

Storage of CellCept Outside of the Original Packaging

This letter responds to your request for information on storage of CellCept® (mycophenolate mofetil) tablets and capsules outside of the original blister and carton packaging.

Rationale for use of the original packaging

CellCept tablets and capsules must be stored in the original blister package within the outer carton to protect from moisture and light.¹

Stability and compatibility considerations

Stability and compatibility of CellCept can only be guaranteed for the original packaging that have been manufactured and packaged under validated conditions and approved with the relevant marketing authorization application.

The stability and compatibility of primary packaged CellCept cannot be transferred to repackaged products in the blistering process due to variable conditions such as

- temperature
- air humidity
- light permeability
- chemical interactions, and
- duration of re-packaging process.^{2,3}

We have no data on the storage of CellCept tablets or capsules outside of the original primary packaging (blister and outer carton).

References

1. Roche Internal Technical Report (Accessed on 28 June 2023).
2. Roche Internal Communication (Accessed on 26 Jun 2023).
3. Roche Internal Communication (Accessed on 9 Aug 2023).