

HPvax

Prescription Only

Recombinant Human Papillomavirus Vaccine
(Types 16, 18) BP

For Intramuscular Injection only

Human Papillomavirus vaccine is for use from the age of 9 years for the prevention of premalignant cervical lesions and cervical cancer causally related to certain oncogenic Human Papillomavirus (16 & 18) types.

Composition

Each vial (0.5 ml of single dose) contains:
Recombinant HPV 16L1 protein: 0.040 mg
Recombinant HPV 18L1 protein: 0.020 mg

Indications

HPvax is a vaccine indicated for the prevention of the following diseases caused by oncogenic Human Papillomavirus (HPV) types 16 and 18:

- Cervical cancer
- Cervical intraepithelial neoplasia (CIN) Grade 2 or worse and adenocarcinoma in situ
- Cervical intraepithelial neoplasia (CIN) Grade 1

Dosage

Age at the time of the first injection	Immunization and schedule
9 to and including 14 years	2 doses 2 nd dose 6 months after 1 st dose or 3 doses at 0,1 and 6 months
From 15 years and above	3 doses at 0,1 and 6 months

The need for a booster dose has not been established. If flexibility in the vaccination schedule is necessary, the second dose can be injected within 1-2 months after the first dose, and 3rd dose can be injected within 5-8 months after the first dose.

Method of Administration

HPvax should be given intramuscularly in the deltoid region of arm in female aged from 9 years. The vaccine should be well shaken before use. The suspension should be used as supplied, no dilution or reconstitution process is needed. Once the vial is opened, the preparation must be used immediately.

Contraindications

The vaccine should not be given to person who is hypersensitive to any of the substances mentioned in composition. Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to HPvax.

Drug Interactions

- Immunosuppressive therapies may reduce the immune response to vaccines.
- Do not mix HPvax with any other vaccine in the same syringe or vial.

Precautions for Use

- Because vaccines may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity.
- HPvax will only protect against disease that are caused by HPV type 16, 18 and to some extent against diseases caused by certain other oncogenic related HPV types. Therefore, appropriate precautions against sexually transmitted diseases should continue to be used.
- HPvax is for prophylactic use only and has no effect on active HPV infections. Therefore, the vaccine is not indicated for treatment of cervical cancer or cervical neoplasia (CIN). It is also not intended to prevent progression of other established HPV related lesions or existing infections with vaccine or non-vaccine types.

Pregnancy

Pregnancy Category B, reproduction studies have been performed in rats at a dose approximately 47 times the human dose (on mg/kg basis) and revealed no evidence of impaired fertility or harm to the fetus due HPV vaccine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this vaccine should be used during pregnancy only if clearly needed.

Lactation

The effect on breast-fed infants of the administration of HPV vaccine to their mothers has not been evaluated in clinical studies. HPV vaccine should only be used during breast-feeding when the possible advantages outweigh the possible risks.

Adverse Effect

- Most common local adverse reactions in $\geq 20\%$ of subjects were pain, redness, and swelling at the injection site.
- Most common general adverse events in $\geq 20\%$ of subjects were fatigue, headache, myalgia, gastrointestinal symptoms, and arthralgia.

Storage

- Keep out of the reach and sight of children
- Store and transport at 2°C to 8°C
- Do not keep in deep fridge
- Discard suspension if frozen
- Protect from light

Commercial Pack

HPvax: Each box contains 1 vial of Recombinant Human Papillomavirus Vaccine (Types 16, 18) BP and 1 sterile disposable syringe.

Manufactured by :



POPULAR PHARMACEUTICALS LTD.
164, TONGI INDUSTRIAL AREA,
GAZIPUR, BANGLADESH

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120822/XYZ