



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 10-13 March 2025 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found on the webpage for [PRAC recommendations on safety signals](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Tegafur, gimeracil, oteracil – Hyperammonaemia (EPITT no 20115)

Summary of product characteristics

4.4 Special warnings and precautions for use

Hyperammonaemia

Hyperammonaemia has been observed with Teysuno. In patients who develop unexplained neurologic symptoms (like ataxia, lethargy or changes in mental status), ammonia levels should be measured and appropriate clinical management should be initiated. If hyperammonaemia neurologic symptoms worsen to hyperammonaemic encephalopathy, discontinuation of Teysuno should be considered.

4.8 Undesirable effects

Metabolism and nutrition disorders

Frequency 'rare/very rare':

Hyperammonaemia

¹ Expected publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



Package leaflet

2. Warnings and precautions

If you develop lack of energy, confusion, sleepiness, seizures or impaired consciousness, please contact your doctor immediately.

4. Possible side effects

Rare side effects (may affect 1 to 10 in 10,000 people) and very rare side effects (may affect less than 1 in 10,000 people) include:

High blood ammonia levels