

**CATRE:****IN ATENTIA:** Dl./Dna.**REF:** Accesul pacientilor din Romania la medicamentul Trileptal (DCI: Oxcarbazepinum)**DATA:****TO:****TO THE ATTENTION OF:** Mr./ Mrs.**RE:** Access of Romanian patients to the medicine Trileptal (INN: Oxcarbazepinum)**DATE:****Stimata Doamna/Stimati Domni,****Dear Madame/Dear Sirs**

Avand in vedere procedura efectuata de catre Novartis Pharma Romania SRL, in calitate de reprezentant local al DAPP pentru medicamentul Trileptal 300 mg si 600 mg (DCI: Oxcarbazepinum), in vederea incetarii punerii pe piata, din motive comerciale, a medicamentului Trileptal (DCI: Oxcarbazepinum), inclusiv prin notificarea acestei decizii catre Agentia Nationala a Medicamentului si Dispozitivelor Medicale (ANMDM) prin notificarea cu nr. 31502/07.09.2016 si in completarea informarii cu nr. de inregistrare 1921/14.11.2017 transmise in atentia dumneavoastra in legatura cu acest subiect,

Va informam prin prezenta ca, in scopul asigurarii accesului pacientilor la terapia cu medicamentul Trileptal (DCI: Oxcarbazepinum), Novartis Pharma Romania SRL extinde comercializarea acestui medicament pe piata din Romania pana la finalul anului 2018.

Astfel, Novartis Pharma Romania SRL doreste sa consolideze angajamentul fata de asigurarea unui acces terapeutic cat mai bun al pacientilor la medicamentele pe care le produce, precum si sa vina in sprijinul medicilor ai caror pacienti nu au fost inca transferati pe terapii alternative, pentru ca acestia sa isi poata continua tratamentul, scop in care Novartis Pharma Romania SRL a luat si va lua toate masurile necesare pentru a asigura, in cursul anului 2018, cantitati suplimentare din medicamentul Trileptal (DCI: Oxcarbazepinum) pentru aprovizionare pe piata din Romania, in contextul in care acest medicament este in prezent retras de pe piata ca urmare a notificarii facute catre ANMDM in acest sens.

Facem precizarea ca Novartis Pharma Romania SRL informeaza in mod constant ANMDM cu

Considering the procedure performed by Novartis Pharma Romania SRL, in capacity as local representative of MAH for the medicine Trileptal 300 mg and 600 mg (INN: Oxcarbazepinum), in view of the cessation to place on the market, for commercial reasons, of the medicine Trileptal (INN: Oxcarbazepinum), including by the notification of such decision to the National Agency for Medicine and Medical Devices (NAMMD) through the notification no. 31502/07.09.2016 and in completion of the letter with registration no. 1921/14.11.2017 sent to your attention in relation to this subject,

We hereby inform you that, in view of ensuring the patients' access to the therapy with the medicine Trileptal (INN: Oxcarbazepinum), Novartis Pharma Romania SRL expands the trading of this medicine on the Romanian market until the end of the year 2018.

Thus, Novartis Pharma Romania SRL wishes to consolidate its commitment towards ensuring to patients the best access to the medicines it produces, as well as to support the health professionals whose patients have not been transferred yet on therapeutic alternatives, so the latter could continue their treatment, for which purpose Novartis Pharma Romania SRL has taken and will take all the necessary measures in view of ensuring, during the course of 2018, additional quantities of Trileptal (INN: Oxcarbazepinum) for supply on the Romanian market, in the context in which such medicine is currently withdrawn from the market following the notification to NAMMD in this respect.

We mention that Novartis Pharma Romania SRL informs NAMMD on a constant basis in relation

privire la cantitatile de medicamente pe care le pune pe piata prin partenerii de distributie.

Contam pe dumneavoastra pentru indeplinirea obligatiilor ce va revin in scopul asigurarii aprovizionarii cu Trileptal (DCI: Oxcarbazepinum) pentru pacienti.

Va multumim pentru colaborare.

Cu stimă,

Adriaan Kooy - Administrator



Novartis Pharma Services România S.R.L.



to the medicines it places on the market through the distribution partners.

We are counting on you for the fulfillment of your obligations in relation to ensuring the supply with the medicine Trileptal (INN: Oxcarbazepinum) for the patients.

Thank you for your cooperation.

Yours sincerely,

Adriaan Kooy - Administrator



Novartis Pharma Services România S.R.L.

