

AUSTRALIAN CONSUMER MEDICINE INFORMATION

ACAM2000®

Smallpox vaccine (live vaccinia virus).

What is in this leaflet

This leaflet answers some common questions about ACAM2000.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ACAM2000 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What ACAM2000 is used for

This medicine is a vaccine which is used to protect people against smallpox disease in a declared outbreak of the disease.

It is used in people who have a high chance of getting the disease.

ACAM2000 contains live vaccinia virus (not small pox virus) to protect against smallpox disease.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you are given ACAM2000

When you must not be given it

ACAM2000 should not be given to you if you have problems with your immune system.

That is if you:

- have leukaemia
- have lymphoma
- have had a bone marrow or organ transplant
- have cancer that has spread
- have HIV, AIDS
- have cellular or humoral immune deficiency

- are being treated with radiation
- are being treated with steroids, prednisone, or cancer drugs (antimetabolites, alkylating agents).

Do not have this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start having this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have any of the following medical conditions:

- skin problems called eczema or atopic dermatitis now or earlier in life
- current skin conditions, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis or uncontrolled acne
- previous heart problems
- serious heart or blood vessel problems including angina, previous heart attack, artery disease, congestive heart failure, stroke or other cardiac problems
- smoke or have high blood pressure, high cholesterol, diabetes, high blood sugar, or a family history of heart problems
- are less than 1 year old
- are taking steroid eye drops or ointment
- have had problems after previous doses or are allergic to ACAM2000 or any part of ACAM2000 such as antibiotics neomycin or polymyxin B or any of the other ingredients listed at the end of this leaflet.

Tell your doctor if you are pregnant or plan to become pregnant or are breast feeding.

Your doctor can discuss with you the risks and benefits involved.

The risks of serious vaccine side effects are greater for these people mentioned above.

It is important to tell your doctor if you:

- live or work with a person who has skin problems (like eczema, dermatitis, burns, psoriasis, bad acne) or is suffering from impetigo, chicken pox, shingles.
 - live or have close contact with a baby, or a person who is pregnant or breastfeeding.
 - live or have close contact with a person who has an immune deficiency or cardiac disease.
- The virus from the vaccination can spread to other people and cause serious side effects.

In an emergency, you should be vaccinated if you are at high risk for getting smallpox disease even if you have health problems (except if you have certain problems with your immune system as discussed under “When you must not be given it”).

If you have not told your doctor about any of the above, tell him/her before you start having ACAM2000.

How you are given ACAM2000

ACAM2000 smallpox vaccine is not a shot like other vaccines. Your doctor will make 15 pokes in the skin of your upper arm with a needle containing ACAM2000. The pokes are not deep, but will cause a drop of blood to form. This is called the vaccination site.

After having ACAM2000

Things you must do

You must take care of your vaccination site until the scab falls off (typically 2 to 4 weeks after you have been vaccinated) to avoid spreading of the virus to other parts of the body.

It is important to always:

- wear bandages or Band-Aids to cover the entire vaccination site
- wear sleeves to cover the site
- wash your hands often

When changing bandages or caring for your vaccination site, wear gloves. Use an absorbent bandage or Band-Aid to completely cover your vaccination site.

Change your bandage when it begins to soak through (at least 1 to 3 days). Throw away gloves and used bandages in sealed or double plastic bags. You may add a little bleach to the bag to kill the virus.

Wear clothes with sleeves to cover the site and prevent scratching the vaccination site.

It is especially important to wear a bandage and sleeves to bed to avoid scratching.

Wash your hands frequently with alcohol based cleaners or soap and water.

Be sure to wash your hands each time you change your bandage or if you touch the vaccination site.

Do not use creams or ointments on the vaccination site because they will delay healing and can spread the virus.

Do not scratch or pick at the vaccination site.

You can take a bath or shower, but don't touch or scrub the vaccination site.

It is best to cover the vaccination site with a waterproof bandage. If the vaccination site gets wet, dry the site with toilet paper and flush it. Do not use a cloth towel because it can spread the virus. Cover the vaccination site with a loose gauze bandage after bathing to allow it to dry out.

Do not use a bandage that blocks air from the vaccination site. This could cause the skin at the vaccination site to soften and wear away.

If you exercise enough to cause sweat to drip, use a waterproof bandage on the vaccination site when exercising.

Wash clothing, towels, bedding or other items that may have come in contact with the vaccination site separately from other wash. Use hot water with detergent and bleach.

When the scab falls off, flush it down the toilet or throw it away (in a sealed or double plastic bag with a little bleach added to kill the virus), in the trash. Wash your hands with soap and hot water.

Tell any other doctors, dentists, and pharmacists who treat you that you have had this medicine.

If you become pregnant within 4 weeks after having this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you have had this medicine.

It may interfere with the results of some tests.

Tell any doctors, dentist or pharmacists who treat you that you have had smallpox vaccination in the month following your vaccination.

Keep all of your doctor's appointments so that your progress can be checked.

What you should expect at the vaccination site and in the weeks following vaccination

If the vaccination is successful, a red and itchy bump forms at the vaccination site in 3 to 4 days. Over the next few days, the bump becomes a blister and fills with pus. During the second week, the blister dries up and a scab forms. The scab falls off after 2 to 4 weeks, leaving a scar. People vaccinated for the first time may have a larger reaction than those being revaccinated. See the expected response for the initial vaccination below:

After 6 to 8 days check that your vaccination site looks like one of these pictures. If it does not, see your doctor because you may need to be revaccinated.



See also: <https://www.cdc.gov/smallpox/clinicians/comparison-vaccinees-images.html>

Certain people, such as laboratory workers who work with smallpox, are at risk of being exposed to smallpox over a long period of time. These people may need a booster vaccination every 3 years to maintain protection against smallpox.

Things you must not do

For 4 weeks after vaccination and until the vaccination site has healed, you should avoid:

- getting pregnant. Smallpox vaccine may rarely cause infection in an unborn baby if the mother is vaccinated during pregnancy. This infection usually results in stillbirth or death.
- handling babies or breastfeeding.
- swimming or baths.
- donating blood

Avoid rubbing, scratching or touching the vaccination site

Until the vaccination scab falls off, do not

- share a bed, clothes, towels, linen, or toiletries with unvaccinated people.

It is not known if the vaccinia virus can be spread to cats, dogs or other household pets, or whether pets can spread the virus to other people in the household. Take the usual protective steps (e.g. wear sleeves, bandages, and wash hands) to keep the vaccinia virus from reaching your pet. Try to keep the vaccine virus from reaching your pet.

Things to be careful of

It is important to take care of the vaccination site properly so the virus doesn't spread to other parts of your body or to other people. **You can infect another part of your body or other people until the scab falls off.**

Possible Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while after you have been given ACAM2000. This medicine may have unwanted side effects in a few people. Some side effects can occur up to 4 weeks after vaccination.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- itching
- swollen lymph nodes
- sore arm
- fever
- headache
- body ache
- mild rash
- fatigue

These symptoms may peak 3 to 12 days after vaccination.
The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain or pressure
- fast or irregular heartbeat
- breathing problems
- problems moving or speaking or lack in coordination.
- problems with the vaccination site blister, such as it becoming infected.
- spreading of the vaccine virus to other parts of your body or to another person.
- severe allergic reaction after vaccination
- swelling of the cornea of the eye causing watery painful eyes and blurred vision or blindness.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Product Description

What it looks like and what it contains

ACAM2000 is a white to off white lyophilized powder. The diluent is a clear colourless solution.

Ingredients

ACAM2000 contains live vaccinia virus from plaque purification cloning from Dryvax® (Wyeth Laboratories, Marietta, PA, calf lymph vaccine, New York Board of Health Strain) and grown in African Green Monkey kidney (Vero) cell lines.

It also contains:

- 6-8 mM HEPES buffer (pH 6.5-7.5)
- 2% albumin
- 0.5-0.7% sodium chloride
- 5% mannitol
- trace amounts of neomycin sulfate and polymyxin B sulfate

The diluent for ACAM2000 contains:

- 50% (v/v) glycerol
- 0.25%(v/v) phenol
- in Water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Name and Address of Australian Sponsor

Emergent Sales and Marketing Australia Pty. Ltd.
Suite 303
74 Pitt Street
Sydney
NSW 2000

Aust R number
153108

Date of Preparation
17 June 2020