



19 APR 2022

FDA ADVISORY
No. **20220936**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:

1. Lidocaine Hydrochloride Injection 5 mL:0.1 g
2. Placentex® 5,625 mg/3 mL Soluzione Iniettabile Polidesossiribonucleotide
3. Vitamin C Injection d'acide ascorbique, USP 25 000 mg/ 50 mL (500mg/mL)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:



Lidocaine Hydrochloride Injection 5 mL: 0.1 g

Figure 1. Unregistered drug product





Placentex®
5,625 mg/3 ml soluzione iniettabile

5 fiale da 3 ml Soluzione iniettabile
Polidesossiribonucleotide

Cicatrizante - Antidistrico
Uso intramuscolare o sottocutaneo

MASTELLI

COMPOSIZIONE
Una fiala da 3 ml contiene
Principio attivo: Polidesossiribonucleotide 5,625 mg
Eccipienti: sodio cloruro, acqua per preparazioni iniettabili

Leggere il foglio illustrativo prima dell'uso.
Tenere fuori dalla vista e dalla portata dei bambini
Da vendersi dietro presentazione di ricetta medica.

Non disperdere il medicinale nell'ambiente, servirsi degli appositi contenitori per la raccolta differenziata dei medicinali.

Prezzo € 30,90


Titolare A.I.C. **MASTELLI S.r.l.** - Via Bussana Vecchia, 32 - Sanremo (IM)
A.I.C. n° 004905129





Placentex® 5,625 mg/3 mL Soluzione Iniettabile Polidesossiribonucleotide
by: Mastelli S.r.l - Via Bussana Vecchia, 32 - Sanremo (IM)

Figure 2. Unregistered drug product



DIN 02245214

Vitamin C
Injection d'acide ascorbique, USP

25 000 mg/50 mL
500 mg/mL

Grand format pour pharmacies. Ne pas employer pour perfusion directe.

Ponction unique
Sans latex
Sans agent de conservation
Pour une utilisation intramusculaire, intraveineuse ou sous-cutanée

Mylan

1 Fiole grand format pour pharmacie

Chaque mL contient : D'acide ascorbique 500 mg, du sel disodique de l'acide éthylènediaminetétracétique à 0,25 mg, hydroxide de sodium 110 mg dans de l'eau pour injection q.s., pH (de 5,5 à 7,0) ajusté avec du bicarbonate de soude et hydroxide de sodium. Ne contient pas d'agent de conservation.

Posologie : Pour la posologie, l'administration, et des instructions détaillées sur l'utilisation de ce produit, consulter le feuillet d'information inclus.

Protéger de la lumière. Entreposer entre (2°C à 8°C). NE PAS CONGELER. Entreposer dans la boîte jusqu'au moment de l'utilisation.

Une pression pourrait se développer durant l'entreposage. Prendre garde lors du retrait.

Pour usage thérapeutique seulement.

Mylan Pharmaceuticals ULC
Etobicoke, ON M8Z 2S6
1-800-575-1379

Mylan
Mylan.ca



DIN 02245214

Vitamin C
Ascorbic Acid Injection, USP

25 000 mg/50 mL
500 mg/mL

Pharmacy bulk package. Not for direct infusion. Grand format pour pharmacies. Ne pas employer pour perfusion directe.

Latex free/Sans latex
Sterile/Stérile

Mylan

Pharmacy Bulk Package Only
Fiole grand format pour pharmacie

Vitamin C Injection d'acide ascorbique, USP 25 000 mg/ 50 mL (500mg/mL)
Manufactured by: Mylan Pharmaceuticals ULC - Etobicoke, ON

Figure 3. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at <https://verification.fda.gov.ph>.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN: 

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