

Applicant: Eli Lilly (S.A.) (Pty) Limited

TA4483/TA4815/TA5337/TA6216_ZA_PIL_v08_MTC

Proprietary Name(s): Verzenio/Yulareb 50 mg, 100 mg, 150 mg & 200 mg

Date: 28 October 2024

Active ingredient: Abemaciclib

Dosage Form and Strength: Film-coated tablets 50 mg, 100 mg, 150 mg & 200 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

YULAREB 50 mg Film-coated tablet

YULAREB 100 mg Film-coated tablet

YULAREB 150 mg Film-coated tablet

YULAREB 200 mg Film-coated tablet

Abemaciclib

Contains sugar (lactose)

Read all of this leaflet carefully before you start taking YULAREB

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor pharmacist, nurse or other health care provider.
- YULAREB 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 YULAREB is and what it is used for
2. What you need to know before you take YULAREB
3. How to take YULAREB
4. Possible side effects
5. How to store YULAREB
6. Contents of the pack and other information

1. What YULAREB is and what it is used for

YULAREB is a cancer medicine containing the active substance abemaciclib and is 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.
- in combination with an aromatase inhibitor as the first endocrine-based therapy to treat women who have gone through menopause (postmenopausal), and men, 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 adults 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.

In pre- or perimenopausal women, the treatment should be combined with a Luteinising hormone-releasing hormone (LHRH) agonist (a medicine that cause the ovaries to stop making oestrogen and progesterone).

- alone to treat post-menopausal women with HR-positive, 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 and prior chemotherapy.

When YULAREB is used in combination with fulvestrant, tamoxifen, or an aromatase inhibitor, also read the Patient Information of the prescribed product. Ask your healthcare provider if you are not sure.

2. What you need to know before you take YULAREB

Do not take YULAREB

If you are hypersensitive (allergic) to abemaciclib or any of the other ingredients of YULAREB (listed in section 6).

If you are currently taking a medicine containing ketoconazole (a medicine used to treat fungal infections).

If you are pregnant or are breastfeeding your infant.

Warnings and precautions

Take special care with YULAREB

- if you develop diarrhoea, it may lead to dehydration and infection.
- if you have fever, chills, or any other signs of an infection.
- if you have liver problems.
- if you are pregnant or plan to become pregnant. YULAREB can harm your unborn baby.
- if you are breastfeeding or plan to breastfeed.
- if you develop pain, swelling and tenderness in one of your legs (usually the calf) contact your health care professional.
- if you have been diagnosed with interstitial lung disease (symptoms may include changes in skin colour, confusion, cough, shortness of breath).
- if you are also receiving hormone therapies, as this can cause blood clots in your arteries.

Other medicines and YULAREB

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Your dose of YULAREB might need to be changed if you are also using other medicines that affect the breakdown of YULAREB such as, clarithromycin (an antibiotic), rifampicin (used in treatment of tuberculosis), digoxin (used for heart disorders). Do not use ketoconazole while taking YULAREB.

YULAREB with food and drink

YULAREB may be taken with or without food.

Avoid grapefruit and grapefruit juice.

Pregnancy, breastfeeding and fertility

YULAREB can harm your unborn baby and you must not take it while you are pregnant or trying to become pregnant. If you are able to become pregnant, your healthcare provider must do a pregnancy test before you

Applicant: Eli Lilly (S.A.) (Pty) Limited
Proprietary Name(s): Verzenio/Yulareb 50 mg, 100 mg, 150 mg & 200 mg
Active ingredient: Abemaciclib
Dosage Form and Strength: Film-coated tablets 50 mg, 100 mg, 150 mg & 200 mg

TA4483/TA4815/TA5337/TA6216_ZA_PIL_v08_MTC
Date: 28 October 2024

start treatment with YULAREB. Females who can become pregnant should use effective birth control during treatment with YULAREB and for at least 3 weeks after the last dose of YULAREB.

Do not breastfeed during treatment with YULAREB and for at least 3 weeks after the last dose of YULAREB.

YULAREB may impair fertility in males.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

The adverse effects of YULAREB may impair your driving ability and your ability to handle machines, e.g., dizziness, diarrhoea, vomiting.

YULAREB contains lactose

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take YULAREB.

YULAREB contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

3. How to take YULAREB

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

Always take YULAREB exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your healthcare provider may change your dose if needed. Do not stop taking YULAREB or change the dose without talking to your healthcare provider.

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.

If you take more YULAREB than you should

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 YULAREB

If you miss or vomit 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.

4. Possible side effects

YULAREB can have side effects.

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

Contact your doctor immediately if you experience any of the following:

- Symptoms such as chills or fever. These could be a sign of low white blood cell counts (which may affect more than 1 in 10 people) and should be treated immediately. If you have cough, fever and difficulty breathing or chest pain, this could be a sign of lung infection. Serious or life-threatening infections are uncommon (may affect up to 1 in 100 people).
- Painful swollen leg, chest pain, shortness of breath, rapid breathing or rapid heart rate as these can be signs of blood clots in the vein (which may affect up to 1 in 10 people).
- Diarrhoea (which may affect more than 1 in 10 people).

Applicant: Eli Lilly (S.A.) (Pty) Limited

TA4483/TA4815/TA5337/TA6216_ZA_PIL_v08_MTC

Proprietary Name(s): Verzenio/Yulareb 50 mg, 100 mg, 150 mg & 200 mg

Date: 28 October 2024

Active ingredient: Abemaciclib

Dosage Form and Strength: Film-coated tablets 50 mg, 100 mg, 150 mg & 200 mg

Refer to Section 2 for more information on any of the possible effects listed above.

Other side effects with YULAREB may include:

Very common side effects include (may affect more than 1 in 10 people):

- nausea (feeling sick), vomiting
- infections
- reduction in red blood cells (anaemia) (pale skin, tiredness, noticeable heartbeats, shortness of breath)
- decreased appetite
- inflammation or sore mouth
- alteration in sense of taste
- hair loss, rash, itching
- tiredness
- dizziness
- reduction in white blood cell counts (leukopenia)
- reduction in platelet count (thrombocytopenia)
- headache
- abnormalities in liver blood tests

Common side effects (may affect up to 1 in 10 people):

- watering eyes
- muscular weakness
- dry skin
- inflammation of the lungs which causes breathlessness, cough and raised temperature
- indigestion or upset stomach, abdominal pain
- nail disorders such as breaking or splitting of nails

Applicant: Eli Lilly (S.A.) (Pty) Limited
Proprietary Name(s): Verzenio/Yulareb 50 mg, 100 mg, 150 mg & 200 mg
Active ingredient: Abemaciclib
Dosage Form and Strength: Film-coated tablets 50 mg, 100 mg, 150 mg & 200 mg

TA4483/TA4815/TA5337/TA6216_ZA_PIL_v08_MTC
Date: 28 October 2024

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of YULAREB.

Alternatively, report suspected adverse reactions to the company at ade_za@lilly.com.

5. How to store YULAREB

Store at or below 30 °C.

Store all medicines out of reach of children.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 YULAREB contains

The active substance is abemaciclib.

YULAREB 50 mg - Each film-coated tablet contains 50 mg abemaciclib.

YULAREB 100 mg - Each film-coated tablet contains 100 mg abemaciclib

YULAREB 150 mg - Each film-coated tablet contains 150 mg abemaciclib.

YULAREB 200 mg - Each film-coated tablet contains 200 mg abemaciclib.

Other ingredients are croscarmellose sodium, lactose monohydrate, microcrystalline cellulose 101, microcrystalline cellulose 102, silica colloidal hydrated and sodium stearyl fumarate.

Applicant: Eli Lilly (S.A.) (Pty) Limited
Proprietary Name(s): Verzenio/Yulareb 50 mg, 100 mg, 150 mg & 200 mg
Active ingredient: Abemaciclib
Dosage Form and Strength: Film-coated tablets 50 mg, 100 mg, 150 mg & 200 mg

TA4483/TA4815/TA5337/TA6216_ZA_PIL_v08_MTC
Date: 28 October 2024

Colour Mixture Beige Ingredients (50 mg and 200 mg tablets): polyvinyl alcohol [E1203], titanium dioxide [E171], polyethylene glycol or macrogol [polyethylene glycol MW 3350 or macrogol 4000] [E1521], talc [E553b], iron oxide yellow [E172] and iron oxide red [E172].

Colour Mixture White Ingredients (100 mg tablet): polyvinyl alcohol [E1203], titanium dioxide [E171], polyethylene glycol or macrogol [polyethylene glycol MW 3350 or macrogol 4000] [E1521] and talc [E553b].

Colour Mixture Yellow Ingredients (150 mg tablet): polyvinyl alcohol [E1203], titanium dioxide [E171], polyethylene glycol or macrogol [polyethylene glycol MW 3350 or macrogol 4000] [E1521], talc [E553b] and iron oxide yellow [E172].

What YULAREB looks like and contents of the pack

YULAREB 50 mg tablets are oval beige tablet with “Lilly” debossed on one side and “50” on the other side.

YULAREB 100 mg tablet are oval white to practically white tablet with “Lilly” debossed on one side and “100” on the other side.

YULAREB 150 mg tablets are oval yellow tablet with “Lilly” debossed on one side and “150” on the other side.

YULAREB 200 mg tablets are oval beige tablet with “Lilly” debossed on one side and “200” on the other side.

YULAREB tablets are supplied in a cold form aluminium foil blister with aluminium foil lidding, packaged in an outer carton in packs of 14 or 28 tablets per pack. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Eli Lilly (S.A.) (Pty) Limited
Ballyoaks Office Park,
35 Ballyclare Drive
Bryanston, 2191

This leaflet was last revised in

Applicant: Eli Lilly (S.A.) (Pty) Limited
Proprietary Name(s): Verzenio/Yulareb 50 mg, 100 mg, 150 mg & 200 mg
Active ingredient: Abemaciclib
Dosage Form and Strength: Film-coated tablets 50 mg, 100 mg, 150 mg & 200 mg

TA4483/TA4815/TA5337/TA6216_ZA_PIL_v08_MTC
Date: 28 October 2024

28 October 2024

Registration numbers

YULAREB 50 mg: 53/26/0438.434

YULAREB 100 mg: 53/26/0439.435

YULAREB 150 mg: 53/26/0440.436

YULAREB 200 mg: 53/26/0441.437

Access to the corresponding Professional Information

Professional information is included in pack.

Manufactured by:

Lilly del Caribe, Inc.

12.6 KM 65th Infantry Road (PR01)

Carolina, Puerto Rico (PR) 00985

USA

Packaged by:

Lilly, S.A.

Avda. de la Industria, 30

28108 Alcobendas, Madrid

Spain

FURTHER INFORMATION FOR YOU

You should read this information in conjunction with the above Patient Information Leaflet.

Diarrhoea

YULAREB may cause diarrhoea, which may be severe in some cases.

- Early therapy is important for the optimal management of diarrhoea. At the first sign of loose stools, you should start antidiarrhoeal therapy and notify your healthcare provider for further instructions and appropriate follow up.
- Increase your oral fluids.
- If your diarrhoea does not resolve with antidiarrhoeal therapy within 24 hours, suspend dosing with YULAREB.

Neutropenia

Neutropenia is a decrease in special infection fighting blood cells, which may predispose you to infections.

Contact your healthcare provider if you develop a fever, particularly in association with any other signs of infection.

Liver damage

Nausea and vomiting may be signs of liver damage. Contact your healthcare provider immediately if such symptoms occur.

Venous Thromboembolism

You should report any signs or symptoms of thromboembolism such as pain or swelling in a leg or an arm, shortness of breath, chest pain, rapid breathing or a rapid heartbeat.

Reproductive damage to babies

Women who are potentially reproductive should use effective contraception during YULAREB therapy and for 3 weeks after the last dose. Inform your healthcare provider of a known or suspected pregnancy.

Applicant: Eli Lilly (S.A.) (Pty) Limited

TA4483/TA4815/TA5337/TA6216_ZA_PIL_v08_MTC

Proprietary Name(s): Verzenio/Yulareb 50 mg, 100 mg, 150 mg & 200 mg

Date: 28 October 2024

Active ingredient: Abemaciclib

Dosage Form and Strength: Film-coated tablets 50 mg, 100 mg, 150 mg & 200 mg

Breastfeeding

Women should not breastfeed their babies while taking YULAREB and for at least 3 weeks after the last dose.

Fertility

YULAREB may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.

Medicines Interactions

- Do not take ketoconazole while taking YULAREB (ketoconazole is used for treating fungal infections). Medicines that have an effect on the liver enzyme CYP3A (either increasing or decreasing its function) may interact with YULAREB.
- Discuss any medicines that you are taking with your healthcare provider, including prescription medicines, over-the-counter drugs, vitamins, and herbal products.
- Grapefruit may interact with YULAREB. You should not consume grapefruit products while on treatment with YULAREB.

Dosing

- Take the doses of YULAREB at approximately the same time every day and to swallow whole (do not chew, crush, or split them prior to swallowing).
- If you vomit or miss a dose, take the next prescribed dose at the usual time.
- YULAREB may be taken with or without food.