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Therapeutic Areas Department

| **Language** | **Heading and text to be inserted in Section 5.1 of the SmPC** |
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| English | Susceptibility testing breakpoints MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for <INN> and are listed here: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Bulgarian | Гранични стойности за изпитване за чувствителност Тълкувателните критерии за MIC (минимална инхибираща концентрация) за изпитване на чувствителността са установени от Европейския комитет за изследване на антимикробната чувствителност (EUCAST) за <INN> и са изброени тук: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Croatian | Granične vrijednosti pri ispitivanju osjetljivosti Interpretacijske kriterije za ispitivanje osjetljivosti za MIK (minimalnu inhibitornu koncentraciju) utvrdio je Europski odbor za ispitivanje osjetljivosti na antimikrobna sredstva (EUCAST) za <INN>, a navedeni su ovdje: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Czech  | Hraniční hodnoty testování citlivosti Evropský výbor pro testování antimikrobiální citlivosti (EUCAST) stanovil pro testování citlivosti <INN> tato kritéria interpretace minimální inhibiční koncentrace (MIC): <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Danish | Grænseværdier ved følsomhedstestning MIC (mindste inhiberende koncentration)-fortolkningskriterierne for følsomhedstestning er fastlagt af European Committee on Antimicrobial Susceptibility Testing (EUCAST) for <INN> og er anført her: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Dutch | Gevoeligheidstestbreekpunten Het Europees Comité voor tests op antimicrobiële resistentie (EUCAST) heeft voor <INN> interpretatiecriteria voor gevoeligheidstests vastgesteld met betrekking tot de MRC (minimale remmende concentratie). U kunt die criteria raadplegen via de volgende link: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Estonian | Tundlikkustestide piirväärtused Antimikroobse tundlikkuse Euroopa analüüsikomitee (EUCAST) on toimeaine <INN> jaoks kehtestanud tundlikkuse testimise MIC (minimaalse inhibeeriva kontsentratsiooni) tõlgendamise kriteeriumid ja need on loetletud siin: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Finnish | Herkkyystestauksen raja-arvot Mikrobilääkeherkkyyttä käsittelevä eurooppalainen komitea (EUCAST) on vahvistanut mikrobilääkeherkkyyden testausta koskevat MIC-arvon (pienin bakteerin kasvun estävä pitoisuus) tulkintakriteerit aineelle <INN>, ja ne luetellaan täällä: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| French | Seuils des tests de sensibilité Les critères d’interprétation des concentrations minimales inhibitrices (CMI) pour les tests de sensibilité ont été établis par le Comité européen des antibiogrammes (EUCAST) pour la <DCI> et sont énumérés ci-dessous: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Gaellic | Brisphointí tástála soghabháltachta Tá liosta de chritéir léirmhínitheacha MIC (íoschoscaire tiúchana) le haghaidh tástáil soghabháltachta curtha le chéile ag an gCoiste Eorpach um Thástáil Soghabháltachta i leith Ábhar Frithmhiocróbach (EUCAST) le haghaidh <INN> agus is féidir teacht air anseo: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| German | Grenzwerte der Empfindlichkeitstestung Die Interpretationskriterien für die Empfindlichkeitstestung in der MHK (minimalen Hemmkonzentration) wurden vom Europäischen Ausschuss für die Untersuchung auf Antibiotikaempfindlichkeit (EUCAST) für <INN> festgelegt und sind hier aufgeführt: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Greek | Όρια δοκιμής της ευαισθησίας Τα ερμηνευτικά κριτήρια για την ελάχιστη ανασταλτική συγκέντρωση (MIC) της δοκιμής ευαισθησίας έχουν θεσπιστεί από την ευρωπαϊκή επιτροπή ελέγχου ευαισθησίας των μικροοργανισμών στα αντιμικροβιακά (EUCAST) για την <INN> και παρατίθενται εδώ: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Hungarian | Érzékenységi vizsgálat határértékei Az Antibiotikum-érzékenységi Vizsgálatok Európai Bizottsága (EUCAST) a(z) <INN> vonatkozásában megállapította a MIC (minimális gátló koncentráció) érzékenységi vizsgálatának értelmezési kritériumait, amelyek felsorolása itt található: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Icelandic | Brotpunktar fyrir næmisprófanir MIC (lágmarks hamlandi styrkur) túlkandi viðmiðanir fyrir næmisprófanir hafa verið settar af Evrópunefnd um næmisprófanir (EUCAST) fyrir <INN> og eru taldar upp hér: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Italian | Valori soglia dei test di suscettibilità I criteri interpretativi della MIC (concentrazione minima inibente) per i test di suscettibilità sono stati stabiliti dal Comitato europeo sui test di suscettibilità antimicrobica (EUCAST) per <INN> e sono elencati al seguente indirizzo: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>.   |
| Latvian | Jutības pārbaudes robežkoncentrācijas MIC (minimālā inhibējošā koncentrācija) interpretācijas kritērijus uzņēmības testēšanai ir noteikusi Eiropas Antimikrobu uzņēmības testēšanas komiteja (*EUCAST*) attiecībā uz &INN>, un tie ir uzskaitīti šeit: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Lithuanian | Jautrumo tyrimų lūžio taškai Jautrumo tyrimų MIK (mažiausios inhibitorinės koncentracijos) aiškinimo kriterijus <INN> nustatė Europos antimikrobinio jautrumo tyrimo komitetas (EUCAST) ir jie yra nurodyti čia: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Maltese | Valuri kritiċi għall-ittestjar tas-suxxettibbiltà Kriterji interpretattivi għall-ittestjar tas-suxxettibbiltà fl-MIC (konċentrazzjoni minima inibitorja) ġew stabbiliti mill-Kumitat Ewropew dwar it-Testijiet tas-Suxxettibbiltà Antimikrobika (EUCAST) għal <INN> u huma elenkati hawn: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Norwegian | Følsomhetstesting av knekkpunkter MIC (minimum hemmende konsentrasjon) fortolkningskriterier for følsomhetstesting er fastsatt av Den europeiske komité for antimikrobiell følsomhetstesting (EUCAST) for <INN> og er oppført her: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Polish | Wartości graniczne badania wrażliwości Kryteria interpretacyjne MIC (minimalnego stężenia hamującego) dla badania wrażliwości zostały ustanowione przez Europejski Komitet ds. Oceny Wrażliwości na środki przeciwdrobnoustrojowe (EUCAST) dla <INN>. Są one wymienione tutaj: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Portuguese | Limites dos testes de suscetibilidade Os critérios interpretativos CIM (concentração inibitória mínima) para os testes de suscetibilidade foram estabelecidos pelo Comité Europeu de Avaliação de Suscetibilidade Antimicrobiana (EUCAST) para <INN> e são enumerados no seguinte endereço: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Romanian | Valori critice pentru testarea sensibilității Criteriile de interpretare pentru testarea sensibilității CMI (concentrație inhibitoare minimă) au fost stabilite de Comitetul European privind Testarea Sensibilității la Antimicrobiene (EUCAST) pentru <INN > și sunt enumerate aici: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Slovak  | Hraničné hodnoty testovania citlivosti Európsky výbor pre testovanie antimikrobiálnej citlivosti (EUCAST) stanovuje tieto interpretačné kritériá na testovanie citlivosti MIC (minimálnej inhibičnej koncentrácie) pre <INN>: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Slovenian | Mejne koncentracije testiranja občutljivosti Merila za razlago MIK (minimalne inhibicijske koncentracije) za testiranje občutljivosti za <mednarodno nelastniško ime (INN)> je določil Evropski odbor za preskušanje protimikrobne občutljivosti (EUCAST) in so navedena tukaj: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Spanish | Valores críticos de las pruebas de sensibilidad Los criterios interpretativos de la CMI (concentración mínima inhibitoria) para las pruebas de sensibilidad han sido establecidos por el Comité Antibiogramas (EUCAST) para <INN> y se enumeran aquí: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |
| Swedish | Brytpunkter för resistensbestämning Tolkningskriterierna för MIC (minsta hämmade koncentration) vid resistensbestämning har fastställts av europeiska kommittén för resistensbestämning (EUCAST) för <INN> och listas här: <<https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx>>   |