



30<sup>th</sup> April 2019

Dear Healthcare Professional,

Sanofi India Ltd would like to remind you following important information regarding indication, treatment regimen, contra-indications and warnings.

### **Summary**

- Preclinical findings indicate a risk of genotoxicity with systemic thiocolchicoside, i.e. oral and intramuscular formulations.
- Thiocolchicoside use is contraindicated and must not be prescribed to pregnant or lactating women and to women of childbearing potential if they are not using effective contraception.
- Women of childbearing potential should be carefully advised of the need for effective contraception while taking the medicine, so as to avoid pregnancy and any subsequent risk to the fetus.
- Healthcare professionals are reminded that the use of systemic thiocolchicoside is restricted to short-term adjuvant treatment of painful muscle contractures of spinal pathology from 16 years onwards. The maximum recommended daily doses and durations of treatment (16 mg daily for up to 7 days by mouth, 8 mg daily for up to 5 days intramuscularly) must be respected.

### **Background on the safety concern**

In non-clinical studies, one of the thiocolchicoside metabolites was shown to induce aneuploidy at concentrations close to those seen in humans who take the maximum recommended oral dose of 8 mg twice daily. Aneuploidy is reported as a risk factor for teratogenicity, embryo-foetotoxicity /spontaneous abortion and impaired male fertility and a potential risk factor for cancer. The risk increases with long-term exposure.

A safety review of this product in Europe, completed in January 2014, introduced new restrictions (including changes to the indication and a maximum recommended daily dose and duration of treatment), warnings and contraindications. These changes were communicated to healthcare professionals as DHPC dated 21st Oct 2014 and included in the product information in Sept 2015.

Preliminary evidence from two ongoing drug utilization studies conducted in some European countries has shown a limited level of adherence in clinical practice to the authorised conditions of use. Consequently, Sanofi India Ltd has decided to disseminate a new DHPC to remind Healthcare professionals about conditions of use of Thiocolchicoside.

### **Further information**

- To further support Healthcare Professionals in prescribing Thiocolchicoside, educational tools (Healthcare Professionals Guide and Patient Card) are being re-distributed with this DHPC. Healthcare professionals are requested to distribute the Patient Card to the concerned patients.
- Further information is available on Sanofi India Ltd website: [www.Sanofi.in](http://www.Sanofi.in)

### ***Adverse Event Reporting:***

Any adverse events experienced by your patients should be reported to Sanofi India Ltd. Please find below the contact details for reporting adverse events:

Email: [PV.india@sanofi.com](mailto:PV.india@sanofi.com)

Toll free Telephone number: 1800 22 2295

### ***Company contact point***

Should you have any question or require additional information, please contact Medical Information at [Medinfo.india@sanofi.com](mailto:Medinfo.india@sanofi.com).

Yours sincerely,

A handwritten signature in blue ink that reads "Manish".

**Dr. Manish VERMA**

Head of Medical Affairs, CHC South Asia Zone