

GLAXOSMITHKLINE SOUTH AFRICA (PTY) LIMITED		TYPE	CLOSING SEQ
CERVARIX (Reg. No. 41/30.1/0366)			GDSv28 (one PFS)
Suspension for Injection (20 µg HPV-16/HPV-18)		Seq	0003 (related seq 0002)

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1.3.2 Patient Information Leaflet

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CERVARIX Patient Information Leaflet

SCHEDULING STATUS:

S2

CERVARIX Suspension for injection

Human Papillomavirus vaccine Types 16 and 18 (Recombinant, AS04 adjuvanted).

Sugar-free

Read all of this leaflet carefully before you or your child start receiving CERVARIX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet:

1. What CERVARIX is and what it is used for
2. What you need to know before you receive CERVARIX
3. How CERVARIX is given
4. Possible side effects
5. How to store CERVARIX
6. Contents of the pack and other information.

1. What CERVARIX is and what it is used for:

CERVARIX is a vaccine intended to protect against the diseases caused by Human Papillomavirus (HPV) types 16 and 18 infection.

These diseases include:

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- cervical cancer (cancer of the cervix i.e. lower part of the uterus or womb), vulvar cancer, vaginal cancer and anal cancer
- precancerous cervical, vulvar, vaginal and anal lesions (changes in cells that have a risk of turning into cancer).

CERVARIX will not protect against all types of Human Papillomavirus. Other HPV types can also cause cervical cancer. HPV types 16 and 18 are responsible for approximately 70 % of cervical cancer cases.

CERVARIX works by stimulating the production of antibodies against HPV types 16 and 18. These antibodies have been shown in clinical trials to protect women aged 15 years and older against HPV-16 and 18 related diseases. The vaccine also stimulates the production of antibodies in 9 to 14 years old children and adolescents, and in 26 to 55 years old women.

Although vaccination may protect you against cervical cancer, **it is not a substitute** for regular cervical screening. You should continue to follow your doctor's advice on cervical smear/Pap test and preventative and protective measures.

CERVARIX is not infectious and so, it cannot cause HPV related diseases.

CERVARIX will not treat HPV related diseases already present at time of vaccination.

As with all vaccines, CERVARIX may not fully protect all people who are vaccinated.

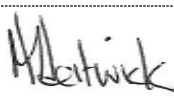
CERVARIX will not protect against other diseases that are not caused by Human Papillomavirus.

The duration of protection is currently unknown. In clinical trials, sustained protection has been observed for at least 9,4 years after the first dose. Long-term studies are ongoing to establish the duration of protection.

2. What you need to know before you receive CERVARIX:

CERVARIX should not be administered to you:

- If you have previously had any allergic reaction to CERVARIX, or any ingredient contained in CERVARIX. The active substances and other ingredients in CERVARIX are listed in section 6 –

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What CERVARIX contains. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Warnings and precautions:

Special care should be taken with CERVARIX if you:

- have a severe infection with a high temperature. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first
- have a bleeding problem or bruise easily.

People with a weakened immune system may not get the full benefit from CERVARIX.

Fainting can occur following, or even before, any needle injection, therefore tell your doctor or nurse if you fainted with a previous injection.

Other medicines or vaccines with CERVARIX:

Always tell your healthcare professional if you are taking any other medicine (this includes complimentary or traditional medicines).

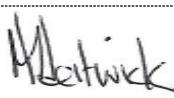
CERVARIX may be given with other normally recommended vaccines at a separate injection site (another part of the body e.g. the other arm) at the same visit. Ask your doctor for advice about which vaccines may be given at the same time as CERVARIX.

CERVARIX may not have an optimal effect if used with medicines that suppress the immune system.

In clinical trials, oral contraceptives (e.g. the pill) did not reduce the protection obtained by CERVARIX.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before you are given CERVARIX.

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Pregnancy: If pregnancy occurs during the course of vaccination or if you are trying to become pregnant, it is recommended to postpone vaccination until after completion of the pregnancy.

Breastfeeding: Ask your doctor for advice about breastfeeding before receiving CERVARIX.

CERVARIX contains sodium chloride:

CERVARIX contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How CERVARIX is given:

You will not be expected to give yourself CERVARIX. It will always be given to you by a person who is qualified to do so.

The doctor will give CERVARIX as an injection into the muscle.

The total number of injections you will receive depends on your age at the time of the first injection.

If you are between 9 and 14 years old, you will receive two injections:

First injection: at chosen date

Second injection: given between 5 and 13 months after the first injection.

If you are 15 years old or above, you will receive 3 injections:

First injection: at chosen date

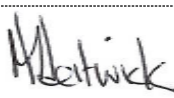
Second injection: 1 month after first injection

Third injection: 6 months after first injection.

If necessary the vaccination schedule can be more flexible. Please speak to your doctor for more information.

If you miss a dose:

It is important that you follow the instructions of your doctor or nurse regarding return visits. If you forget to go back to your doctor at the scheduled time, ask your doctor for advice. If you do not finish

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the complete vaccination course, you may not get the best response to and protection from the vaccination.

4. Possible side effects:

CERVARIX can cause side effects.

Not all side effects reported for CERVARIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects during the CERVARIX vaccination period, please consult your doctor, pharmacist or other healthcare professional.

Allergic reactions: If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- itchy rash of the hands and feet
- swelling of the eyes and face
- difficulty in breathing or swallowing
- sudden drop in blood pressure and loss of consciousness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CERVARIX. You may need urgent medical attention or hospitalisation.

These reactions will usually occur before leaving the doctor's surgery. However, if your child gets any of these symptoms you should contact a doctor urgently.

Other side effects include:

- **Very common side effects:**

- pain or discomfort at the injection site
- redness or swelling at the injection site
- headache
- aching muscles, muscle tenderness or weakness, not caused by exercise
- tiredness

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- **Common side effects:**

- gastrointestinal symptoms including nausea, vomiting, diarrhoea and abdominal pain
- itching, red skin rash, hives
- joint pain
- fever ($\geq 38^{\circ}\text{C}$).

- **Uncommon side effects:**

- upper respiratory tract infection
- dizziness
- swollen glands in neck, armpit and groin
- other injection site reactions such as hard lump, tingling or numbness.

Other side effects include:

- allergic reactions
- fainting sometimes accompanied by shaking or stiffness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CERVARIX.

5. How to store CERVARIX:

DO NOT FREEZE. DISCARD IF THE VACCINE HAS BEEN FROZEN.

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

Store in a refrigerator ($+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$).

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Do not use CERVARIX after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

WHAT CERVARIX CONTAINS:

CERVARIX contains Human Papillomavirus type 16 L1 protein and Human Papillomavirus type 18 L1 protein as active substances and is adjuvanted with the AS04 adjuvant system (composed of aluminium hydroxide, hydrated and 3-O-desacyl-4'-monophosphoryl lipid A (MPL)).

The other ingredients are sodium chloride, sodium dihydrogen phosphate dihydrate, water for injections.

What CERVARIX looks like and contents of the pack:

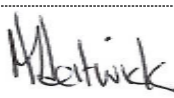
CERVARIX is presented as a turbid white suspension. Upon storage, a fine white deposit with a clear colourless supernatant can be observed.

CERVARIX is presented as a suspension for injection in 1 dose or 2 dose vials or in 1 dose pre-filled syringe (1 dose = 0,5 mL):

- 0,5 mL of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber cap with or without needles

Or

- 0,5 mL of suspension in a vial (type I glass) for 1 dose with a stopper (butyl rubber)

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Or

- 1 mL of suspension in a vial (type I glass) for 2 doses with a stopper (butyl rubber).

Registration number:

41/30.1/0366

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

This leaflet was last revised in:

26 November 2024

GDS-28

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AMENDMENT HISTORY

Submitted to MCC 12 December 2008

Response to Biological Committee recommendation 15 May 2008. MCC letter 28 April 2009 recommend that the proposed amendments be approved.

Update to GDS 018 submitted to MCC 30 September 2011.

PROPOSED PACKAGE INSERT: 30 September 2011 in-line with GDS 018 –**Approved by Bio Com 2012.03.30, Approved by MCC 2012.06.21**

Amended: 08 July 2013 (Inclusion of additional indication (vulvar and vaginal cancers) + 2-dose schedule + safety). Approved BMC 02/10/2013.

Amended: 23 Jan 2014 (Removal of table 8). **Ratified: 27 March 2014**

Amended: 13 November 2013. Inclusion of VVM under Storage Instructions. **Approved by MCC 28-02-2014.**

Amended: 27 May 2014 (to bring in line with GDSv23 wrt 2-dose and pregnancy safety). **Approved 08-12-2014**

Amended: 29 April 2015 (to extend indication to include anal lesions and cancers in males and females). Approved

Amended: 11 August 2023 (Safety update to bring in line with GDSv25-27. Approved 24 November 2024

Amended: 17 August 2023. CMC update to include GDSv28 (OBH000000190981 new single syringe type to be used as a replacement for currently approved syringe types). Approved 24-October-2025

Amended 18-Dec-2025: Closing sequence for One PFS

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