PATIENT & CAREGIVER EDUCATION

Dapagliflozin and Metformin

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Xigduo XR

Brand Names: Canada

APO-Dapagliflozin/Metformin; AURO-Dapagliflozin/Metformin; Xigduo

Warning

- Rarely, metformin may cause too much lactic acid in the blood (lactic acidosis). The risk is higher in people who have kidney problems, liver problems, heart failure, mitochondrial disease, use alcohol, or take certain other drugs, including topiramate. The risk is also higher in people who are 65 or older and in people who are having surgery, an exam or test with contrast, or other procedures. If lactic acidosis happens, it can lead to other health problems and can be deadly. Kidney tests may be done while taking this drug.
- Do not give this drug to your child if your child has a very bad infection, low oxygen, or a lot of fluid loss.
- Call the doctor right away if your child has signs of too much lactic acid in the blood (lactic acidosis) like confusion; fast breathing; fast or slow heartbeat; a heartbeat that does not feel normal; very bad stomach pain, upset stomach, or throwing up; feeling very sleepy; shortness of breath; feeling very tired or weak; very bad dizziness; feeling cold; or muscle pain or cramps.

What is this drug used for?

- It is used to help control blood sugar in people with type 2 diabetes.
- If your child has been given this drug for some other reason, talk with the doctor about the benefits and risks. Talk with the doctor if you have questions or concerns about giving this drug to your child.

Regular-release tablets:

- This form of this drug is not approved for use in children. Only the extended-release form has been approved for children. However, your child's doctor may decide the benefits of taking this drug outweigh the risks. If your child has been given this form of this drug, ask your child's doctor for information about the benefits and risks. Talk with your child's doctor if you have questions about this drug.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has type 1 diabetes. Do not use this drug to treat type 1 diabetes.

- If your child has any of these health problems: Acidic blood problem, kidney disease, or liver disease.
- If your child is on dialysis.
- If your child has had a recent heart attack or stroke.
- If your child has a mitochondrial disease like MELAS syndrome (mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes) or MIDD (maternally inherited diabetes and deafness).
- If your child is not able to eat or drink like normal, including before certain procedures or surgery.
- If your child is having an exam or test with contrast, or has had one within the past 48 hours, talk with the doctor.
- If your child is taking or has recently taken drugs that suppress your child's immune system to treat kidney disease.

If your child is pregnant or breast-feeding a baby:

- Do not give this drug to your child if your child is in the second or third trimester of pregnancy.
- Be sure your child does not breast-feed a baby while taking this drug.

This is not a list of all drugs or health problems that interact

with this drug.

Tell the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- If your child is old enough to drive, do not let your child drive if their blood sugar has been low. There is a greater chance of having a crash.
- To lower the chance of feeling dizzy or passing out, have your child rise slowly if your child has been sitting or lying down. Have your child be careful going up and down stairs.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- This drug may affect certain lab tests. Be sure the doctor

and lab workers know your child uses this drug.

- Talk with your child's doctor about which glucose tests are best to use.
- Check your child's blood sugar as you have been told by the doctor.
- Alcohol may interact with this drug. Be sure your child does not drink alcohol.
- Have your child follow the diet and exercise plan your child's doctor told you about.
- If your child is on a low-sodium or sodium-free diet, talk with your child's doctor.
- It may be harder to control blood sugar during times of stress such as fever, infection, injury, or surgery. A change in physical activity, exercise, diet, or weight may also affect your child's blood sugar.
- Have your child be careful in hot weather or while your child is being active. Have your child drink lots of fluids to stop fluid loss.
- Long-term treatment with metformin may lead to low vitamin B-12 levels. If your child has ever had low vitamin B-12 levels, talk with the doctor.
- Too much acid in the blood or urine (ketoacidosis) has happened with this drug. This may need to be treated in

the hospital and can be deadly. This can happen even when blood sugar is less than 250. People with diabetes or pancreas problems have a higher risk of ketoacidosis. The risk of ketoacidosis is also higher in people who are sick or dehydrated, cannot eat or drink like normal, skip meals, are on a ketogenic diet, or have surgery. The risk is also higher in people who use insulin and take less than the normal insulin dose or miss the dose. Check your child's ketones as you have been told by the doctor. If you have questions, talk with your child's doctor.

- Severe urinary tract infections (UTIs) have happened with this drug. Sometimes, this needed to be treated in a hospital.
- Kidney problems have happened. Sometimes, these may need to be treated in the hospital or with dialysis.
- If your child cannot drink liquids by mouth or has upset stomach, throwing up, or diarrhea that does not go away; your child needs to avoid getting dehydrated. Contact your child's doctor to find out what to do. Dehydration may lead to new or worse kidney problems.

If your child is or may be sexually active:

- There is a chance of pregnancy in people of childbearing age who have not been ovulating. To avoid pregnancy,

have your child use birth control while taking this drug.

If your child is pregnant:

- This drug may cause harm to the unborn baby if your child takes it during pregnancy. If your child is pregnant or gets pregnant while taking this drug, call the doctor right away.

Extended-release tablets:

- You may see something that looks like the tablet in your child's stool. This is normal and not a cause for concern. If you have questions, talk with your child's doctor.

What are some side effects that I need to call my child's doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your child's doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of fluid and electrolyte problems like mood changes, confusion, muscle pain or weakness, fast or abnormal heartbeat, severe dizziness or passing out, increased thirst, seizures, feeling very tired or weak, decreased appetite, unable to pass urine or change in the amount of urine produced, dry mouth, dry eyes, or severe upset stomach or throwing up.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Vaginal yeast infection. Report itching, bad odor, or discharge.
- Yeast infection of the penis. Report pain, swelling, rash, or discharge.
- It is common to have stomach problems like upset stomach, throwing up, or diarrhea when starting this drug. If your child has stomach problems later during treatment, call the doctor right away. This may be a sign of an acid health problem in the blood (lactic acidosis).
- A rare but severe infection has happened with drugs like

this one. This infection may be deadly. Get medical help right away if your child's genitals or the area between your child's genitals and rectum becomes red, swollen, tender, or painful, and your child has a fever or does not feel well.

- Low blood sugar can happen. The chance may be raised when this drug is used with other drugs for diabetes. Signs may be dizziness, headache, feeling sleepy or weak, shaking, fast heartbeat, confusion, hunger, or sweating. Call the doctor right away if your child has any of these signs. Follow what you have been told to do for low blood sugar. This may include giving your child glucose tablets, liquid glucose, or some fruit juices.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Diarrhea, upset stomach, or throwing up.
- Headache.
- Nose or throat irritation.

These are not all of the side effects that may occur. If you

have questions about side effects, call your child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- Give this drug with food.
- Give in the morning.
- Have your child swallow whole. Do not let your child chew, break, or crush.
- Have your child drink lots of noncaffeine liquids unless told to drink less liquid by your child's doctor.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child's next dose, skip the missed dose and call the doctor.
- Do not give 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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