

Direct healthcare-professional communication (DHPC)

28 Sep 2016

Tiapride (Tiapridal ® and generics): changes in the therapeutic indications, in the maximum recommended daily dose

Information intended for psychiatrists, neurologists, and hospital pharmacists.

Dear Healthcare professional,

In agreement with the Saudi Food and Drug Authority (SFDA), the pharmaceutical companies marketing tiapride-containing medicines (Tiapridal ® and generics) wish to inform you that the Summaries of Product Characteristics (SPC) and Package leaflets of these products will be updated to help contribute to their proper use.

Accordingly, Sanofi-Aventis, would like to inform you of the following:

Summary

Further to the re-evaluation of the benefit/risk balance of Tiapride-containing medicines, changes have been made to the drug's indications in adults and children.

Proprietary medicinal products for oral use

In adults:

- **Short-term treatment (less than 4 weeks) of episodes of agitation and aggressiveness, particularly when there are associated psychotic symptoms,**
- **Severe chorea in Huntington disease.**

In adults and children over 3 years of age (oral solution) or 6 years of age (scored tablets):

- **Severe form of the tic disorder Tourette syndrome not adequately controlled by non-pharmacological treatment.**

Other information

The benefit/risk balance of these medicinal products remains positive. In addition to changes to the indications, other changes have been introduced in the following sections of the SPC:

- Adverse reactions (see section 4.8 of the SPC for Tiapride-containing medicines);
- Interactions with other medicinal products, to include a contraindication with hydroxyzine and Piperazine (see section 4.3 and 4.5 of the SPC for Tiapride-containing medicines).

Reporting of adverse reactions

The healthcare professionals must immediately report any adverse effects suspected to be caused by a medicinal product. For reporting kindly contact the National Pharmacovigilance and Drug Safety Center in the SFDA or SANOFI Saudi Arabia Pharmacovigilance Center directly as shows below:

- **Saudi Food and Drug Authority-Drug sector**

National Pharmacovigilance and Drug Safety Center

Call NPC at: +966-11-2038222

Ext: 2317 -2356-2340

Toll free phone: 8002490000

Fax: +966-11-2057662

Mail: npc.drug@sfda.gov.sa

Online: <http://ade.sfda.gov.sa/>

- **SANOFI Saudi Arabia Pharmacovigilance Center**

Phone: +966-12-669318

Ext: 1603-1147

Fax: +966-12-6636191

Mail: Ksa_pharmacovigilance@sanofi.com

Mobile: + 966-54-428-4797

Kind regards,

Mossab Shafy, Pharm.D, M.Sc., MBA
Qualified Person for Pharmacovigilance (QPPV)

