PRAC reviewing risk of encephalitis with varicella vaccines

15/07/2025 | Circular Number P07/2025

Information on Varicella vaccines

- Varilrix and Varivax are authorised for vaccination of adults and children from 12 months of age, and in certain populations from 9 months of age, against chickenpox. They contain live attenuated (weakened) varicella virus.

Information on Varicella and Encephalitis

- Varicella is caused by the varicella-zoster virus, which also causes shingles (herpes zoster).
- Varicella mainly affects children aged 2-8 years where it is usually a mild disease and children recover quickly.
- In some cases, varicella can cause complications including bacterial infection of the skin or blood, pneumonia (infection and inflammation of the lungs) and encephalitis.
- Encephalitis can also be caused by other viral or bacterial infections. While most people with encephalitis recover, the condition can be life-threatening.
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In Malta the following products are authorised via national procedure:

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
Varicella Virus Oka Strain (Live attenuated) 10 plaque forming unit(s)/dose	Varilrix powder and solvent for solution for injection	Powder and Solvent for solution for injection	POM	MA170/00801	GlaxoSmithKline Biologicals S.A.
Varicella Virus Oka/Merck strain (Live, Attenuated)	Varivax powder and solvent for suspension for	Powder and Solvent for suspension for	POM	MA224/00501	Merck Sharp & Dohme B.V.

plaque forming unit(s)/dose	injection in pre-filled syringe	injection			
Varicella Virus Oka Strain (Live Attenuated) 206.6 plaque forming unit(s)/millilitre	Varilrix powder and solvent for solution for injection in pre-filled syringe (live) varicella vaccine	Powder and Solvent for solution for injection	POM	PI1438/03001A	NM Pharma Limited
Varicella Virus Vaccine Live (Oka/Merck) 10 plaque forming unit(s)/dose	Varilrix powder and solvent for solution for injection	Powder and Solvent for solution for injection	POM	MA170/00802	GlaxoSmithKline Biologicals S.A.
Varicella Virus Oka strain (Live, Attenuated) 10PFU/dose	Varilrix powder and solvent for solution for injection in pre-filled syringe varicella vaccine live	Powder and Solvent for solution for injection in pre-filled syringe	POM	PI770/20101A	JV Healthcare Limited
Varicella virus Oka strain (Live, Attenuated) 1350/0.5 plaque forming unit(s)/millilitre	Varivax powder and solvent for suspension for injection in a pre-filled syringe	Powder and Solvent for solution for injection	POM	PI770/20601A	JV Healthcare Limited

Information from the EMA about the safety concern

- EMA's safety committee (PRAC) is reviewing the known risk of encephalitis (inflammation of the brain) with two varicella (chickenpox) vaccines, Varilrix and Varivax, following a report of a fatal outcome after vaccination with Varilrix.
- This review was initiated by the PRAC following a case report in Poland of a child who developed encephalitis a few days after receiving the Varilrix vaccine. The patient died of the consequences of encephalitis several days later. As a precaution, the Polish medicines agency has suspended the distribution of vaccines from the batch in question.
- These vaccines are widely used across the EU, and encephalitis is listed as a side effect in their product information based on rare reports during post-marketing surveillance.
- The committee will now assess all available evidence to better understand the risk of encephalitis and to determine if any regulatory action is necessary.

- While EMA is investigating the issue, the vaccines can continue to be used in line with the approved product information.

For more information visit the European Medicines Agency's website at www.ema.europa.eu

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on varicella vaccines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 **or** online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Malta Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

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