

Dear Healthcare Professional Letter

Flemoxin Solutab® (Amoxicillin trihydrate) dispersible tablets

Flemoclave Solutab® (Amoxicillin+clavulanic acid) dispersible tablets

Wilprafen Solutab® (Josamycin propionate) dispersible tablets

Suprax Solutab® (Cefixime) dispersible tablets

Unidox Solutab® (Doxycycline) dispersible tablets

Modification for Method of Administration

Dear Healthcare Professional,

In coordination with «Scientific Center of Drug and Medical Technology Expertise after Academic E. Gabrielyan», Astellas Pharma Europe B.V. (the Netherlands) would like to inform you of the following new data regarding the safety of their medicinal products, as well as the change in the recommended method of administration:

Summary

- There was a single case report of a serious adverse event (fatal mechanical asphyxia in a three-year-old child) after ingestion of a whole tablet of Flemoxin Solutab®, without prior dissolution in water.
- To minimize risks, we urgently recommend to all healthcare professionals, who may prescribe Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab® to inform each patient about the need to dissolve the tablet in water (**at least 50 mL**) and stir the mixture thoroughly prior to ingestion.
- ‘Posology and Method of Administration’ section of Patient Information Leaflet (PIL) and/or Summary of Product Characteristics (SmPC) for Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab® will be updated to include the following recommendation:
 - SmPC: Add the tablet to a glass of water and mix thoroughly until uniform mixture is formed (**at least 50 mL**). Swallow the mixture immediately.
 - PIL: Always use this medicinal product precisely as directed by your physician or pharmacist. Consult your physician or pharmacist if you are not sure how to use the medicinal product.
- Add the tablet to a glass of water and mix thoroughly until uniform mixture is formed (**at least 50 mL**). Swallow the mixture immediately.
- Since Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab® are available as dispersible tablets; do not try to swallow the whole tablet. These medicinal products should only be taken after dissolving in water.

Safety issue description

Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab® are intended for treatment of infectious and inflammatory diseases caused by susceptible organisms in adults and children. Flemoxin Solutab® is available as dispersible tablets containing 125, 250, 500 and 1000 mg of the active ingredient; Flemoclave Solutab® - as dispersible tablets

containing 125 mg/31.25 mg, 250 mg/62.5 mg, 500 mg/125 mg and 875 mg/125 mg of active ingredients; Wilprafen Solutab® - as dispersible tablets containing 1000 mg of the active ingredient; Suprax Solutab® - as dispersible tablets containing 400 mg the active ingredient, and Unidox Solutab – as dispersible tablets containing 100 mg of the active ingredient.

A single spontaneous case of death due to mechanical asphyxia was reported on the territory of the Russian Federation. A three-year-old child ingested whole tablet of Flemoxin Solutab® without prior dissolution in water. It is reported that the tablet partially dissolved in the child's oral cavity and turned into a pasty substance that filled the respiratory tract, thereby causing suffocation and death.

Although the above-mentioned single case is related to Flemoxin Solutab® only, Astellas would like to follow a more conservative approach to the method of administration and update the Patient Information Leaflet (PIL) and/or Summary of Product Characteristics (SmPC) not only for Flemoxin Solutab®, but also for other medicinal products available as dispersible tablets.

To minimize the risk for all patients, but primarily for those at higher risk of suffocation (children, elderly subjects and patients with difficulty swallowing), the PIL and/or SmPC will indicate that Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab® in the form of dispersible tablets should always be dissolved in water (**at least 50 mL**) before ingestion. It is not recommended to swallow the whole tablet.

It is imperative to inform all stakeholders about the need to use Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab® according to the methodology described above.

Contact details for adverse reactions reporting

We ask healthcare professionals to be aware of the need to continue reporting about suspected adverse reactions associated with the use of medicinal products, according to the applicable requirements for spontaneous reporting.

All suspected adverse reactions associated with the use of Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab® are to be reported in accordance with the current pharmacovigilance legislation of the Republic of Armenia.

Suspected adverse reaction reports for these medicinal products can also be sent to the Representative Office of Astellas Pharma Europe B.V. (the Netherlands) via e-mail or fax using the following contacts.

Company's contact details

Please contact the Representative Office of Astellas Pharma Europe B.V. (the Netherlands) in Ukraine for any questions regarding the use of Flemoxin Solutab®, Flemoclave Solutab®, Wilprafen Solutab®, Suprax Solutab®, and Unidox Solutab®:

Tel.: +38 044 490 68 25, факс+38 044 490 68 26.

Email: pharmacovigilance.ua@astellas.com.

Health care professionals should report any adverse reaction to Pharmacovigilance department «SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELIAN» via following contacts:

Address: 49/4 Komitas av., 0051 Yerevan, Armenia.
Phone: +37410231682 (ext: 123)
Hot line for ADR reporting: + 37410237265
Email: vigilance@pharm.am

Kindest regards,

Pharmacovigilance Specialist

A handwritten signature in black ink, appearing to read 'O. Virsta', with a horizontal line extending to the right.

Olga Virsta