Crushing or Splitting CellCept Tablets

This article responds to your request for information on crushing or splitting CellCept® (mycophenolate mofetil). This response was developed according to the principles of evidence-based medicine and contains data from clinical trials.

CellCept preparation and administration precautions

CellCept tablets are not formulated to be split as they are not scored.[1] Splitting the tablets may also expose patients and healthcare professionals (HCP) to health risks through powder aerosolization.[2]

CellCept has demonstrated teratogenic effects and irritation of mucosal lining in humans.[2] Patients and HCPs should avoid contact with the powder in broken tablets. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water. Refer to applicable special handling and disposal procedures outlined in the local label for more information.

External experience with extemporaneous preparation of CellCept

Please note, CellCept is not approved for extemporaneous preparation into an oral suspension from tablets or capsules. Any decision to extemporaneously prepare CellCept from tablets or capsules would be considered off-label and a clinical decision to be made by the HCP after an analysis of the benefit-risk ratio.

Fahimi et al. studied the stability of extemporaneously prepared mycophenolate mofetil 50 mg/mL suspension after compounded in a vertical flow hood from:

- CellCept tablets or capsules
- OraPlus® aquaous-based suspending vehicle, and
- cherry essence.[3]

Storage and stability of hospital-prepared mycophenolate mofetil suspension

Samples were stored in amber bottles at 5ºC and 40ºC for 24 hour periods during the first week, then kept at 5°C, 25°C or 40°C for 50 days.[3] Stability-indicating high-performance liquid chromatography (HPLC) assays were used to determine stability of the samples. Samples prepared with tablets were coarser and had a lower measured concentration right after preparation as compared with those prepared with capsules (49 mg/mL vs. 50 mg/mL).

Study results of capsule vs. tablet-based suspension samples

Capsule-based suspension samples stored at 5°C were stable for 14 days.[3] Tablet-based suspension samples were were not at optimal concentrations after 7 days according to the HPLC method.

References

1. Roche Internal Communication. Accessed 13 Jul 2023.
2. Roche Internal Regulatory Document. Accessed 13 Aug 2023.

3. Fahimi F, Baniasadi S, Mortazavi S, et al. Physical and Chemical Stability of Mycophenolate Mofetil (MMF) Suspension Prepared at the Hospital. Iran J Pharm Res 11:171-5. https://www.ncbi.nlm.nih.gov/pubmed/24250439