



Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Unternehmen/Frau/Herr
Organisationseinheit (optional)
(z. H.) Vorname Nachname
Straße
PLZ Ort

Datum: 3. Dezember 2020
Kontakt: Aktuelles Datum eintragen
Tel: Mag. pharm. Dr. Ulrike Rehberger
E-Mail: +43 50555 36258
pv-implementation@basg.gv.at

Unser Zeichen: PHV-13721098-A-201203

Ihr Zeichen: .

PHV-issue: Bupropion

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Naltrexon/Bupropion-PSUSAs (EMA/H/C/PSUSA/00010366/201909) und der folgenden Variation (EMA/H/C/003687/II/0044/G) kam das CMDh zu dem Schluss, dass die Ergebnisse aus dem PSUR Assessment für alle Arzneimittel, die Bupropion enthalten, relevant sind.

Bei der Umsetzung in die Produktinformation der betroffenen Arzneispezialitäten beachten Sie auch den CMDh Press release (Meeting vom 13. bis 14. Oktober 2020): <https://www.hma.eu/249.html>



Auszug aus dem Report des CMDH meetings vom 13. bis 14. Oktober 2020

Bupropion-containing medicinal products

Following the latest PSUSA procedure on naltrexone/bupropion - MYSIMBA (EMA/H/C/PSUSA/00010366/201909) and the assessment of the subsequent variation procedure (EMA/H/C/003687/II/0044/G), the PRAC considered the causal association between bupropion and the occurrence of cutaneous lupus erythematosus as well as aggravation of systemic lupus erythematosus as being probable/likely based on available evidence from literature reports. Since the adverse drug reactions are attributed to the active substance bupropion, all MAHs of medicinal products containing bupropion are requested to update their product information accordingly.

Summary of Product Characteristics

Section 4.8 Undesirable effects

Skin and subcutaneous tissue disorders: **Systemic lupus erythematosus syndrome aggravated, Cutaneous lupus erythematosus (frequency not known)**

Package leaflet

4. Possible side effects

Serious side effects

Tell your doctor straight away, if you notice any of the following serious side effects:

(...)

Lupus skin rash or worsening of lupus symptoms

Not known - frequency cannot be estimated from the available data in people taking <PRODUCT NAME>

Lupus is an immune system disorder affecting the skin and other organs. If you experience lupus flares, skin rash or lesions (particularly on sun-exposed areas) while taking <PRODUCT NAME>, contact your doctor straight away, as it might be necessary to stop the treatment.