

Dear Healthcare Providers,

Information about the updated PIL

Janssen Egypt in agreement with Pharmaceutical Vigilance General Administration (PVGA) would like to inform you that an updated Patient Information Leaflet (PIL) for TECVAYLI® (teclistamab), dated 11 July 2024, has been approved by Egyptian Drug Authority. This version includes new safety information compared with the previous PIL dated 7 December 2023 which is still currently on the market and will be available till Sep 2026 or depletion of the current stock in Egypt. Janssen Egypt is actively working to ensure that the updated PIL of TECVAYLI is made available as soon as possible.

This communication is an informative letter to ensure the continued safe and effective use of TECVAYLI®, in alignment with the current approved PIL for Tecvayli.

Summary

Below you will find the key updates (highlighted in yellow) in the latest approved PIL.

Current Details (PIL 7 December 2023.)	Approved Details (PIL 11 July 2024)
Warnings and precautions Talk to your doctor or nurse before you are given TECVAYLI if you have had a stroke or seizure within the past 6 months.	Warnings and precautions Talk to your doctor or nurse before you are given TECVAYLI if you - have had a stroke or seizure within the past 6 months. - have ever had or might now have a hepatitis B infection. This is because TECVAYLI could cause hepatitis B virus to become active again. Your doctor will check you for signs of this infection before, during and for some time after treatment with TECVAYLI. Tell your doctor or nurse if you get worsening tiredness, or yellowing of your skin or white part of your eyes. At any time during or after your treatment, tell your doctor or nurse immediately if you - notice any new or worsening symptoms of Progressive Multifocal Leukoencephalopathy (PML). PML is a serious and potentially fatal brain infection. Symptoms may include, but are not limited to, blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.

Common (may affect up to 1 in 10 people): • Effects on your nervous system. These may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS). Some of the symptoms are: ○ feeling confused ○ feeling less alert ○ having difficulty writing ○ having difficulty speaking ○ sleepiness ○ loss of ability to carry out skilled movement and gestures (despite having the physical ability and desire to perform them) Tell your doctor right away if you notice any of the above-listed serious side effects. Very common (may affect more than 1 in 10 people): • lung infection (pneumonia) • COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2) • infected nose, sinuses or throat (upper respiratory tract infection) • feeling sick (nausea), diarrhoea, constipation, vomiting • headache • nerve damage that may cause tingling, numbness, pain or loss of pain sensation • high blood pressure (hypertension) • bleeding, which can be severe (haemorrhage) Common (may affect up to 1 in 10 people): • severe infection throughout the body (sepsis) • skin infection causing redness (cellulitis) • low number of a type of white blood cell with a fever (febrile neutropenia) • low levels of 'fibrinogen,' a type of protein in the blood, making it more difficult to form clots • change in brain function (encephalopathy) • low level of 'calcium' or 'sodium' in the blood (hypocalcaemia or hyponatraemia) • high level of 'potassium' in the blood (hyperkalaemia)	• Common (may affect up to 1 in 10 people): • Effects on your nervous system. These may be signs of a serious immune reaction called 'immune effector cell-associated neurotoxicity syndrome' (ICANS). Some of the symptoms are: ○ feeling confused ○ feeling less alert ○ having difficulty writing ○ having difficulty speaking ○ sleepiness ○ loss of ability to carry out skilled movement and gestures (despite having the physical ability and desire to perform them) Uncommon (may affect up to 1 in 100 people): • a serious and potentially fatal brain infection called Progressive Multifocal Leukoencephalopathy (PML). Some of the symptoms are: ○ blurred, loss of or double vision ○ difficulty speaking ○ weakness in an arm or a leg ○ a change in the way you walk or problems with your balance ○ persistent numbness ○ decreased sensation or loss of sensation ○ memory loss or confusion Very common (may affect more than 1 in 10 people): • lung infection (pneumonia) • COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2) • infected nose, sinuses or throat (upper respiratory tract infection) • urinary tract infection • low levels of red blood cells (anaemia) • low levels of blood platelets (cells that help blood to clot; thrombocytopenia) • feeling sick (nausea), diarrhoea, constipation, vomiting, stomach pain (abdominal pain) - headache • nerve damage that may cause tingling, numbness, pain or loss of pain sensation • muscle spasms • high blood pressure (hypertension) • bleeding, which can be severe (haemorrhage)
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low level of 'albumin' in the blood (hypoalbuminaemia) • low level of oxygen in the blood (hypoxia) • increased level of 'gamma-glutamyltransferase' in the blood • increased level of liver enzymes 'transaminases' in the blood • increased level of 'creatinine' in the blood • increased level of 'amylase' in the blood (hyperamylasaemia) • increased level of 'lipase' in the blood (hyperlipasaemia) • blood tests may show it takes longer for blood to clot (INR increased and PTT prolongation)	• low blood pressure (hypotension) Common (may affect up to 1 in 10 people): • severe infection throughout the body (sepsis) • skin infection causing redness (cellulitis) • low number of a type of white blood cell with a fever (febrile neutropenia) • low levels of 'fibrinogen,' a type of protein in the blood, making it more difficult to form clots • change in brain function (encephalopathy) • low level of 'calcium' or 'sodium' in the blood (hypocalcaemia or hyponatraemia) • high level of 'potassium' in the blood (hyperkalaemia) • low level of 'albumin' in the blood (hypoalbuminaemia) • low level of sugar in the blood (hypoglycaemia) • low level of oxygen in the blood (hypoxia) • increased level of 'gamma-glutamyltransferase' in the blood • increased level of liver enzymes 'transaminases' in the blood • increased level of 'creatinine' in the blood • increased level of 'amylase' in the blood (hyperamylasaemia) • increased level of 'lipase' in the blood (hyperlipasaemia) • blood tests may show it takes longer for blood to clot (INR increased and PTT prolongation)
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Background

TECVAYLI is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Labelling update is a part of routine risk minimization activity mandated by Janssen Egypt in collaboration with The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority

1. New Safety Warnings and Precautions:

Talk to your doctor or nurse before you are given TECVAYLI® if you

- have ever had or might now have a hepatitis B infection. This is because TECVAYLI® could cause hepatitis B virus to become active again. Your doctor will check you for signs of this infection before, during and for some time after treatment with TECVAYLI®. Tell your doctor or nurse if you get worsening tiredness, or yellowing of your skin or white part of your eyes.

- At any time during or after your treatment, tell your doctor or nurse immediately if you notice any new or worsening symptoms of Progressive Multifocal Leukoencephalopathy (PML). PML is a serious and potentially fatal brain infection. Symptoms may include, but are not limited to, blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.

2. Very common (may affect more than 1 in 10 people) Possible Side Effects

The updated PIL includes **additional adverse reactions**, such as:

- Urinary tract infection
- stomach pain (abdominal pain)
- Muscle spasms
- low blood pressure (hypotension)

3. Common (may affect up to 1 in 10 people) Possible Side Effects

- low level of sugar in the blood (hypoglycaemia)

4. Uncommon (may affect up to 1 in 100 people) Possible Side Effects

- a serious and potentially fatal brain infection called Progressive Multifocal Leukoencephalopathy (PML). Some of the symptoms are:

- blurred, loss of or double vision
- difficulty speaking
- weakness in an arm or a leg
- a change in the way you walk or problems with your balance
- persistent numbness
- decreased sensation or loss of sensation
- memory loss or confusion

Reference :

www.ema.europa.eu/en/documents/product-information/tecavayli-epar-product-information_en.pdf

Call for reporting

Healthcare Prescribers are asked to report any suspected adverse reactions via the Egyptian reporting system:

•General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

Hotline: 15301

QR Code :



•Company contact points :

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