



January 2024

Direct Healthcare Professional Communication (DHPC)

Tamiflu® (oseltamivir) 45 mg Hard Capsules: Different colour ink used on blister pack

Dear Healthcare professional,

Roche Products Ltd, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **A different colour ink (red, instead of Pantone magenta) has been used to print the strength of Tamiflu (45 mg) on the aluminium foil of certain batches.**
- **There is no impact on product quality, safety or efficacy.**
- **This is being communicated to ensure there are no concerns that these batches are counterfeit. No further action is required by healthcare professionals.**

Background on the safety concern

Tamiflu is indicated for:

- Treatment of influenza in adults and children including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.
- Prevention of influenza:
 - Post-exposure prevention in individuals 1 year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.
 - The appropriate use of Tamiflu for prevention of influenza should be determined on a case by case basis by the circumstances and the population requiring protection. In exceptional situations (e.g. in case of a mismatch between the

M-GB-00015060
Roche Products Limited
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circulating and vaccine virus strains, and a pandemic situation) seasonal prevention could be considered in individuals one year of age or older.

- Post-exposure prevention of influenza in infants less than 1 year of age during a pandemic influenza outbreak .

Tamiflu 45 mg Hard Capsules are packaged in a triplex blister pack (PVC/PE/PVDC, sealed with aluminium foil). On the aluminium foil, the strength of Tamiflu (45 mg) is normally printed in Pantone magenta coloured ink. For certain batches, the strength has instead been printed in red ink. The batches affected can be found below:

- Batch number: M1045M1, expiry date: 04/2033
- Batch number: M1045M2, expiry date: 04/2033
- Batch number: M1045M3, expiry date: 04/2033
- Batch number: M1045M4, expiry date: 04/2033
- Batch number: M1045M5, expiry date: 04/2033
- Batch number: M1045M6, expiry date: 04/2033
- Batch number: M1045M7, expiry date: 04/2033
- Batch number: M1045M9, expiry date: 04/2033

No other differences are associated with these batches and there is no impact on the product's quality, on patient's safety, or efficacy. We are taking steps to ensure this is communicated to healthcare professionals to ensure there are no concerns that these batches are counterfeit. No further action is required by healthcare professionals.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store

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- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

Company contact point

Should you have any questions regarding the use of Tamiflu, please feel free to contact:

Roche Medical Information by phone on +44(0)800 328 1629 or via e-mail medinfo.uk@roche.com

Thank you in advance for your understanding and cooperation in this additional information.

Yours faithfully,

Roche Products Limited

A handwritten signature in black ink, appearing to read "Marius Scholtz".

Dr Marius Scholtz

Chief Medical Officer