POLIO SABIN™ (oral) MULTIDOSE

Live Oral Poliomyelitis vaccine
CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about POLIO SABIN (oral) MULTIDOSE vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of your child (or you) having POLIO SABIN (oral) MULTIDOSE against the expected benefits.

If you have any concerns about POLIO SABIN (oral) MULTIDOSE talk to your doctor, nurse or pharmacist.

POLIO SABIN (oral) MULTIDOSE is mainly given as a childhood vaccine, so from now on we will refer to its use in ‘your child’. However, the following information is still applicable to adults receiving POLIO SABIN (oral) MULTIDOSE.

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

WHAT POLIO SABIN (oral) MULTIDOSE IS USED FOR

POLIO SABIN (oral) MULTIDOSE is a vaccine used in infants, children and adults to prevent poliomyelitis (polio). The vaccine contains a weakened form of polio viruses. It works by causing the body to produce its own protection (antibodies) against this disease.

Polio 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, polio infection causes paralysis of the muscles, including those needed for breathing and walking. Polio infection can leave a person unable to breathe without the help of an iron lung machine, unable to walk without leg braces, or confined to a wheelchair. The limbs affected by the disease may be painfully deformed.

There is no cure for polio, and how a person will react to infection can not be predicted. Therefore vaccination is the best way to protect against this disease. The vaccine will not protect against diseases caused by other types of viruses, bacteria or organisms.

BEFORE VACCINATION

POLIO SABIN (oral) MULTIDOSE SHOULD NOT BE GIVEN IF:

• your child has had an allergic reaction to POLIO SABIN (oral) MULTIDOSE, neomycin, polymyxin or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. POLIO SABIN (oral) MULTIDOSE can be used in people who have previously developed a skin rash after applying the antibiotic ‘neomycin’ to the skin.

If your child had POLIO SABIN before and became unwell, tell your doctor, nurse or pharmacist before the first dose is given.

• your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before vaccination.

• your child has ongoing diarrhoea or vomiting

• your child has lowered immunity. This can occur in persons:
  * with inherited (or family history of) immune deficiency conditions
  * with abnormal blood conditions or blood protein (immunoglobulin) disorders
  * with cancer including blood cancer (leukaemia), and cancer of the bone marrow or lymph glands (lymphoma)
  * with Human Immunodeficiency Virus (HIV) infection
  * receiving or who have received certain drugs (ie cyclosporin, corticosteroids, and cancer medicines)
  * receiving or who have received radiation therapy
• the expiry date printed on the packaging has passed.
• the packaging is torn or shows signs of tampering.

If you are not sure whether your child should be given POLIO SABIN (oral) MULTIDOSE, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for your child.

BEFORE POLIO SABIN (oral) MULTIDOSE IS GIVEN TELL YOUR DOCTOR OR NURSE IF:

• your child has had an allergic reaction to any other polio vaccine (ie injectable polio vaccine)
• your child has any muscle weakness
• your child has a viral infection
• your child is on any special diet, such as a low sugar diet. The vaccine is sometimes given with a lump of sugar.
• your child lives with adults who are unvaccinated or only partially vaccinated against polio
• your child lives with or is in close contact with someone with lowered immunity
• your child has allergies to any other medicines or substances, such as dyes, foods or preservatives
• your child has received another vaccine within the last month. POLIO SABIN (oral) MULTIDOSE should not be given at the same time as oral typhoid vaccine.
• your child is having any prescription or OTC (over-the-counter) medicines.

Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if POLIO SABIN (oral) MULTIDOSE is to be given with another vaccine or medicine.

ADULTS AND ADOLESCENTS: BEFORE HAVING POLIO SABIN (oral) MULTIDOSE TELL YOUR DOCTOR OR NURSE IF:

• you are or think you may be pregnant, or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving POLIO SABIN (oral) MULTIDOSE during pregnancy.
• you are breast feeding. Vaccination of breastfeeding mothers, does not usually cause problems in nursing babies. However, the infant should be checked for any reactions.

HOW POLIO SABIN (oral) MULTIDOSE IS GIVEN

The doctor or nurse will give the vaccine into the mouth. If you have any concerns about how POLIO SABIN (oral) MULTIDOSE is to be given, talk to your doctor, nurse or pharmacist.

HOW MUCH IS GIVEN
The dose is 2 drops for infants, children and adults.

HOW IS IT GIVEN
POLIO SABIN (oral) MULTIDOSE is given into the mouth either alone, or on a lump of sugar.

The vaccine should never to given by injection.

WHEN WILL IT BE GIVEN
Infants and Children: A total of three doses of POLIO SABIN (oral) MULTIDOSE are given. Each dose is given on a separate visit. The first dose is generally given when the child is 2 months of age. The remaining two doses are given at 4 months, and 6 months of age.
• First dose: 2 months of age
• Second dose: 4 months of age
• Third dose: 6 months of age

It is important to return at the recommended times for each dose.

POLIO SABIN (oral) MULTIDOSE is usually given to infants at the same time as immunisation against Diphtheria, Tetanus, Pertussis, Haemophilus influenzae type b (Hib) and Hepatitis B vaccines which are given by injection.

Adults: A total of three doses of POLIO SABIN (oral) MULTIDOSE are given. Each dose is given on a separate visit. The first dose is given on an elected date. The remaining two doses are given 4-8 weeks apart.
• First dose: at an elected date
• Second dose: 4-8 weeks after the first dose
• Third dose: 4-8 weeks after the second dose

BOOSTER DOSES
Children are given one routine booster dose to ensure long term protection against polio. This is normally given at age 4 years.
Adults at ongoing risk of infection are advised to have a booster dose of POLIO vaccine every 10 years. **Talk to your doctor or nurse about the possible need for booster dosing.**

**IF A DOSE IS MISSED**
Talk to your doctor or nurse and arrange another visit as soon as possible, if a scheduled dose is missed.

### WHILE USING POLIO SABIN (oral) MULTIDOSE

**THINGS YOU MUST DO:**
- It is important to practice strict personal hygiene for 6-8 weeks after vaccination.

If you are in close contact with a recently vaccinated baby/child, ensure your hands are washed thoroughly:
  - after changing nappies
  - before eating or handling food

If you have been vaccinated, ensure your hands are washed thoroughly:
  - after going to the toilet
  - before eating or handling food

- Keep all follow-up visits with the doctor or clinic. Your child needs all 3 doses of POLIO SABIN (oral) MULTIDOSE to be completely protected.

- Tell the doctor or nurse your child has had POLIO SABIN (oral) MULTIDOSE, if another vaccine is to be given within 1 month of polio vaccination.

### SIDE EFFECTS

Tell your doctor or nurse as soon as possible if your child does not feel or look well during or after having had a dose of POLIO SABIN (oral) MULTIDOSE.

POLIO SABIN (oral) MULTIDOSE helps protect most children from polio, but it may have unwanted side effects in a few children. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment.

The risk of your child having a serious side effect with POLIO SABIN (oral) MULTIDOSE is very much less than the risk of your child being permanently injured by natural polio infection.

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

Most unwanted effects with POLIO SABIN (oral) MULTIDOSE are mild and usually disappear quickly. However in extremely rare instances, polio and paralysis have occurred after vaccination in the person vaccinated or in a close contact of the person vaccinated (1 case reported in 1 to 10 million people vaccinated and their close contacts).

**MILD EFFECTS**
- Tell your doctor if your child has any of the following that are troublesome or ongoing:
  - fever, headache, vomiting, diarrhoea or feeling generally unwell

**SERIOUS EFFECTS THAT MAY OCCUR RARELY**
- As with all vaccines there is a very small risk of serious allergic reaction. Contact your doctor immediately or take your child to the casualty department of your nearest hospital if any of the following happens:
  - swelling of limbs, face, eyes, inside of nose, mouth or throat
  - shortness of breath, breathing or swallowing difficulties
  - hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
  - unusual tiredness or weakness that is sudden and severe

Allergy to POLIO SABIN (oral) MULTIDOSE is very rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other side effects not listed above, can also occur during or soon after a dose of POLIO SABIN (oral) MULTIDOSE.

**Check with your doctor or nurse if your child has any other effects.**

Do not be alarmed by this list of possible side effects. Most children will not experience any side effect.

### STORAGE

POLIO SABIN (oral) MULTIDOSE is usually stored at the doctor’s clinic or surgery, or at the pharmacy. But if you need to store POLIO SABIN always:

- Keep POLIO SABIN (oral) MULTIDOSE in the refrigerator stored between +2 C and +8 C. Do not store it in the bathroom, or leave it in the car on hot days. Avoid
exposing the vaccine to sunlight. HEAT CAN DESTROY THE VACCINE.

- Keep the vaccine out of the reach of children.
- Keep POLIO SABIN (oral) MULTIDOSE in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over POLIO SABIN (oral) MULTIDOSE that has expired or has not been used.

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE
POLIO SABIN (oral) MULTIDOSE is a light yellow to light red coloured liquid that comes in a vial.

INGREDIENTS:
The active ingredients of POLIO SABIN (oral) MULTIDOSE are three live weakened polio viruses (types 1, 2 and 3).

The inactive ingredients in the vaccine are: magnesium chloride (stabiliser), neomycin B sulphate (trace amounts), polymyxin B sulfate (trace amounts), L-arginine, polysorbate 80, and water.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

FURTHER INFORMATION

POLIO SABIN (oral) MULTIDOSE is only available if prescribed by a doctor.

POLIO SABIN (oral) MULTIDOSE comes in the following: Multidose glass vials with plastic dropper: 10 doses, in packs of 100 (AUST R 13046).

MANUFACTURER
GlaxoSmithKline Biologicals S.A rue de l'Institut 89, 1330 Rixensart, Belgium.

DISTRIBUTED IN AUSTRALIA BY
GlaxoSmithKline Australia Pty Ltd 1061 Mountain Highway Boronia 3155 VIC

Date of Preparation: 5 February 2004