

PATIENT INFORMATION

REVTORPYK (rev-tor-pik)
(gedatolisib)
for intravenous infusion

Important: REVTORPYK is used with fulvestrant and may also be used with palbociclib. You should also read the Patient Information that comes with fulvestrant and palbociclib.

What is REVTORPYK?

REVTORPYK is a prescription medicine used in combination with the medicine fulvestrant, with or without the medicine palbociclib to treat adults who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that:

- has spread to nearby tissue or lymph nodes (locally advanced) or that has spread to other parts of the body (metastatic), without an abnormal “*PIK3CA*” gene and
- whose cancer has come back and has spread to other parts of the body on or after at least 1 treatment with hormone (endocrine) therapy for metastatic disease.

Your healthcare provider will test your cancer for an abnormal “*PIK3CA*” gene to make sure that REVTORPYK is right for you.

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

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

- have diabetes.
- are pregnant or plan to become pregnant. REVTORPYK can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with REVTORPYK.
- Use effective birth control (contraception) during treatment with REVTORPYK and for 2 weeks after the last dose.
- Your healthcare provider will tell you how long you should use birth control (contraception) after your treatment with fulvestrant and palbociclib.
- Talk to your healthcare provider about birth control methods that may be right for you during treatment with REVTORPYK.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with REVTORPYK.

Males with female partners who are able to become pregnant:

- Use effective birth control (contraception) during treatment with REVTORPYK and for 2 weeks after the last dose.
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she may be pregnant during your treatment with REVTORPYK.
- are breastfeeding or plan to breastfeed. It is not known if REVTORPYK passes into breast milk.
 - **Do not** breastfeed during treatment with REVTORPYK and for 2 weeks after the last dose.
 - Your healthcare provider will tell you how long you should not breastfeed after your treatment with fulvestrant and palbociclib.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

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

How will I receive REVTORPYK?

- You will receive REVTORPYK into your vein through an intravenous (IV) line by your healthcare provider.
- REVTORPYK is usually given 1 time every week for 3 weeks followed by 1 week off (28-day treatment cycle).
- You will receive your infusion over 30 minutes.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider may slow down or temporarily stop your infusion of REVTORPYK if you have an infusion-related reaction or permanently stop REVTORPYK if you have severe infusion reactions.
- If you miss a planned dose of REVTORPYK, call your healthcare provider right away to schedule an appointment. Do not wait until the next planned treatment cycle.

What are the possible side effects of REVTORPYK?

REVTORPYK can cause serious side effects, including:

- **Mouth sores (stomatitis).** REVTORPYK can cause severe mouth sores, including mouth ulcers. Your healthcare provider will prescribe a steroid-containing mouthwash that is alcohol-free when starting REVTORPYK to help prevent and treat mouth sores. Use the mouthwash as instructed by your healthcare provider. **Do not** eat or drink for at least 1 hour after using the steroid-containing mouthwash. Tell your healthcare provider if you develop any of the following in your mouth:
 - pain
 - swelling
 - redness
 - ulcers
- **Skin reactions.** REVTORPYK can cause skin reactions, including severe rash. You should limit your time in sunlight during treatment with REVTORPYK. Tell your healthcare provider right away if you get a new rash.
- **High blood sugar levels (hyperglycemia).** REVTORPYK can cause severe hyperglycemia. Your healthcare provider will monitor your blood sugar levels before and during treatment with REVTORPYK. It is not known if REVTORPYK is safe in people with Type 1 diabetes or Type 2 diabetes that is not controlled. Tell your healthcare provider right away if you develop signs and symptoms of hyperglycemia, including:

○ excessive thirst ○ more frequent urination than usual or a higher amount of urine than normal ○ blurred vision	○ confusion ○ headache ○ increased appetite with weight loss ○ tiredness
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Your healthcare provider may change your dose, temporarily stop or permanently stop treatment with REVTORPYK if you get serious side effects.

The most common side effects of REVTORPYK when used with fulvestrant and palbociclib include:

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| <ul style="list-style-type: none"> ○ decreased white blood cell counts ○ decreased red blood cell counts ○ mouth sores ○ nausea ○ decreased platelet counts ○ increased sugar levels (glucose) in the blood ○ tiredness ○ vomiting ○ rash | <ul style="list-style-type: none"> ○ constipation ○ diarrhea ○ increased liver function tests ○ muscle and joint pain ○ decreased sodium levels in the blood ○ increased number of eosinophils (a type of white blood cells) in the blood |
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The most common side effects of REVTORPYK when used with fulvestrant include:

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| <ul style="list-style-type: none"> ○ mouth sores ○ increased sugar levels (glucose) in the blood ○ increased number of eosinophils (a type of white blood cells) in the blood ○ decreased red blood cell counts ○ nausea ○ rash | <ul style="list-style-type: none"> ○ increased liver function tests ○ tiredness ○ muscle and joint pain ○ vomiting ○ itching ○ diarrhea |
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REVTORPYK may affect fertility in females and males, which may affect the ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of REVTORPYK.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of REVTORPYK.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about REVTORPYK that is written for health professionals.

What are the ingredients in REVTORPYK?

Active ingredient: gedatolisib

Inactive ingredients: hydroxypropyl β cyclodextrin and lactic acid and may include hydrochloric acid or sodium hydroxide for pH adjustment.

Manufactured for: Celcuity Inc., 2800 Campus Dr, Suite 140, Minneapolis, MN 55441
 REVTORPYK is a trademark of Celcuity Inc.
 For more information, go to www.celcuity.com or call 1-877-423-5284 (1-877-4-CELCUITY).