دانشگاه علوم پزشکی و خدمات
بهداشتی – درمانی استان قزوین
معاونت غذا و دارو

تاریخ : ۱۴۰۰/۰۶/۰۹
شماره: ۵۳/۳۳۸۳۱۶/
۲۸
پیوست: دارد
۱۱:۵۳

معاونت محترم بهداشتی دانشگاه علوم پزشکی قزوین
معاونت محترم درمان دانشگاه علوم پزشکی قزوین
ریاست محترم سازمان نظام پزشکی استان قزوین
ریاست محترم انجمن داروسازان استان قزوین
مدیریت محترم شبکه بهداشت و درمان شهرستان آوج/آبیک/ بوئین زهرا/ البرز/تاکستان
مدیر عامل محترم مرکز آموزشی درمانی مستقل ولایت / بوعلی سینا
ریاست محترم مرکز آموزشی درمانی شهید رجایی/قدس /کوثر /۲۲ بهمن
ریاست محترم بیمارستان شفاء تاکستان/ امیرالمونین بویین زهرا/تامین اجتماعی رازی/تامین اجتماعی تاکستان/ پاستور/ دهخدا/مهرگان/ولیعصر آبیک / ارتش
سرپرست محترم بیمارستان شهدای آبیک / رحیمیان
موسس و مسئول فنی محترم داروخانه .....

با سلام و احترام

با توجه به نامه شماره ۶۵۵/۲۹۵۲۵ مورخ ۱۴۰۰/۰۶/۰۱ معاون محترم وزیر و رئیس سازمان غذا و دارو ، در خصوص داروی تقلبی **رمدسویر شرکت گیلیاد** به آگاهی می رساند، گزارشی مبنی بر هشدار در خصوص داروی تقلبی مذکور که در منطقه آمریکایی سازمان بهداشت جهانی شناسایی شده دریافت گردیده، لذا مشخصات آن **به پیوست** جهت اقدام و بررسی به حضور ایفاد می گردد.

با عنایت به احتمال وجود داروهای تقلبی در بازار سیاه دارویی کشور، لذا تاکید مجدد بر لزوم اصالت همه فرآورده های سلامت محور در سامانه ردیابی و رهگیری اصالت (TTAC)، به کلیه مراکز دارویی، درمانی و بهداشتی می گردد.

دکتر پیمان قجربیگی
معاون غذا و دارو
ازطرف دکتر امید کارآگاه

آدرس: بلوار آزادگان (خیابان آباد) - نبش مفتح - ساختمان شماره ۲ ستاد دانشگاه معاونت غذا و دارو کدپستی ۳۴۱۴۸۵۳۱۳۵ تلفن: ۳۳۶۸۶۴۰۰ نمابر: ۳۳۶۷۲۷۸۳
Website:http://vcdf.qums.ac.ir E - Mali: drugandfood@qums.ac.ir

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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.

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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.

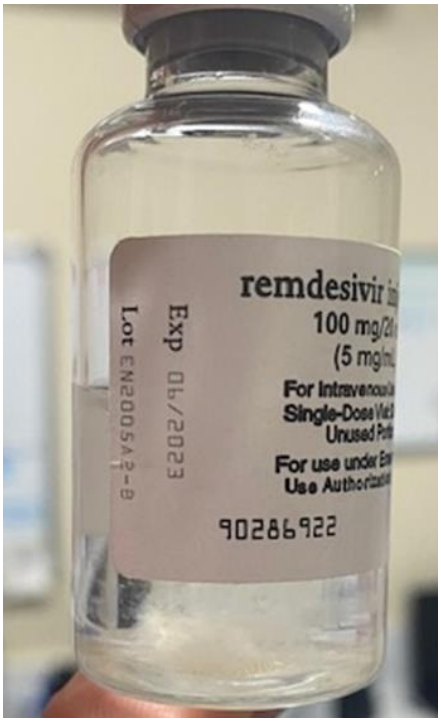
All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

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

Falsified remdesivir injection100mg/20ml (5mg/ml) identified in Mexico **Batch EN2005A2-B**	
	

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For more information, please visit our website

Email: rapidalert@who.int