

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

POLIO SABIN ONE AND THREE (ORAL), ORAL SUSPENSION

BIVALENT ORAL POLIOMYELITIS VACCINE TYPES 1 AND 3 (LIVE, ATTENUATED)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Polio Sabin One and Three (oral) is and what it is used for
2. Before you receive Polio Sabin One and Three (oral)
3. How Polio Sabin One and Three (oral) is given
4. Possible side effects
5. How to store Polio Sabin One and Three (oral)
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1. WHAT POLIO SABIN ONE AND THREE (ORAL) IS AND WHAT IT IS USED FOR

Polio Sabin One and Three (oral) is a vaccine used in individuals of all age groups to prevent infection caused by poliomyelitis viruses of type 1 and type 3. The vaccine contains a live, weakened form of these viruses (live attenuated vaccine). When a person is given the vaccine, the immune system (the body's natural defence system) will make antibodies against poliomyelitis viruses of type 1 and type 3. These antibodies protect against infection caused by these 2 types of poliomyelitis viruses.

Poliomyelitis is a viral infection that can have variable effects. Often it causes only a mild illness but, in some people, it causes permanent injury or death. In its severest form, poliomyelitis infection causes paralysis of the muscles, including those needed for breathing and walking.

There is no cure for poliomyelitis, and how a person will react to infection cannot be predicted. Therefore, vaccination is the best way to protect against this disease.

As with all vaccines, Polio Sabin One and Three (oral) may not fully protect all people who are vaccinated.

2. BEFORE YOU RECEIVE POLIO SABIN ONE AND THREE (ORAL)

Polio Sabin One and Three (oral) should not be given if you

- have previously had any allergic reaction to Polio Sabin One and Three (oral) or any component contained in this vaccine. The active substances and other ingredients contained in the vaccine are listed under section 6 of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- have previously had an allergic reaction to GlaxoSmithKline Biologicals' vaccines against oral poliomyelitis
- are known to be allergic to neomycin or polymyxin (antibiotic)

Tell your doctor if you have any illness which may affect your immune system (immunodeficiency) or if you are receiving medicines or treatment which may affect your immune system and therefore reduce your resistance to infection.

Check with your doctor if you think any of these apply to you.

Take special care with Polio Sabin One and Three (oral)

Your doctor needs to know before you start taking Polio Sabin One and Three (oral) if you:

- have a severe infection with a high temperature. In this case, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem but talk to your doctor first.
- have ongoing diarrhoea or vomiting

After you have been vaccinated, the viruses from the vaccine multiply in the gut. Because of this, the viruses get into the stools (faeces). This means that it is important that you wash your hands carefully after using the toilet or changing your baby's nappy for several weeks after receiving the vaccine.

The vaccine may not prevent or modify the course of the disease in subjects already infected with type 1 or type 3 poliovirus.

Using other medicines or vaccines

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or have recently received any other vaccine.

Polio Sabin One and Three (oral) may be given at the same time you receive other normally recommended vaccinations, such as rotavirus vaccine, Haemophilus influenzae type b vaccine, hepatitis B vaccine, diphtheria, pertussis and/or tetanus vaccine, inactivated polio vaccine (IPV), measles, rubella and/or mumps vaccine, or BCG vaccine.

Taking/Using Polio Sabin One and Three (oral) with food and drink

The vaccine may be given either alone or mixed with beverages or foods such as syrup, milk, bread or a lump of sugar.

Pregnancy and breast-feeding

The vaccine should not be given to pregnant women unless they are exposed to a definite risk of infection with wild polioviruses.

Also, women should avoid getting pregnant for 3 months following vaccination.

Polio Sabin One and Three (oral) may be used during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW POLIO SABIN ONE AND THREE (ORAL) IS GIVEN

The doctor or nurse will administer the recommended dose of Polio Sabin One and Three (oral) to you. The vaccine will be given into the mouth. Under no circumstance should this vaccine be given using a needle and syringe.

The number of doses that you will receive depends of the vaccination schedule recommended in the country where you are being vaccinated.

One dose (0.1 ml) consists of two drops.

If you have ongoing diarrhoea or vomiting at the time of receiving the vaccine, you may have to receive a repeated dose after having recovered from diarrhoea or vomiting. The doctor will advise you.

If you miss a dose of Polio Sabin One and Three (oral)

It is important that you follow the instructions of the doctor or nurse regarding return visits. If you forget to go back to the doctor at the scheduled time, ask the doctor for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Polio Sabin One and Three (oral) can cause side effects, although not everybody gets them.

Paralysis has very rarely occurred after vaccination with oral poliomyelitis vaccines (less than one case per 1 million doses administered).

Fever, vomiting and diarrhoea have been observed after vaccination with Polio Sabin One and Three (oral). Allergic reactions (these may be local or widespread rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness) have been described after vaccination with a similar GlaxoSmithKline Biologicals' oral poliomyelitis vaccine, and therefore could happen with this one.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE {PRODUCT NAME}

Keep out of the reach and sight of children.

Do not use Polio Sabin One and Three (oral) after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a freezer (-20°C).

Store in the original package in order to protect from light.

After opening, multidose containers should be kept in a refrigerator (2°C – 8°C) and used ideally within eight hours because of the possibility of contamination of the vaccine. If these conditions are not fulfilled, the vaccine should be discarded.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Polio Sabin One and Three (oral) contains

- The active substances are:

1 dose (0.1 ml) contains:

Virus Polio Type 1, strain LSc, 2ab ≥ 106.0 CCID₅₀

Virus Polio Type 3, strain Leon 12a, 1b ≥ 105.8 CCID₅₀

- The other ingredients are: magnesium chloride, L-arginine, polysorbate 80 and water for injections.

What Polio Sabin One and Three (oral) looks like and contents of the pack

Polio Sabin One and Three (oral) is supplied as a clear liquid, yellowish-to pink suspension in multidose glass vials (10 doses and 20 doses) with a separate polyethylene dropper.

Polio Sabin One and Three (oral) is available in packs of 100.

Manufacturer

GlaxoSmithKline Biologicals s.a.

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