight and reach of children.

Store Yulareb at room temperature, do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

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 protect the environment.

Product Description

- What it looks like

Yulareb 50 mg Film-coated Tablets: oval beige tablet with “Lilly” debossed on one side and “50” on the other side.

Yulareb 100 mg Film-coated Tablets: oval white to practically white tablet with “Lilly” debossed on one side and “100” on the other side.

Yulareb 150 mg Film-coated Tablets: oval yellow tablet with “Lilly” debossed on one side and “150” on the other side.

Yulareb 50 mg, 100 mg and 150 mg are available in blister packs of 2 x 7 tablets.

Ingredients

- Active ingredient

The active substance is abemaciclib.

- Yulareb 50 mg Film-coated Tablets: Each tablet contains 50 milligrams of abemaciclib.

- Yulareb 100 mg Film-coated Tablets: Each tablet contains 100 milligrams of abemaciclib.

- Yulareb 150 mg Film-coated Tablets: Each tablet contains 150 milligrams of abemaciclib.

- Inactive ingredients

The other ingredients are: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, sodium stearyl fumarate and silicon dioxide.

Colour mixture ingredients are: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide yellow, and iron oxide red.

MAL numbers

Yulareb 50 mg Film-coated Tablets – MAL20046079ARZ

Yulareb 100 mg Film-coated Tablets – MAL20046080ARZ

Yulareb 150 mg Film-coated Tablets – MAL20046081ARZ

Manufacturer

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Product Registration Holder

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