

<Date>

Avtozma 20 mg/mL concentrate for solution for infusion: incorrect strength stated on peel-off vial label for specific batches

Dear Healthcare professional,

Celltrion Healthcare Hungary Kft. in agreement with the European Medicines Agency and the <National competent authority> would like to inform you of the following:

Summary

- **An incorrect strength declaration has been identified on the peel-off section of the vial label for specific batches of Avtozma 400 mg. This affects batches with labels in Danish / Finnish/ Swedish.**
- **The peel-off label incorrectly states “400 mg/10 mL” instead of “400 mg/20 mL”.**
- **The issue is limited to the printed peel-off label only; the actual product strength, composition and quality remain compliant with approved specifications.**
- **To date, only two batches have been identified as affected by this issue: 5E4065 and 2101914B.**

Background on the safety concern

Avtozma 400 mg (tocilizumab) is indicated as described in the section 4.1 of the approved Summary of Product Characteristics (SmPC). For full details, please refer to the product information available at the following link:

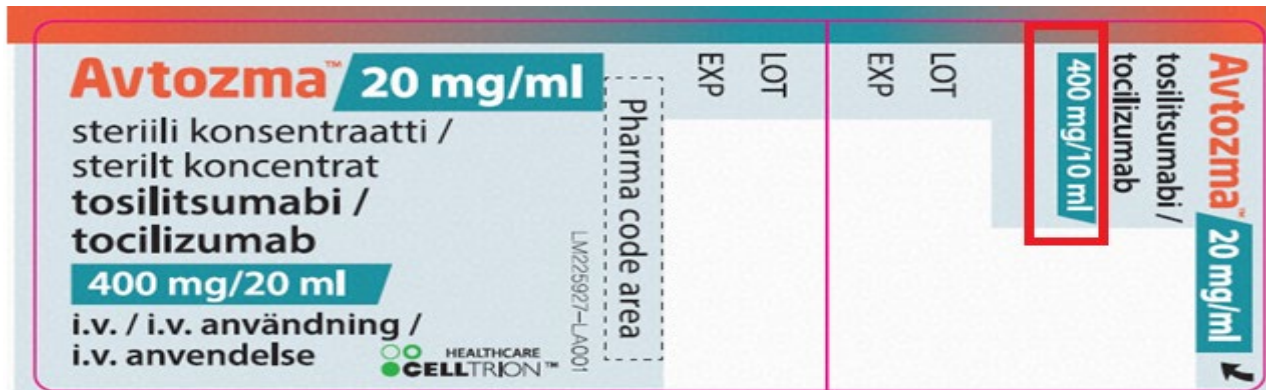
https://www.ema.europa.eu/en/documents/product-information/avtozma-epar-product-information_en.pdf

Product complaints were received from Finland and Estonia regarding an incorrect strength declaration on the peel-off section of the vial label (Lot No. 5E4065) of Avtozma 400 mg. The peel-off label incorrectly states “400 mg/10 mL” instead of the correct “400 mg/20 mL”.

The issue has been confirmed to affect additional batches of Avtozma 400 mg (Lot No. 2101914B), which have been distributed in Finland and Estonia.

The incorrect strength declaration is limited to the peel-off part of label. The main label attached to the vial, outer carton, and package leaflet all show the correct strength information consistent with the EMA-approved product information. Please refer to the image below for details.

<Vial Label>



<Main Label with correct strength >

<Peel-off Part with incorrect strength>

If dosing calculations are based solely on the peel-off section of the vial label, this may potentially lead to administration of a lower dose than intended. Therefore, it is recommended to refer to the dosing information specified on the outer carton and in section 6 of the package Leaflet, as shown in the below figures with correct strength.

<Carton with correct strength>

<p>1 injektiopullo à 20 ml</p> <p>Avtozma™ 20 mg/ml</p> <p>infuusiokonsentraatti, liuosta varten tosilitsumabi 400 mg/20 ml</p> <p>Laskimonsisäiseen infuusion laimentamisen jälkeen</p> <p>Yksi injektiopullo sisältää 400 mg tosilitsumabia.</p> <p>Apuaineet: L-histidiini, L-histidiinimonohydrokloridimonohydraatti, L-treoniini, L-metioniini, polysorbaatti 80 ja injektioesteisiin käytettävä vesi.</p> <p>Katso lisätiedot pakkausselosteesta. Lue pakkausseloste ennen käyttöä</p> <p>Säilytä jääkaapissa</p> <p>Ei saa jäätyä</p> <p>Pidä injektiopullo ulkopakkauksessa. Herkkä valolle</p> <p>Ei lasten ulottuville eikä näkyville</p> <p>Laimennettu valmiste tulisi käyttää välittömästi</p>	<p>1 injektionsflaska med 20 ml</p> <p>Avtozma™ 20 mg/ml</p> <p>koncentrat till infusionsvätska, lösning tocilizumab 400 mg/20 ml</p> <p>För intravenös infusion efter spädning</p> <p>1 injektionsflaska innehåller 400 mg tocilizumab.</p> <p>Hjälpämnen: L-histidin, L-histidinmonohydrokloridmonohydrat, L-treonin, L-metionin, polysorbat 80 och vatten för injektionsvätskor.</p> <p>Se bipacksedeln för ytterligare information. Läs bipacksedeln före användning</p> <p>Förvaras i kylskåp</p> <p>Får ej frysas</p> <p>Förvara injektionsflaskan i ytterkartongen. Ljuskänsligt</p> <p>Förvaras utom syn- och räckhåll för barn</p> <p>Den utspädda produkten ska användas omedelbart</p>	<p>1 hætteglas à 20 ml</p> <p>Avtozma™ 20 mg/ml</p> <p>koncentrat til infusionsvæske, opløsning tocilizumab 400 mg/20 ml</p> <p>Til intravenøs infusion efter fortynding</p> <p>1 hætteglas indeholder 400 mg tocilizumab.</p> <p>Hjælpstoffer: L-histidin, L-histidin-hydroklorid-monohydrat, L-threonin, L-methionin, polysorbat 80 og vand til injektionsvæsker.</p> <p>Se indlægssedlen for yderligere information. Læs indlægssedlen inden brug</p> <p>Opbevares i køleskab</p> <p>Må ikke nedfryses</p> <p>Opbevar hætteglasset i den ydre karton for at beskytte mod lys</p> <p>Opbevares utilgængeligt for børn</p> <p>Det fortyndede præparat skal bruges omgående</p>

<Section 6 of Leaflet with correct strength >

6. Pakkauksen sisältö ja muuta tietoa

Mitä Avtozma sisältää

- Vaikuttava aine on tosilitsumabi.
Yksi 4 ml:n injektiopullo sisältää 80 mg tosilitsumabia (20 mg/ml).
Yksi 10 ml:n injektiopullo sisältää 200 mg tosilitsumabia (20 mg/ml).
Yksi 20 ml:n injektiopullo sisältää 400 mg tosilitsumabia (20 mg/ml).
- Muut aineet ovat L-histidiini, L-histidiinimonohydrokloridimonohydraatti, L-treoniini, L-metioniini, polysorbaatti 80 ja injektionesteisiin käytettävä vesi.

Call for reporting

Healthcare professionals are reminded to report any suspected adverse reactions in accordance with the national spontaneous reporting system and include batch/Lot numbers if available. < include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

In particular, for the affected batches (5E4065, 2101914B), where an incorrect strength is stated on the vial peel-off label, healthcare professionals are requested to report any adverse events that may be related to potential dosing or administration errors.

Company contact point

< Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>.

Further information can be obtained by contacting:

Celltrion Healthcare Finland Oy

Tel: +358 29 170 7755

Address: Energiakatu 4, 00180 Helsinki, Finland

Email: contact_fi@celltrionhc.com

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Avtozma (tocilizumab)
Marketing authorisation holder(s)	Celltrion Healthcare Hungary Kft.
Safety concern and purpose of the communication	<p>This DHPC is intended to inform healthcare professionals about an incorrect strength declaration identified on the peel-off section of the vial label for specific batches of lot no. 5E4065 and lot no. 2101914B</p> <p>The peel-off label incorrectly states "400 mg/10 mL" instead of the approved "400 mg/20 mL". This discrepancy is limited to the printed labeling, while the actual product strength, composition, and quality remain compliant with the approved specifications.</p> <p>The purpose of this communication is to ensure awareness of the issue and to provide guidance for appropriate product identification and use.</p>
DHPC recipients	<p>Hospital pharmacists.</p> <p>The target group should be further defined at national level, in agreement with the respective national competent authority.</p>
Member States where the DHPC will be distributed	Finland, Estonia
Timetable <i>Delete steps which are not applicable</i>	
	Date
DHPC and communication plan (in English) agreed by CHMP/CMDh	31 March 2026
Submission of translated DHPCs to the national competent authorities for review	1 April 2026
Agreement of translations by national competent authorities	2 April 2026*
Dissemination of DHPC	3 April 2026*

*. Anticipated, based on immediate turn around by national CAs.