

Date: 26 January 2023

***** URGENT – DRUG RECALL *******Product: Celestone Soluspan Injectable (DIN 00028096) Market RECALL**

Product Name	Affected Lot Numbers
CELESTONE SOLUSPAN 6MG/ML 1ML VIAL	Lot: U032954 (exp: 20.03.2023) Lot: W007348 (exp: 06.06.2023) Lot: U020391 (exp: 06-11-2022)
CELESTONE SOLUSPAN 6MG/ML 5ML VIAL	Lot: W002690 (exp: 14.04.2023) Lot: W016687 (exp: 29.09.2023) Lot: U022001 (exp: 08.12.2022)

Dear Customer,

The drug product listed above which you have received or sold is being recalled from the Canadian market to Healthcare Establishments / Retailers level.

Organon Canada is initiating this recall due to the potential presence of stainless-steel particles in the product, arising from the manufacturing process in certain batches of **Celestone Soluspan Injectable (DIN 00028096)**.

In the unlikely event of patients being exposed to the minute levels of the sterile and inert particulates found in this investigation, there is an extremely low likelihood of harm to patients when these products are used as indicated. However, if a patient is administered an intra-articular injection from a potentially impacted product that might contain any of these types of tiny particulates, then there could be a worsening of the patient's joint inflammation.

All batches manufactured since investigation into the particulates have been thoroughly monitored for quality in accordance with Organon's practices and industry standards, and all batches released were compliant with quality standards, site procedures, product specifications, and in accordance with their marketing authorizations. In the unlikely event of exposure to particulates in the impacted products, the risk of patient harm associated with exposure to the material in scope is remote. There have been no reported adverse events attributable to particulate matter in the potentially impacted and distributed product batches.

16766 Trans-Canada Highway
Kirkland, Qc, Canada, H9H 4M7

Organon is proceeding with a market action of a **Type II** recall to Healthcare Establishments level in Canada. A type II recall is defined as a situation where the use of, or exposure to, a recalled product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote.

Due to this recall, you are required to:

- Immediately stop all sale or distribution of these lot number(s).
- Advise your consignees or customers/ Healthcare Establishments having received the recalled lots and have them follow the instructions to stop the usage of the product immediately. The product should be returned to you for further consolidation and then returned to the address described below.
- If you purchased the product from a wholesaler, please contact them to arrange the return of the product to them.
- Return the product with the above lot number(s).
- Immediately conduct an inventory assessment. E-mail the attached Product Return Form to: services.canada@organon.com. For any questions, you can contact Organon Canada Order Management Center at **1-800-663-1326**.
- Return all stock for the above listed lot(s) to:

**RETRAIT DE MARCHÉ/RECALL - ORGANON,
1375 Newton, Boucherville, QC J4B 5H2**

Return instructions are provided in the attached Product Return Form.

Please return the completed form by **January 31st, 2023** and the return the product by **February 3rd 2023**. We have notified Health Canada about this recall.

Thank you for your cooperation and assistance. Please do not hesitate to contact us if you need further information.

Sincerely,

Michael Casia
President & Managing Director

***** PRODUCT RETURN FORM *******RE: Celestone Soluspan Injectable Market (DIN 00028096) RECALL**

To the attention of wholesalers: Please ensure that this information is transmitted to the Healthcare Establishments that have received the product. Follow instructions below.

Product Name	Affected Lot Numbers
CELESTONE SOLUSPAN 6MG/ML 1ML VIAL	Lot: U032954 (exp: 20.03.2023) Lot: W007348 (exp: 06.06.2023) Lot: U020391 (exp: 06-11-2022)
CELESTONE SOLUSPAN 6MG/ML 5ML VIAL	Lot: W002690 (exp: 14.04.2023) Lot: W016687 (exp: 29.09.2023) Lot: U022001 (exp: 08.12.2022)

What you should do:**If you are a wholesaler, you are required to:**

1. Immediately stop all sale or distribution of **Celestone Soluspan Injectable (DIN 00028096)** of the lot number(s) mentioned above.
2. Advise your consignees including Healthcare Establishments of this recall. Send your Drug Recall letter along with Organon communications, to all your direct customers who might have received the impacted lots of **Celestone Soluspan Injectable (DIN 00028096)**. All your customers must respond to your notification. If not, please follow up with them until they respond.
3. Consignees must return the recall product to you.
4. Immediately conduct an inventory assessment. Complete and return the attached **Product Return Form** by **January 31st, 2023**. Please indicate the amount of product per lot you currently have in stock. If you do not have stock in your possession, mark "0" for each lot. We will follow up with you if we do not receive a reply by: **January 31st, 2023**. Please send the form by e-mail to:

services.canada@organon.com

16766 Trans-Canada Highway
Kirkland, Qc, Canada, H9H 4M7

5. Return the recalled product by **February 3rd, 2023** to:

**RETRAIT DE MARCHÉ/RECALL - ORGANON /
1375 Newton, Boucherville, QC J4B 5H2**

6. Please use the service of ATS (transport company) **exclusively** using the account number **4006891**.

If you are a healthcare practitioner and purchased this product directly from Organon Canada Inc., you are required to:

1. Immediately stop dispensing and/or administering **Celestone Soluspan Injectable (DIN 00028096)** of the impacted lots mentioned above.
2. Immediately conduct an inventory assessment. Complete and return the attached **Product Return Form** by **January 31st, 2023**, and send by e-mail to: services.canada@organon.com
3. Return all recalled products by **February 3rd, 2023** to:

**RETRAIT DE MARCHÉ/RECALL - ORGANON /
1375 Newton, Boucherville, QC J4B 5H2**

Should you have any questions regarding how to proceed with the return or with **Product Return Form** attached, please contact the Organon Canada Order Management Center at **1-800-663-1326** or by email at services.canada@organon.com

We recognize and regret any inconvenience caused by this situation and appreciate your understanding and collaboration.

Sincerely,

Organon Quality Assurance Department

16766 Trans-Canada Highway
Kirkland, Qc, Canada, H9H 4M7

***** PRODUCT RETURN FORM *****

Product Details

Product Number	Product Name	Lot Number	Quantity in Stock
00028096	CELESTONE SOLUSPAN 6MG/ML 1ML VIAL	Lot: U032954 (exp: 20.03.2023)	
00028096	CELESTONE SOLUSPAN 6MG/ML 1ML VIAL	Lot: W007348 (exp: 06.06.2023)	
00028096	CELESTONE SOLUSPAN 6MG/ML 1ML VIAL	Lot: U020391 (exp: 06-11-2022)	
00028096	CELESTONE SOLUSPAN 6MG/ML 5ML VIAL	Lot: W002690 (exp: 14.04.2023)	
00028096	CELESTONE SOLUSPAN 6MG/ML 5ML VIAL	Lot: W016687 (exp: 29.09.2023)	
00028096	CELESTONE SOLUSPAN 6MG/ML 5ML VIAL	Lot: U022001 (exp: 08.12.2022)	

Note: Please fill the form and return to sender. If no stock remaining, please indicate "0" and return the form.

Wholesaler/ Healthcare practitioner Information

Name:	
Address:	
Account Number:	

Authorized Signature

Signature of authorized person:	
Date (yyyy-mm-dd):	
Printed Name:	