

**Egyptian  
Pharmaceutical  
Vigilance Center  
(EPVC)**

**Pharmacovigilance  
Department**

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## “Cetal”- Recall of certain batches due to mistake in the Arabic leaflets

The Drug Factories Inspection Department at the Central Administration of Pharmaceutical Affairs (CAPA) has decided to recall all batches produced during years 2015-2016 of all dosage forms of the pharmaceutical product “Cetal”, manufactured by EPICO; because of typing mistake in some Arabic insert leaflets regarding the calculation of “Cetal drops” dose in infants & children.



This decision was circulated to the Manufacturers, Marketing Authorization Holders (MAH) and Distributors to discontinue distribution of stocks of and recall the amount **sold of these batches** from pharmacies.

This decision was taken based on a pharmacovigilance committee recommendation, because although no “overdose” case reports were reported up till now; however this mistake in dose calculation (in the Arabic translation only) may result in overdoses.

If you are taking Cetal drops/Suspension, please adhere to the dose stated in the English leaflet.

CETAL (Paracetamol /acetaminophen) is a pain reliever and a fever reducer. It is available in Tablets- Drops — Suspension – Suppositories

## Lidocaine solution to treat infants and children with teething pain

In response to a recent Facebook post warning from using lidocaine solution to treat infants and children with teething pain based on a safety communication published in 2014 by the US Food and Drug Administration (FDA), the Egyptian Pharmaceutical Vigilance Center (EPVC) emphasizes that this warning is concerned with prescription oral viscous lidocaine 2 percent solution. These products are not approved to treat teething pain, and

use in infants and young children can cause serious harm, including death .

Pharmacovigilance Committee (PVC) recommended on 17/07/2014 regarding (Oral Viscous solution containing Lidocaine in Concentration 2%) based on “Egyptian Pharmacovigilance Center (EPVC) assessment”; in addition to “FDA recommendations on 26/06/2014” the following:

1. Oral Viscous solution containing Lidocaine in Concentration 2% or higher; should not be used to treat infants and children with teething pain.
2. Addition of this warnings to label information of Oral Viscous solution containing Lidocaine in Concentration 2%

There are other preparations registered in Egypt containing lidocaine, but this warning does not apply on them. Dentinox teething gel contains lidocaine with concentration of 0.33% only. It is still registered and marketed in the UK till date for use to relieve the pain of baby's teething and soothes the gums.

Other prepararion "Micoban", it contains lidocaine with a concentration of 0.66% (less than 2%) and is used as curative prophylactic therapy for oral candidiasis, and is not used to treat teething pain in Children .

#### References:

1. FDA Drug Safety Communication ([Click here](#))
2. Emc-dentinox teething gel label ([Click here](#))

## **Case Report from Sohag- Angular cheilitis with pain and burning sensation induced by Formo Cresol**

The Egyptian pharmaceutical Vigilance regional center in Sohag had received 2 ICSRs about angular cheilitis with pain and burning sensation induced by Formo Cresol, the cases was for female patients 27 & 35 years old, who complained from pain in their maxillary tooth.

They were diagnosed with acute irreversible pulpitis and Deep Caries in the particular tooth, then the dentist performed root canal treatment, they performed access opening and bio-mechanical preparation in the particular tooth and gave them dressing using Formo cresol-soaked cotton with temporary filling, then after 24 hours they suffered from angular cheilitis with pain and burning sensation. Oral examination revealed ulceration in the angle of their mouth on the right side and their mouth opening was reduced.

The patients were immediately advised to rinse her mouth with OROVEX Mouth Wash, Vaseline Jelly was applied all over the ulcerated surface An analgesic was also given to relieve the symptoms of pain



**Formo Cresol:**

Formo cresol was first used as a root canal medication. It is widely used in dentistry because of its antibacterial properties in root canal disinfection, it contains formaldehyde, an effective alkylating agent, and cresol, a protein-coagulating phenolic compound, and its action is believed to be due to the release of formaldehyde vapors which act as a germicidal agent.

**Angular cheilitis:**

Angular cheilitis is a condition that causes red, swollen patches in the corners of your mouth where your lips meet and make an angle. Other names for it are perleche and angular stomatitis.

You can get it on one side of your mouth or on both sides at the same time.

**Upon search it was found that:**

1. Nowadays, many improved medications and anesthetics are available which obviate the need for the use of formo cresol as a root canal medication or as a pulp devitalizer. Due to the caustic nature of the material, use of formo cresol should be avoided.
2. The International Agency for Research on Cancer has recently classified formaldehyde as carcinogenic to human beings. Since Buckley's Formo cresol contains 19% formaldehyde in its full strength and, therefore, 1% in a 20% dilution.

3. Powell *et al.* have shown that when formo cresol was implanted subcutaneously in the connective tissue of rats, the surrounding tissue was severely damaged; causing necrosis and abscess formation.
4. Allergies have also been reported after the application of formo cresol.
5. Formaldehyde is one of the components of formo cresol that interacts with cellular proteins. The addition of cresol to formaldehyde appears to potentiate the effect of formaldehyde on protein. In a study using human pulp fibroblast cultures, formaldehyde was shown to be the major component of formo cresol that caused cytotoxicity and that was more toxic than cresol.
6. Gargle and mouthwashes are used to treat infections of the mouth as well as throat and mouth ulcers. Topical antihistamines and corticosteroid applications meant to tooth painful ulcers may be helpful.
7. Avoiding spicy or hot foods may reduce the pain.

**References:**

1. *Drugs.com-Formo Cresol* ([Click here](#))
2. *Abstract-pubmed* ([Click here](#))
3. *WebMD-angular cheilitis* ([Click here](#))