[Medical Product Alert]

"Torfen (Ibuprofen 200mg/5ml) Suspension"

M/s Kaizen Pharmaceuticals,
Plot No. E-127 E-128 & E-129
North Western Zone Port Qasim Authority
Karachi.

Subject: DRUG RECALL OF SUBSTANDARD Sub-Standard Torfen Suspension, 
Reg. No. 073895, Batch No. 035, Mfg. date 06-20, Exp. Date 05-22.
Manufactured by M/s Kaizen Pharmaceuticals, (Pvt.) Ltd., Karachi

I am directed to refer to the subject cited above and CDL, Karachi report vide
No.KQ.220/2020 dated 09th October, 2020 wherein your product "Torfen (Ibuprofen
200mg/5ml) Suspension", Reg. No. 073895, Batch No. 035, Mfg. date 06-20, Exp. Date 05-
22, has been declared of Substandard quality. Details of CDL reports are as under:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Test</th>
<th>Specifications</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Description</td>
<td>Orange flavor orange color suspension</td>
<td>Complies</td>
<td>Mfg. Specs.</td>
</tr>
<tr>
<td>2</td>
<td>Identification</td>
<td>The identification test must identify Ibuprofen</td>
<td>Complies</td>
<td>USP 43</td>
</tr>
<tr>
<td>3</td>
<td>pH</td>
<td>3.6 to 4.6</td>
<td>4.6 Complies</td>
<td>USP 43</td>
</tr>
<tr>
<td>4</td>
<td>Assay Ibuprofen (label claim 200mg/5ml)</td>
<td>90.0% to 110.0%</td>
<td>311.6% Does not comply</td>
<td>USP 43</td>
</tr>
</tbody>
</table>

02. You are therefore directed to recall all the stock of above-mentioned batch of product
"Torfen (Ibuprofen 200mg/5ml) Suspension" from market, alert your sales
officers/suppliers/ distributors to issue instructions to the pharmacies/hospitals, point of
sales/purchase/use for the return of suspected stocks of product in question. Furthermore, you
are directed to submit a compliance report of recall to this division within seven (07) days
positively.

-/sd-
(Shahid Nawaz)
Assistant Director (QC-II)
Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please:

1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary (SHC&ME) Health Department (Government of KPK).
5. The Secretary (SHC&ME) Health Department (Government of Baluchistan).
6. The Secretary (SHC&ME) Health Department (Government of AJ&K).
7. The Director General Health, M/o NHSR&C, Islamabad.
8. The Director General Health, Government of Punjab.
10. The Director General Health, Government of KPK.
11. The Director General Health, Government of Baluchistan.
12. The Director General Health, Government of AJ&K.

Copy to:-

i. The Director, QA&LT, DRAP, Islamabad.
ii. The Additional Director MIS with request to upload it on official website in the larger interest of public.
iii. FID-VII, DRAP, Karachi for information record and necessary action, if any, please.
iv. PS to CEO, DRAP, Islamabad.
v. Assistant Director QC-I, DRAP, Islamabad.
vi. Office copy.

(Assistant Director QC-II)