PATIENT & CAREGIVER EDUCATION

Darunavir and Cobicistat

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

Prezcobix; Prezcobix Ped

Brand Names: Canada

Prezcobix

What is this drug used for?

- It is used to treat HIV infection.

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 liver disease.
- If your child is taking another drug that has the same drug in it.
- If your child takes any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for high cholesterol, migraines, mood problems, and others. There are many drugs that must not be taken with this drug.
- If your child is also taking tenofovir and has kidney problems or takes a drug that may harm the kidneys.

- If your child is pregnant, may become pregnant, or is breast-feeding a baby. Before giving this drug to your child, you will need to talk about the benefits and risks to your child and the baby. You will also need to talk about the best way for your child to prevent passing HIV to the baby.

This is not a list of all drugs or health problems that interact with this drug.

This drug interacts with many other drugs. The chance of severe, life-threatening, or deadly side effects may be raised. 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 has a sulfa (sulfonamide) allergy, talk with the doctor.
- High blood sugar has happened with this drug. This includes diabetes that is new or worse.
- Check your child's blood sugar as you have been told by the doctor.
- Some people with hemophilia have had times of more bleeding when taking drugs like this one. If your child has hemophilia, talk with the doctor.
- Very bad kidney problems like kidney failure have happened in people taking cobicistat with tenofovir.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- The tablets of this drug are not the same as the tablets for oral suspension. Check your child's drug every time it is filled to be sure you get the right one.
- If your child's weight changes, talk with the doctor. The dose of this drug

may need to be changed.

- This drug is not a cure for HIV. Keep giving this drug to your child as you have been told by the doctor or other health care provider, even if your child feels well. Be sure your child stays under the care of the doctor and has regular appointments.
- This drug helps to lower how much HIV is in the blood. Lowering the amount of HIV in the blood until it is not detected on blood tests can help lower the risk of spreading HIV to others. There are also other ways to help prevent the spread of HIV to others. This includes using condoms during sex and not sharing needles and other injection equipment. Talk with your child's doctor or other health care provider about the best way to prevent spreading HIV to others.

If your child is or may be sexually active:

- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Be sure your child uses some other kind of birth control also, like a condom, when taking this drug.

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 high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- 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.

- Feeling very tired or weak.
- Change in body fat.
- Muscle or joint pain.
- Severe skin reactions may happen with this drug. These include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious reactions. Sometimes, body organs may also be affected. These reactions can be deadly. Get medical help right away if your child has signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in the mouth, throat, nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.
- Changes in your child's immune system can happen when your child starts taking drugs to treat HIV. If your child has an infection that you did not know was there, it may show up when your child takes this drug. Tell your child's doctor right away if your child has any new signs after starting this drug, even after taking it for several months. This includes signs of infection like fever, sore throat, weakness, cough, or shortness of breath.
- Liver problems have rarely happened with this drug. Sometimes, this has been deadly. Call your child's doctor right away if your child has signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

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:

- Headache.
- Diarrhea, stomach pain, upset stomach, or throwing up.

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.

All products:

- Give this drug with food.
- Give this drug at the same time of day.
- It is important that your child does not miss or skip a dose of this drug during treatment.
- Do not run out of this drug.
- If your child is also taking didanosine, give it at least 1 hour before or 2 hours after this drug.

Tablets:

- If taking the **675/150 mg** tablets: For those who weigh at least 55 pounds (25 kg) and are not able to swallow the tablets whole, tablets of this strength may be broken by hand in half on the score line. Have your child take both pieces right away after breaking. Do not break tablets in half to make a different strength. Do not break other strengths of this drug in half.

Tablets for suspension:

- Do not let your child swallow whole, chew, or crush.
- To give this drug, place the tablet in a clean empty cup. Add 30 mL non-carbonated room temperature drinking water to the cup. Do not crush the tablet. Stir well with a spoon until the tablet fully comes apart. The prepared drug will be reddish purple. Have your child swallow right away after mixing. After giving this drug, add another 5 mL of non-carbonated drinking water, swirl, and have your child swallow. Repeat until the whole dose has been

taken.

- If your child has trouble taking this drug, you may add 10 mL non-carbonated room temperature drinking water or orange juice after mixing. Or, you may add 1 tsp (5 mL) applesauce or yogurt to this drug after mixing. Mix well, and have your child swallow right away.
- If you spill any of this drug while mixing, throw away the rest and make a new dose.

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it, with food.
- If it is close to the time for your child's next dose, skip the missed dose and go back to your child's normal time.
- Do not give 2 doses at the same time or extra doses.
- If you are not sure what to do if your child misses a dose, call the doctor.

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

All products:

- 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.

Tablets for suspension:

- Store in the original container to protect from light.
- Keep lid tightly closed.

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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