Direct Healthcare Professional Communication

Oct 2023

Lamotrigine: reminder of proper use in order to limit the risk of serious skin rash, particularly at the start of treatment

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following **reminder of proper use in order to limit the risk of serious skin rash**:

Summary:

The main recommendations to reduce this risk:
As monotherapy,
follow the necessary titration during the first 4 weeks of treatment
In case of combination with valproic acid or its derivatives (valpromide, divalproate), the risk of rash is increased taking into account a pharmacokinetic interaction (reduction of lamotrigine metabolism and increase of the half-life of lamotrigine by approximately 2-fold). In this case, a very conservative titration is recommended:

- In adults and adolescents from 13 years of age, titration should be done over 6 or even 10 weeks:
  - the initial dosage of lamotrigine should be halved (12.5 mg, or 1 tablet of 25 mg every other day for 2 weeks), and then increased to 25 mg / day for 2 weeks,
  - Then, depending on clinical response, the dosage should be increased in increments of 25 mg to 50 mg every 1 to 2 weeks until maintenance dose is reached.
- In children and adolescents aged 2 to 12 years:
  - the initial dosage of lamotrigine should be halved (0.15 mg / kg / day for 2 weeks) and then increased to 0.3 mg / kg / day for 2 weeks,
  - Then, depending on clinical response, the dosage will be increased in increments of 0.3 mg/kg/day every 1 to 2 weeks until maintenance dose is reached.

All patients (adults and children) who develop rash on lamotrigine should be promptly evaluated and lamotrigine should be discontinued immediately if it is suspected to be responsible.

In patients who have discontinued treatment due to rash, it is recommended:

- to carry out a specialized dermatological and allergological evaluation
- not to reintroduce lamotrigine if the link with the product has been confirmed

Advise your patients to seek immediate medical attention or emergency department if the following symptoms develop: rash or redness with blisters and peeling, fever, flu-like symptoms, swelling of the face, appearance of lymph nodes, ulcers of the mouth, throat, nose or genitals, irritation of the mouth or eyes, unexpected bruising or bleeding, sore throat.

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Further information on the safety concern and the recommendations

Lamotrigine-based medicinal products are indicated:

In adults and adolescents 13 years of age and older:

- Either as monotherapy or in combination in the treatment of partial and generalized epilepsy, including tonic-clonic seizures;
- In combination with another treatment (but lamotrigine may be the first-line anti-epileptic drug) in the treatment of seizures associated with Lennox-Gastaut syndrome;

In children and adolescents aged 2 to 12 years:

- In combination in the treatment of partial and generalized epilepsy, including tonic-clonic seizures and seizures associated with Lennox-Gastaut syndrome;
- As monotherapy in the treatment of typical absences;

In adults 18 years of age and older:

- In prevention of depressive episodes in patients with bipolar I disorder who have a predominance of depressive episodes.

These drugs are not indicated for the acute treatment of manic or depressive episodes.

Reference:

ANSM: https://ansm.sante.fr/informations-de-securite/lamotrigine-lamictal-et-generiques-rappel-du-bon-usage-afin-de-limiter-le-risque-deruption-cutanee-grave-en-particulier-au-debut-du-traitement

Call for reporting

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

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

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

Hotline: 15301

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