

To: [5.1.2e] [5.1.2e] @cbg-meb.nl]
Cc: [5.1.2e] [5.1.2e] @cbg-meb.nl]
From: [5.1.2e]
Sent: Wed 1/8/2025 8:42:41 AM
Subject: FW: Ivermectin ? RE: Case 794501 Proactive PV monitoring of COVID-19
Received: Wed 1/8/2025 8:42:42 AM

En nog meer.

From: [5.1.2e].

Sent: donderdag 9 april 2020 11:08

To: [5.1.2e] <[5.1.2e]@cbg-meb.nl>; [5.1.2e] <[5.1.2e]@cbg-meb.nl>

Subject: RE: Ivermectin ? RE: Case 794501 Proactive PV monitoring of COVID-19

Ja off-label gebruik.

Mvg

[5.1.2e]

Van: [5.1.2e] <[5.1.2e]@cbg-meb.nl>

Verzonden: donderdag 9 april 2020 10:40

Aan: [5.1.2e] <[5.1.2e]@cbg-meb.nl> [5.1.2e] <[5.1.2e]@cbg-meb.nl>

Onderwerp: RE: Ivermectin ? RE: Case 794501 Proactive PV monitoring of COVID-19

Het gaat hier toch vooral om monitoren van de humane middelen en voorsnog niet om inzet van veterinaire producten voor
 humaan gebruik. Klopt dat?

Van: [5.1.2e].

Verzonden: donderdag 9 april 2020 10:23

Aan: [5.1.2e] [5.1.2e]

Onderwerp: FW: Ivermectin ? RE: Case 794501 Proactive PV monitoring of COVID-19

Ter info

Topical formuleringen zijn FT4 en systemisch FT1.

Veterinair oa als antiworm middel

Mvg

[5.1.2e]

Van: [5.1.2e].

Verzonden: maandag 6 april 2020 11:24

Aan: [5.1.2e] <[5.1.2e]@cbg-meb.nl>

Onderwerp: RE: Ivermectin ? RE: Case 794501 Proactive PV monitoring of COVID-19

Nee idd dat is reelee bezorgdheid.

Safety vd systemische formuleringen zijn natuurlijk bekend bij oa rivierblindheid indicatie

Mvg

[5.1.2e]

Van: [5.1.2e] <[5.1.2e]@cbg-meb.nl>

Verzonden: maandag 6 april 2020 11:21

Aan: [5.1.2e] <[5.1.2e]@cbg-meb.nl>

Onderwerp: RE: Ivermectin ? RE: Case 794501 Proactive PV monitoring of COVID-19

Nog niet gezien, dank!

Hopelijk gaat men nu niet hoofdлуismiddel slikken....

Van: [5.1.2e].

Verzonden: maandag 6 april 2020 11:12

Aan: [5.1.2e] [5.1.2e]

CC: [5.1.2e]; [5.1.2e]; [5.1.2e]; [5.1.2e] [5.1.2e]

Onderwerp: Ivermectin ? RE: Case 794501 Proactive PV monitoring of COVID-19

Wellicht al gezien?

<https://www.sciencedirect.com/science/article/pii/S0166354220302011>

<https://www.medicalfacts.nl/2020/04/04/coronavirus-doorbraak-is-ivermectine-de-mogelijke-doorbraak-bij-de-behandeling-covid-19/>

Ik zag m nog niet staan in de lijst van 'kandidaat' middelen.

@ [5.1.2e] ik zag dat FR lead MS is, correct?

Mvg

[5.1.2e]

Van: [5.1.2e] <[5.1.2e]@cbg-meb.nl>

Verzonden: donderdag 2 april 2020 11:31

Aan: [REDACTED] 5.1.2e <[REDACTED] 5.1.2e @cbg-meb.nl>

Onderwerp: FW: Case 794501 Proactive PV monitoring of COVID-19

Ter info,

[REDACTED] 5.1.2e

Van: [REDACTED] 5.1.2e [REDACTED] 5.1.2e [REDACTED] @ema.europa.eu]

Verzonden: woensdag 1 april 2020 18:31

Aan: [REDACTED] 5.1.2i Functionele emailadressen

CC: [REDACTED] 5.1.2e ; [REDACTED] 5.1.2e ; [REDACTED] 5.1.2e ; [REDACTED] 5.1.2e ; [REDACTED] 5.1.2e ; [REDACTED] 5.1.2e ; [REDACTED] 5.1.2e

Onderwerp: Case 794501 Proactive PV monitoring of COVID-19

Dear PRAC Colleagues,

Further to discussions we had with the PRAC chair and vice chair, this is to inform you on actions undertaken so far and planned to ensure proactive PV monitoring of COVID-19. This is our starting point and as more information and updates becomes available we will keep you consulted and informed.

An extraordinary SMART is organised on 3 April to further discuss practicalities around the actions undertaken so far and the need for additional points to consider.

Attachments: sample of dashboard and notes for users (link to the dashboard for EVDAS users below), list of observational studies and data sources (initial version), list of therapeutics (version 1), literature review by EMA on CQ/HCQ for COVID-19

New tools (in addition to existing routine eRMRs):

- A **descriptive dashboard** of all EV reports received from 01/01/2020 where the MedDRA preferred terms "Corona virus infection", "Coronavirus test positive" or "Severe acute respiratory syndrome" are reported in either the Reaction, Drug Indication or Patient Medical History sections of the ICSR. There will also be a searchable case line listing, available to registered EVDAS users from EMA and NCAs; link: [dashboard](#); example attached
- A **dedicated eRMR** file based on the same dataset (to allow for tracking of assessments and actions). This will be primarily screened by EMA staff and made available to NCAs (under development and will be available at later stage)
- A common platform for sharing published literature on COVID-19 screened by the EMA - we are investigating the possibility of setting this up.
- A **list of substances used in COVID-19** with background information. Please find attached the first version and note that updated list will be provided regularly.

Acknowledging the need for close monitoring of therapeutics used in COVID-19, we have contacted the Lead MS to discuss the need for more frequent monitoring of the eRMRs for NAPs. For CAP EMA monitors in collaboration with the Rapporteur.

Several studies are on-going or planned in different European countries as regards the effect of medicinal products such as NSAIDs (including ibuprofen) and anti-hypertensives (such as antagonist receptor blockers and ACE inhibitors) on the severity of Covid-19 infections. The EMA is considering to launch a procurement in order to create a European-wide cohort of COVID-19 patients in order to perform studies answering questions that will arise in the coming weeks or months. EMA will also launch a procurement in order to ensure preparedness for the monitoring vaccines when they arrive on the market.

Attached is a **list of observational studies and data sources** that will be updated regularly by [REDACTED] 5.1.2e team. Note that it should not be circulated or published. There are already several studies registered in the EU PAS Register.

Many thanks to colleagues across the agency (in cc) that contributed, notably PHV office and [REDACTED] 5.1.2e teams.

Best Wishes,

[REDACTED] 5.1.2e (on behalf of the team)

[REDACTED] 5.1.2e

[REDACTED] 5.1.2e

European Medicines Agency