Year 2000

DCA News Update (DCA 118 - 24/10/2000)

Box Label on Sodium Valproate : Pancreatitis

The DCA has agreed that for all product-containing Sodium Valproate, the box warning to be included on the package insert under section Warning is as listed below:

> PANCREATITIS:
>
> CASES OF LIFE-THREATENING PANCREATITS HAVE BEEN REPORTED IN BOTH CHILDREN AND ADULTS RECEIVING VALPROATE. SOME OF THE CASES HAVE BEEN DESCRIBED AS HEMORRHAGIC WITH A RAPID PROGRESSION FROM INITIAL SYMPTOMS TO DEATH. CASES HAVE BEEN REPORTED SHORTLY AFTER INITIAL USE AS WELL AS AFTER SEVERAL YEARS OF USE. PATIENTS AND GUARDIANS SHOULD BE WARNED THAT ABDOMINAL PAIN, NAUSEA, VOMITING AND/OR ANOREXIA CAN BE SYMPTOMS OF PANCREATITIS THAT REQUIRE PROMPT MEDICAL EVALUATION. IF PANCREATITIS IS DIAGNOSED, VALPROATE SHOULD BE DISCONTINUED.

Additional Warning on Thioridazine HCl

The DCA has agreed that the warning for product-containing Thioridazine is to be amended:

a. The approved box warning on Thioridazine to be included on the package insert under section "Warning" is as listed below:

> WARNING:THIORIDAZINE HCl HAS BEEN SHOWN TO PROLONG THE QTc INTERVAL IN A DOSE RELATED MANNER DRUGS WITH THIS POTENTIAL, INCLUDING THIORIDAZINE HCl, HAVE BEEN ASSOCIATED WITH TORSADE DE POINTES - TYPE ARRYTHMIAS AND SUDDEN DEATH. DUE TO ITS POTENTIAL FOR SIGNIFICANT POSSIBLY LIFE-THREATENING, PROARRYTHMIC EFFECTS, THIORIDAZINE HCl SHOULD BE RESERVED FOR USE IN THE TREATMENT OF SCHIZOPHRENIC PATIENTS WHO FAIL TO SHOW AN ACCEPTABLE RESPONSE TO ADEQUATE COURSES OF TREATMENT WITH OTHER ANTIPSYCHOTIC DRUGS, EITHER BECAUSE OF INSUFFICIENT EFFECTIVENESS OR THE INABILITY TO ACHIEVE AN EFFECTIVE DOSE DUE TO INTOLERABLE ADVERSE EFFECTS FROM THOSE DRUGS.

b. The warning to be included under section "Warning" on the package insert:
"It is recommended that patients being considered for Thioridazine treatment have a baseline ECG performed and potassium levels measured. Serum potassium should be normalized before initiating treatment and patients with a QTc interval greater than 450 msec should not receive Thioridazine treatment.

It may also be useful to periodically monitor ECG's and serum potassium during Thioridazine treatment, especially during a period of dose adjustment. Thioridazine should be discontinued in patients who are found to have a QTc interval over 500 msec.

c. CONTRAINDICATIONS
The information listed below is to be included on the package insert under section "Contraindications" for product-containing Thioridazine:

"Thioridazine HCl use should be avoided in combination with other drugs that are known to prolong the QTc interval and in patients with congenital long QT syndrome or history of cardiac arryhthmias.

Thioridazine HCl use is also contraindicated with drugs that inhibit/reduce the activity of cyctochrome P450 2D6 isoenzyme (e.g. Fluoxetine) and other drugs that inhibit the metabolism of Thioridazine (e.g. Fluvoxamine).

Thioridazine HCl is also contraindicated with people that are known to have a genetic defect leading to reduce levels of activity of P450 2D6 isoenzymes as well as in patients with congenital long QT syndrome or a history of cardiac arrhythmias".

[Back To Top]

DCA News Update (DCA 117 - 24/08/2000)

Actions Taken on Product Containing Cisapride (Prepulsid)

Due to serious adverse effects on the heart, associated with the use of cisapride, the DCA has taken several actions and implement the new registration conditions on cisapride.

The new registration conditions imposed are:

i. Registration Conditions:
ii. The use of cisapride is limited only to related specialist.
iii. Cisapride is to be used as the last-line therapy.
iv. The "Prescribing Assurance and Compliance Programme (Patient Screening Form)" is to be filled up for the patient prescribed and to be used as a record by the registration holder for monitoring patients on cisapride.
v. Supply of cisapride is NOT allowed from the community/retail pharmacy.
vi. The Patients are to be informed on the adverse effect(s) and drug interaction(s) before being prescribed.

vii. The registration holders has to monitor the adverse effect(s) experienced by the patients with the help from related specialist and submit the report to the DCA immediately.

Amend the indication as:

To be used as l*ast line therapy* for patients who cannot be treated with alternative therapies and who meet eligibility criteria as defined in the "Prescribing Assurance and Compliance Programme (Patient Screening Form)" in the following conditions:

- Neonates: Patients with refractory feeding intolerance
- Paediatrics : Refractory gastro-oesophageal reflux disease (GORD/GERD)
- Adults: GORD, gastroparesis

a. Amend the leaflet for prepulsid in line with the new indication.

b. Update the contraindication(s) and drug interaction(s) with recent information on cisapride and the information on the "Prescribing Assurance and Compliance Programme (Patient Screening Form)].

Cisapride is to be prescribed for selected and appropriate patient in accordance with the "Prescribing Assurance and Compliance Programme (Patient Screening Form)".

Recall for all product stocks containing cisapride from wholesalers, community/retail pharmacy and clinics is being carried out by the registration holder.

[Back To Top]

DCA News Update (DCA 116 - 27/07/2000)

Requirements for Patient Information Leaflet for Registered Products

The benefit which the patients can obtain by introducing patient Information Leaflet / PIL for registered products is improved understanding on the use of drugs. It also promotes the safe use of drugs and the confidence in the user on the medication being used.

i. The DCA has agreed that the PIL be required as an additional document for the registration of product and it will be implemented in stages for all registered products.

ii. The information on the PIL must contain:

- Name of product
- Description
- Active Ingredient(s)
- Strength of drug(s)
- Indication
- Dosage and instruction on usage
- Adverse effect(s)
- Drug Interaction
- Symptoms of over dosage
- Storage conditions

- Name of manufacturer / Importer
- Registration Number

iii. The language used should be simple, not too technical and easily to understand by the consumer. The sentences should be short and the titles clear.

iv. The use of the PIL will finally be broadened to all products registered with the DCA.

v. The information on the PIL is to be submitted to the BPFK in a diskette or CD, so that it can be downloaded to the website.

[Back To Top]

Registration of Insect Repellent

The Pesticide Control Division has agreed that all registration holders should contact them for further information on the registration of insect repellent. all registration holders and applicants had been officially informed about this change.

[Back To Top]

DCA News Update (DCA 114 - 27/04/2000)

Warning for NSAIDs

the DCA has agreed that changes should be made to the existing ruling on box warning for all NSAIDs, including type COX-2 due to the following reasons:

NSAIDs are found to have different gastrointestinal toxicity profiles.

The warning has generally been simplified for all NSAIDs products.

In addition the DCA has also agreed that the warning should not necessarily be in a box form. Example:

WARNINGS

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are

common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

[Back To Top]

DCA News Update (DCA 113 - 04/04/2000)

1. Requirements on Separate Controlled Facilities for Manufacturing Cephalosporin Products

All manufacturers are required to improve their facilities if they want to manufacture cephalosporin products. Separate manufacturing facilities for producing cephalosporin is required in order to prevent cross contamination between products. Currently, there are 81 cephalosporin products which are manufactured locally by 27 manufacturers and 144 products are imported.

Decision:

DCA has agreed to implement the requirement of separate facilities and areas for manufacturing cephalosporin products.

Implementation date:

- New products (local/imported) : immediate
- Existing Products

a) Imported : 31st December 2000
b) Locally manufactured : 30th June 2001

[Back To Top]

2. Change of Site for registered product; by the same company

Lately, many applications received by companies requesting that the procedures for change of site to be simplified for imported and locally manufactured products. Merging of companies is identified as the main factor contributing for the increasingly high activity for change of site. Last but not least, for local products, the change of site is mainly due to upgrading the good manufacturing practice facilities whereby the company has to move to the new premise, which approved and licensed by the DCA.