



## Direct Healthcare Professional Communication

July 2022

### Colchicine Serious Poisoning– Reminder of the Rules of Proper Use

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

#### *Summary*

- Colchicine is a drug with a narrow therapeutic margin which exposes you to the risk of serious overdoses, the first signs of which are manifested by digestive disorders (diarrhoea, nausea, vomiting). Depending on the dose ingested, multi-visceral failure, sometimes fatal, can occur (respiratory, cardiovascular, hematological, neurological damage, etc.)
- These risks which can be reduced by respecting the indications of the Marketing Authorization the dosage, the contraindications and the drug interactions.

#### *Background information on the security concerns*

Colchicine is indicated in the management of acute attacks of gout, in prophylaxis of acute attacks of gout in patients with gout chronic, in other microcrystalline attacks (chondrocalcinosis and hydroxyapatite rheumatism), in periodic disease, Behçet's disease and idiopathic pericarditis.

#### Instructions for prescribers and pharmacists:

- Comply with the dosage regimen recommended in the Marketing Authorization for each medicinal product;
- Reduce the dosage in the elderly (especially over 75 years old), hepatic insufficiency, renal insufficiency or subjects at risk of renal insufficiency (risk of dehydration, concomitant medications) and ensure special monitoring of these patients;
- Respect the contraindications:
  - ⇒ in subjects with severe renal impairment (creatinine clearance < 30 ml/min)
  - ⇒ in severe hepatic impairment
- Check the risks of drug interactions
- Do not combine colchicine with pristinamycin and macrolides (except spiramycin) (combinations contraindicated);
- Inform patients of the importance of:





⇒ adhering to the dosage;

⇒ consult quickly in the event of the onset of diarrhoea, nausea, vomiting. Dosage reduction or discontinuation should be considered.

## References

### ANSM

<https://ansm.sante.fr/uploads/2022/06/29/20220629-dhpc-colchicine.pdf>

## Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 - 23610497

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Online reporting: <https://primaryreporting.who-umc.org/EG>  
QR Code:

Hotline: 15301

