PATIENT & CAREGIVER EDUCATION

Smallpox Vaccine Live

This information from Lexicomp® 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

ACAM2000

Warning

- Very bad heart problems like swelling of the heart tissue have happened with this vaccine. This can lead to a heartbeat that does not feel normal and sometimes death. Some health problems can raise the chance of these effects. Tell the doctor about all current or past health problems. Call the doctor right away if chest pain or pressure, fast heartbeat, a heartbeat that does not feel normal, or breathing problems happen.
- Very bad health problems have happened with this drug. These include swelling of the brain or spinal cord, eye problems, allergic reactions, very bad skin problems, and vaccine site infections. These health problems can lead to disability or problems that may not go away, like blindness. Sometimes, they can lead to death. The chance is raised in infants younger than 12 months. Some health problems can raise the chance of these effects. Tell the doctor if your child has a weak immune system or if your child takes drugs to weaken the immune system. Tell the doctor if your child has ever had heart disease or skin problems like eczema. Tell the doctor if your child has eye disease and uses steroid eye drops or ointment.
- This vaccine is a live virus. It can spread to other parts of the body. It can also spread to other people until the vaccine scab falls off (2 to 4 weeks after getting the vaccine). If the virus is spread to another person, it can cause very bad and life-threatening side effects. Talk with the doctor.

If your child is pregnant:

- Use of this drug during pregnancy has caused smallpox infection and death in the unborn baby. If your child is pregnant, talk with the doctor. You will need to talk about the benefits and risks of using this vaccine while your child is pregnant.

What is this drug used for?

- It is used to prevent smallpox 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 a weak immune system.

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.
- Like all vaccines, this vaccine may not fully protect all people who get it. If you have questions, talk with the doctor.
- This drug may affect certain lab tests. Tell all of your child's health care providers and lab workers that your child takes this drug.
- This drug has a live virus in it. The virus can spread to other people and cause severe side effects. The chance may be raised if your child has close contacts with skin problems, impetigo, chickenpox, shingles, heart problems, or immune system problems. The chance may also be raised if your child is in close contact with a baby, or someone who is pregnant or breast-feeding. If you have questions, talk with your child's doctor.
- You must take care of the vaccine site to prevent spread of the virus. Very bad effects and death have happened in other people who have come into contact with the vaccine site. Have your child wear certain types of bandages to cover the whole vaccine site. If you are not sure which type of bandage to use, talk with the doctor. Have your child wear sleeves to cover the site.
- Wear gloves when you change bandages. Throw away the gloves and used bandages in sealed or double plastic bags. You may add some bleach to the bag to kill the virus.
- Wash your hands well after changing the bandage. Wash your hands well after any other contact with the vaccine site.
- Do not let your child donate blood or an organ for at least 30 days after getting this vaccine.
- Do not put creams or ointments on the vaccine site. Do not let your child scratch or pick at the

vaccine site.

If your child is breast-feeding a baby:

- Tell the doctor if your child is breast-feeding a baby. You will need to talk about any risks to the baby.

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.
- Change in eyesight.
- Loss of eyesight.
- Seizures.
- A burning, numbness, or tingling feeling that is not normal.
- If bright lights bother your child’s eyes.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go away, and sometimes death. Get medical help right away if your child has signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, 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:

- Pain, redness, swelling, or other reaction where the injection was given.
- Itching.
- Feeling very tired or weak.
- Feeling hot.
- Fever or chills.
- Headache.
- Constipation, diarrhea, throwing up, or upset stomach.
- Swollen gland.
- Muscle pain.

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.

- It is given as a shot.

What do I do if my child misses a dose?

- Call your child's doctor to find out what to do.

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

- If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

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.
- 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.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your 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.

Additional Information

The CDC has given a link to the FDA approved Medication Guide in place of the Vaccine Information Statement (VIS).

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142576.pdf

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

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If you have any questions, contact a member of your care team directly. If you're a patient at MSK and you need to reach a provider after 5 p.m., during the weekend, or on a holiday, call 212-639-2000.

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

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