

شماره: ۶۵۵/۲۹۵۲۵
تاریخ: ۱۴۰۰/۰۶/۰۱
پیوست: دارد



معاون محترم غذا و داروی دانشگاه های علوم پزشکی و خدمات بهداشتی درمانی سراسر کشور

موضوع: هشدار سازمان جهانی بهداشت در خصوص ویال رمدسیویر قلبی شرکت گیلیاد- معاونین غذا و داروی سراسر کشور

با سلام؛

با احترام، عطف به نامه شماره ۱۳۵/۱۳۸۵/د مورخ ۱۴۰۰/۵/۳۰ مدیرکل محترم امور بین الملل وزارت متبوع، در خصوص داروی قلبی رمدسیویر به آگاهی می رساند، سازمان متبوع گزارشی مبنی بر هشدار در خصوص داروی قلبی رمدسیویر شرکت گیلیاد، که در منطقه آمریکایی سازمان جهانی بهداشت شناسایی و به آن سازمان گزارش شده، مطابق مشخصات اعلام شده در پیوست دریافت نموده است.

با عنایت به احتمال وجود داروهای قلبی در بازار سیاه دارویی کشور، ضمن تاکید مجدد بر لزوم کنترل اصالت همه فرآورده های سلامت محور در سامانه ردیابی و رهگیری اصالت (TTAC)، خواهشمنداست دستور فرمایید، مراتب به همه مراکز دارویی، درمانی و بهداشتی تحت پوشش آن معاونت محترم اطلاع رسانی شود.

دکتر محمدرضا شانه ساز
معاون وزیر و رئیس سازمان غذا و دارو

تهران روبروی درب اصلی دانشگاه تهران، خیابان فخر رازی، نبش خیابان شهید وحید نظری، سازمان غذا و دارو

تلفن: ۹-۶۶۴۶۷۲۶۸ نمابر: ۶۶۴۶۹۱۲۲ کد پستی: ۱۳۱۴۷۱۵۳۱۱

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شماره ۵/۱۳۵/۱۳۸۵
تاریخ ۱۴۰۰/۰۵/۳۰
پوست دارد

جناب آقای دکتر شانه ساز
معاون محترم وزیر و رئیس سازمان غذا و دارو

سلام علیکم

با احترام، به پیوست تصویر نامه شماره ۸/۵۲ مورخ ۱۵ آگوست ۲۰۲۱ دفتر نمایندگی سازمان جهانی بهداشت در ج.ا.ایران در خصوص "هشدار آن سازمان در مورد داروی قلبی رمدسیویر، N^o 4/2021: CRM:0557734" جهت استحضار ایفاد می گردد.

لازم بذکراست، آن سازمان در نظر دارد، هشدار بین المللی و آگاهی در خصوص محصول دارویی قلبی رمدسیویر را که در منطقه آمریکایی سازمان جهانی بهداشت شناسایی و به آن سازمان گزارش شده است، را افزایش دهد. لذا خواهشمند است دستور فرمایید، نسبت به هماهنگی های لازم جهت اطلاع رسانی موضوع فوق به واحدهای های ذیربط اقدام مقتضی معمول نمایند.

شایان ذکر است، گزارش آن سازمان که حاوی اطلاعات دقیقی در مورد محصول دارویی قلبی مذکور می باشد، جهت مزید استحضار به پیوست ایفاد می گردد.

دکتر محسن اسدی لاری
مدیر کل همکاری های بین الملل

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Ref. WR/IRN/8/52
File: HSD/VM

2 September 2021

Medical Product Alert N° 4/2021: Falsified Remdesivir CRM:0557734

Dear Dr Asadi Lari,

I am writing to bring to your kind attention to visit the [WHO Medical Product Alert N° 4/2021](#) regarding the falsified remdesivir identified in the WHO region of the Americas.

The related WHO Global Medical Product Alert is enclosed for your information and further dissemination to the respected departments/entities such as National Regulatory Authorities, procurers and any other relevant colleagues and organizations in the I. R. of Iran. WHO calls for increased scrutiny for these products.

Thank you,

Yours sincerely,

Dr Syed Jaffar Hussain
WHO Representative
I.R. Iran

Dr Mohsen Asadi Lari
Director General for International Affairs
MOHME, I.R. Iran

CC: Dr Hamidreza Inanloo
Director General, International Relations Department
Food and Drug Administration

Encls. As stated above

Ref. RPQ/REG/ISF/Alert N°4 2021

August 2021

Medical Product Alert N° 4/2021

Falsified Remdesivir identified in WHO region of the Americas

Alert Summary

This WHO Medical Product Alert refers to two batches of falsified remdesivir injection 100mg/20ml (5mg/ml) identified in the WHO Region of the Americas and reported to WHO in July 2021. These products claim to be manufactured by GILEAD. However, GILEAD has confirmed that the remdesivir products listed in this alert are falsified and were not manufactured by them. These falsified products have been reported at patient level (including at a hospital) in Mexico and are illicitly supplied on the internet.

Remdesivir is a broad-spectrum antiviral medication that was approved or authorized for emergency use to treat COVID-19 in several countries. In November 2020, WHO updated a conditional recommendation against remdesivir in hospitalized patients with COVID-19. This recommendation is part of the [WHO Therapeutics and COVID-19: living guideline](#) and states “A conditional recommendation is issued when the evidence around the benefits and risks of an intervention are less certain. In this case, there is a conditional recommendation against the use of remdesivir. This means that there isn’t enough evidence to support its use.”

The products identified in this alert are confirmed as falsified on the basis that they deliberately / fraudulently misrepresent their identity, composition, or source. The composition of the vials is currently unknown and laboratory analyses are to be conducted.

- Batch EN2005A2-B: the batch number and the expiry date (06/2023) do not correspond to any remdesivir manufactured by GILEAD.
- Batch EN2009D7-Q: the batch number does not correspond to any remdesivir manufactured by GILEAD.

Table 1: Products subject of WHO Medical Product Alert N°4/2021

ProductName	remdesivir injection100mg/20ml (5mg/ml)	
Stated manufacturer	GILEAD	
Stated active ingredient	remdesivir	
Batch / Lot	EN2005A2-B	EN2009D7-Q
Exp date	06/2023	Non stated
Packaging language	English	Non stated
Identified in	Mexico	Mexico

For photographs of the above products, please refer to Table 2 on page 2 of this Alert.

Advice to regulatory authorities and the public

WHO requests increased vigilance within the supply chains of countries and regions likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies, and any other suppliers of medical products.

All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

If you are in possession of the above falsified products, please do not use them.

If you have used these products, or you suffered an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities / National Pharmacovigilance Centre.

National regulatory / health authorities are advised to immediately notify WHO if these falsified products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int

Table 2: Photographs of products subject of WHO Medical Product Alert N°4/2021**WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products**

For more information, please visit our [website](#)

Email: rapidalert@who.int

Ref. RPQ/REG/ISF/Alert N°4 2021

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