

# Tepotinib + Carbamazepine/Itraconazol

M 8570

| Onderbouwend | Stof                      | Effect                                                                                                                                                                                                      | Code |
|--------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| spc Tepmetko | tepotinib + carbamazepine | ↓AUCinf tepotinib met 35% en Cmax met 11%; de verminderde blootstelling is niet klinisch relevant.<br>Regime: tepotinib 450 mg 1x en carbamazepine 300 mg 2dd gedurende 14 dagen bij gezonde vrijwilligers. | 2A   |
| spc Tepmetko | tepotinib + itraconazol   | ↑AUC inf tepotinib 1.22x, en Cmax ongewijzigd; wordt niet als klinisch relevant beschouwd.<br>Regime: tepotinib 450 mg 1x en itraconazol 200 mg 1dd gedurende 11 dagen bij gezonde vrijwilligers.           | 2A   |

| Overig                                                                                                         | Stof                                            | Effect                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Spc + EPAR Tepmetko<br><br>Tepmetko Procedural-steps-taken-scientific-information-after-authorisation 21-07-23 | tepotinib + CYP- en P-gp-inductoren             | verminderde blootstelling door cbz is niet klinisch relevant.<br>tepotinib is P-gp-substraat.<br><br>Based on the final results of drug-drug interactions studies, sections 4.4, 4.5 and 5.2 of the SmPC have been updated in order to delete the warning that concomitant use of strong CYP and P gp inducers should be avoided. These interactions are no longer considered clinically relevant and no dose adjustment is needed.                                                                                                                                                                                                                                     |
| Spc + EPAR Tepmetko<br><br>Tepmetko Procedural-steps-taken-scientific-information-after-authorisation 21-07-23 | tepotinib + duale sterke CYP3A- en P-gp-remmers | tepotinib is P-gp-substraat.<br>effect itraconazol wordt ingedeeld als zwakke interactie en de waargenomen veranderingen in systemische blootstelling aan tepotinib worden niet als klinisch relevant beschouwd. Daarom wordt niet verwacht dat CYP3A- en P-gp-remmers invloed hebben op de blootstelling aan tepotinib.<br><br>Based on the final results of drug-drug interactions studies, sections 4.4, 4.5 and 5.2 of the SmPC have been updated in order to delete the warning that concomitant use of dual strong CYP3A and P gp inhibitors should be avoided. These interactions are no longer considered clinically relevant and no dose adjustment is needed. |
| Cortot A.<br>Clin Lung Cancer<br>2022;23:195-207.                                                              | tepotinib                                       | Review; tepotinib is a substrate of CYP3A4 and CYP2C8, and transported by P-gp; thus, avoid concomitant use with strong CYP3A inducers or with dual strong CYP3A and P-gp inhibitors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

## Opmerkingen

Stockley: -

PubMed: niets op tepotinib and carbamazepine of itraconazol.

|                      |  |
|----------------------|--|
| Risicofactoren       |  |
| Mitigerende factoren |  |

|                      | Interactie | Actie | Datum   |
|----------------------|------------|-------|---------|
| Beslissing WG OncolA | ja         | Nee   | 25-6-25 |