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2. Empagliflozin/metformin

Empagliflozin and metformin

Generic name: empagliflozin and metformin [EM-pa-gli-FLOE-zin-and-met-FOR-min]

Brand names: Synjardy, Synjardy XR

Dosage forms: oral tablet (12.5 mg-1000 mg; 12.5 mg-500 mg; 5 mg-1000 mg; 5 mg-500 mg), oral tablet, extended release (10 mg-1000

mg; 12.5 mg-1000 mg; 25 mg-1000 mg; 5 mg-1000 mg)

Drug class: Antidiabetic combinations



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Uses Side effects Warnings Before taking Dosage Interactions

What is empagliflozin and metformin?

Empagliflozin and metformin is a combination medicine used together with diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus.

Empagliflozin and metformin is also used to lower the risk of death from heart attack, stroke, or heart failure in adults with type 2 diabetes who also have heart disease.

empagliflozin and metformin is not for treating type 1 diabetes.

Empagliflozin and metformin may also be used for purposes not listed in this medication guide.

Empagliflozin and metformin side effects

Get emergency medical help if you have **signs of an allergic reaction**: hives; trouble swallowing, difficult breathing; swelling of your face, lips, tongue, or throat.

Seek medical attention right away if you have signs of a serious genital infection (penis or vagina): burning, itching, odor, discharge, pain, tenderness, redness or swelling of the genital or rectal area, fever, not feeling well. These symptoms may get worse quickly.

Stop taking this medicine and call your doctor at once if you have:

- a light-headed feeling, like you might pass out;
- dehydration--dizziness, confusion, feeling very thirsty, less urination;
- ketoacidosis (too much acid in the blood)--nausea, vomiting, stomach pain, confusion, unusual drowsiness, or trouble breathing;
- lactic acidosis--unusual muscle pain, trouble breathing, stomach pain, vomiting, irregular heart rate, dizziness, feeling cold, or feeling very weak or tired; or

• signs of a bladder infection--pain or burning when you urinate, blood in your urine, pain in pelvis or back.

Some side effects may be more likely to occur in older adults.

Common side effects of empagliflozin and metformin may include:

- low blood sugar;
- indigestion, stomach pain, gas, nausea, vomiting, diarrhea;
- a bladder infection;
- yeast infection in women (vaginal itching or discharge);
- · headache, weakness; or
- runny or stuffy nose, sore throat.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

1 Empagliflozin / metformin side effects (more detail)

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Warnings

Stop taking empagliflozin and metformin and call your doctor at once if you have **signs of a serious side effect**, such as severe stomach pain (may spread to your back), vomiting, tiredness, or trouble breathing.

Tell your doctor if you are sick with vomiting or diarrhea, or if you eat or drink less than usual.

Get emergency medical help if you have **symptoms of lactic acidosis** such as unusual muscle pain, trouble breathing, irregular heartbeats, or if you feel very weak.

This medicine can cause serious infections around the penis or vagina. Get medical help right away if you have burning, itching, odor, discharge, pain, tenderness, redness or swelling of the genital or rectal area, fever, or if you don't feel well.

Before taking this medicine

You should not use this medicine if you are allergic to empagliflozin or metformin, or if you have:

- severe kidney disease (or if you are on dialysis); or
- metabolic acidosis or diabetic ketoacidosis (call your doctor for treatment).

If you need to have surgery or any type of x-ray or CT scan using a dye that is injected into your veins, you may need to temporarily stop taking this medicine. Be sure your caregivers know ahead of time that you are using empagliflozin and metformin.

Tell your doctor if you have ever had:

- liver or kidney disease;
- a bladder infection or urination problems;
- · congestive heart failure, a heart attack or stroke;
- a genital infection (penis or vagina);
- · problems with your pancreas, including surgery;
- if you are on a low salt diet; or
- if you are 65 or older.

You may develop lactic acidosis, a dangerous build-up of lactic acid in your blood. Ask your doctor about your risk.

Follow your doctor's instructions about using this medicine **if you are pregnant or you become pregnant.** Controlling diabetes is very important during pregnancy.

You should not use empagliflozin and metformin during the second or third trimester of pregnancy.

Metformin may stimulate ovulation in a premenopausal woman and may increase the risk of unintended pregnancy. Talk to your doctor about your risk.

Do not breastfeed.

Not approved for use by anyone younger than 18 years old.

How should I take empagliflozin and metformin?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose. Use the medicine exactly as directed.

Take with meals.

Swallow the extended-release tablet whole and do not crush, chew, break, or dissolve it. Tell your doctor if you have

trouble swallowing the tablet.

Your blood sugar will need to be checked often, and you may also need to test the level of ketones in your urine. **Empagliflozin can cause life-threatening ketoacidosis (too much acid in the blood).** Even if your blood sugar is normal, contact your doctor if a urine test shows that you have high ketones in the urine.

Blood sugar can be affected by stress, illness, surgery, exercise, alcohol use, or skipping meals.

Low blood sugar **(hypoglycemia)** can make you feel very hungry, dizzy, irritable, or shaky. To quickly treat hypoglycemia, eat or drink hard candy, crackers, raisins, fruit juice, or non-diet soda. Your doctor may prescribe glucagon injection in case of severe hypoglycemia.

You may get dehydrated during prolonged illness. Call your doctor if you are sick with vomiting or diarrhea, or if you eat or drink less than usual.

Tell your doctor if you have a planned surgery.

empagliflozin and metformin can affect the results of certain medical tests. Tell any doctor who treats you that you are using empagliflozin and metformin.

Your doctor may have you take extra vitamin B12 while you are taking empagliflozin and metformin. Take only the amount of vitamin B12 your doctor has prescribed.

Your treatment may also include diet, exercise, weight control, and special medical care.

Store at room temperature away from moisture and heat.

Detailed Empagliflozin / metformin dosage information

What happens if I miss a dose?

Take the medicine (with food) as soon as you can, but skip the missed dose if it is almost time for your next dose. **Do not** take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose may cause lactic acidosis. Symptoms may include unusual muscle pain, trouble breathing, irregular heartbeats, or if you feel very weak.

What should I avoid while taking empagliflozin and metformin?

Avoid drinking alcohol. It may increase your risk of lactic acidosis.

Avoid getting up too fast from a sitting or lying position, or you may feel dizzy.

What other drugs will affect empagliflozin and metformin?

Other drugs may increase or decrease the effects of empagliflozin and metformin on lowering your blood sugar.

Tell your doctor about all your current medicines and any you start or stop using, especially:

- insulin, or other oral diabetes medicine; or
- a diuretic or "water pill."

This list is not complete. Other drugs may affect empagliflozin and metformin, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Empagliflozin / metformin drug interactions (more detail)

Does empagliflozin/metformin interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

empagliflozin/metformin
+
Enter a drug name
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More about empagliflozin / metformin

- Check interactions
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Patient resources

- Empagliflozin and Metformin Extended-Release Tablets patient information
- Empagliflozin and Metformin Tablets

Other brands

Synjardy, Synjardy XR

Professional resources

Other brands

Synjardy, Synjardy XR

Related treatment guides

• Type 2 Diabetes

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ঝ Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

Drug history at FDA

User Reviews & Ratings

5.6 / 10

37 Reviews

Images

Synjardy (empagliflozin / metformin) empagliflozin 12.5 mg / metformin hydrochloride 1000 mg (Logo S12 1000)





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