

## “Teroda Success Story”

### Introduction:

Teroda is Potassium iodide "KI" tablets locally developed and manufactured by SPIMACO in its Qassim pharmaceutical plant.

### Background:

- Potassium iodide is strategic human medicinal product for the country to ensure the national security.
- Based on Center for Disease Control and prevention (CDC), Potassium iodide is a pharmaceutical countermeasure for radiation emergency.
- Potassium iodide is oral tablet used during a nuclear radiation emergency to block radioactive iodine from being absorbed by the thyroid gland. For this purpose, the medicine is usually taken only once or twice.
- Its mode of action starts when the tablet dissolves in the stomach and releases stable iodine, the medication then carried by the blood stream to the thyroid gland to fill it with stable iodine, which helps block radioactive iodine from being absorbed.

### History:

- In the past, this product was exclusively supplied by only one Swedish company with extremely high prices.
- That is why, in 2019 during conference in UAE SPIMACO has been approached by the MOH in UAE to provide them with Potassium iodide tablets.



### Actions:

- Immediately after the conference, SPIMACO studied the case on local and regional basis for KSA and UAE.
- At that time, the project has been endorsed by the governmental sales.
- SPIMACO succeeded to independently develop the product in its national pharmaceutical plant in Qassim.
- SPIMACO approached the SFDA and regulatory body in UAE to get their approval for registration.

### Outcomes:

- The SFDA was supportive, as they gave SPIMACO two exemptions. One related to dissolution and the other is related to stability.
- Ultimately, in 2021 this product has been approved in KSA and UAE under “TERODA®” as trade name with two strengths (65 mg and 130 mg) with two pack sizes for each, registration certificates are attached below.
- This achievement will represent SPIMACO as strategic pharmaceutical partner for both countries to ensure the public national security.
- SPIMACO is proud to be on track to achieve Saudi Arabia 2030 vision on two aspects:
  - 1) Ensure the national security for the public.
  - 2) Localization of pharmaceutical industry to ensure national drug security.

UNITED ARAB EMIRATES  
MINISTRY OF HEALTH & PREVENTION



الإمارات العربية المتحدة  
وزارة الصحة ووقاية المجتمع

DATE: 31/01/2022  
TO: CITY MEDICAL STORE - SOLE PROPRIETORSHIP L.L.C, Abu Dhabi, United Arab Emirates  
Attn.: SPIMACO (AL QASSIM PHARMACEUTICAL PLANT), Al Qassim City, Saudi Arabia  
Dear Sirs,  
Sub: **APPROVED PRICES**  
REF.: Ministerial Decree(s) No. 0189/2021 ,dated 23/12/2021  
Registration No.: DPRIC-2021-001018  
Registration Date: 31/01/2022

SI #	Product Name/ Strength	Form	Pack Size	CIF / Ex-Factory		Price to Pharmacy	Price to Public	Price Status
				Currency	Price			
1	TERODA® 130 mg (130 mg/Tablet)	Tablet	10 tablets [10's blister x 1]	USD	21.07	88.93 AED	110.5 AED	Temporary Approval

With reference to the above, the following are the approved prices of the enlisted product(s) of your company, effective from the date of this letter.

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REF.: Ministerial Decree(s) No. 0189/2021 ,dated 23/12/2021  
Registration No.: DPRIC-2021-001019  
Registration Date: 31/01/2022

SI #	Product Name/ Strength	Form	Pack Size	CIF / Ex-Factory		Price to Pharmacy	Price to Public	Price Status
				Currency	Price			
1	TERODA® 130 mg (130 mg/Tablet)	Tablet	100 tablets [10's blister x 10]	USD	210.7	889.26 AED	1043.5 AED	Temporary Approval

With reference to the above, the following are the approved prices of the enlisted product(s) of your company, effective from the date of this letter.

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Dear Sirs,  
Sub: **APPROVED PRICES**  
REF.: Ministerial Decree(s) No. 0189/2021 ,dated 23/12/2021  
Registration No.: DPRIC-2021-001021  
Registration Date: 31/01/2022

SI #	Product Name/ Strength	Form	Pack Size	CIF / Ex-Factory		Price to Pharmacy	Price to Public	Price Status
				Currency	Price			
1	TERODA® 65 mg (65 mg/Tablet)	Tablet	100 tablets [10's blister x 10]	USD	9.7	40.94 AED	50.5 AED	Temporary Approval

With reference to the above, the following are the approved prices of the enlisted product(s) of your company, effective from the date of this letter.

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Dear Sirs,  
Sub: **APPROVED PRICES**  
REF.: Ministerial Decree(s) No. 0189/2021 ,dated 23/12/2021  
Registration No.: DPRIC-2021-001020  
Registration Date: 31/01/2022

SI #	Product Name/ Strength	Form	Pack Size	CIF / Ex-Factory		Price to Pharmacy	Price to Public	Price Status
				Currency	Price			
1	TERODA® 65 mg (65 mg/Tablet)	Tablet	10 tablets [10's blister x 1]	USD	0.97	4.09 AED	5 AED	Temporary Approval

With reference to the above, the following are the approved prices of the enlisted product(s) of your company, effective from the date of this letter.

Certificate No.: 0000011144 رقم الشهادة:  
Issue Date: 11/08/2021 تاريخ الإصدار:  
Expiry Date: 11/08/2026 تاريخ الانتهاء:

شهادة تسجيل مستحضر صيدلاني  
Registration Certificate of a Pharmaceutical Product

الهيئة العامة للغذاء والدواء  
Saudi Food & Drug Authority

Subject To Medical Prescription	طريقة الوصف Legal Status	TERODA	الاسم التجاري Trade Name
By Licensed Doctor In KSA		See Appendix	الاسم العلمي . التركيز . الوحدة Generic Name, Strength, Unit
GP		1108210926	رقم التسجيل Registration Number
SPIMACO ADDWAEIH	الوكيل Marketing Authorization Holder (Agent)	Tablet	الشكل الصيدلاني Dosage Form
Saudi Pharmaceutical Industries and Medical Appliances Corporation SPIMACO ADDWAEIH, Saudi Arabia	الشركة المسوقة و جنسيتها Marketing Company, Nationality	18 mo	مدة الصلاحية Shelf Life
SPIMACO ADDWAEIH, Saudi Arabia	الشركة الصانعة و جنسيتها Manufacturers, Nationality	Blister	نوع العبوة Packaging Type
6.195 / 36.227	سعر التصدير المصنع ر.س CIF/Ex-Factory Price(S.R)	10/1 {tablet}	حجم العبوة Packaging Size/Volume
8.549	سعر الجمهور ر.س Public Price (S.R)	Store below 30°C	ظروف التخزين Storage Conditions

Stamp



Certificate No.: 0000011145 رقم الشهادة:  
Issue Date: 11/08/2021 تاريخ الإصدار:  
Expiry Date: 11/08/2026 تاريخ الانتهاء:

شهادة تسجيل مستحضر صيدلاني  
Registration Certificate of a Pharmaceutical Product

الهيئة العامة للغذاء والدواء  
Saudi Food & Drug Authority

Subject To Medical Prescription	طريقة الوصف Legal Status	TERODA	الاسم التجاري Trade Name
By Licensed Doctor In KSA		See Appendix	الاسم العلمي . التركيز . الوحدة Generic Name, Strength, Unit
GP		1108210924	رقم التسجيل Registration Number
SPIMACO ADDWAEIH	الوكيل Marketing Authorization Holder (Agent)	Tablet	الشكل الصيدلاني Dosage Form
Saudi Pharmaceutical Industries and Medical Appliances Corporation SPIMACO ADDWAEIH, Saudi Arabia	الشركة المسوقة و جنسيتها Marketing Company.Nationality	18 mo	مدة الصلاحية Shelf Life
SPIMACO ADDWAEIH,Saudi Arabia	الشركة الصانعة و جنسيتها Manufacturers.Nationality	Blister	نوع الصوة Packaging Type
135.177 / 826.281	سعر التصدير المصنع رس CIF/Ex-Factory Price(S.R)	100/1 {tablet}	حجم الصوة Packaging Size/Volume
170.998	سعر الجمهور رس Public Price (S.R)	Store below 30°C	ظروف التخزين Storage Conditions

Stamp





Certificate No.: 0000011146 رقم الشهادة:  
Issue Date: 11/08/2021 تاريخ الإصدار:  
Expiry Date: 11/08/2026 تاريخ الانتهاء:

شهادة تسجيل مستحضر صيدلاني  
Registration Certificate of a Pharmaceutical Product

الهيئة العامة للغذاء والدواء  
Saudi Food & Drug Authority

Subject To Medical Prescription	طريقة الوصف Legal Status	TERODA	الاسم التجاري Trade Name
By Licensed Doctor In KSA		See Appendix	الاسم العلمي . التركيز . الوحدة Generic Name, Strength, Unit
GP		1108210923	رقم التسجيل Registration Number
SPIMACO ADDWAEIH	الوكيل Marketing Authorization Holder (Agent)	Tablet	الشكل الصيدلاني Dosage Form
Saudi Pharmaceutical Industries and Medical Appliances Corporation SPIMACO ADDWAEIH, Saudi Arabia	الشركة المسوقة و جنسيتها Marketing Company, Nationality	18 mo	مدة الصلاحية Shelf Life
SPIMACO ADDWAEIH, Saudi Arabia	الشركة الصانعة و جنسيتها Manufacturers, Nationality	Blister	نوع العبوة Packaging Type
67.588 / 413.14	سعر التصدير المصنح ر.س CIF/Ex-Factory Price(S.R)	100/1 {tablet}	حجم العبوة Packaging Size/Volume
85.498	سعر الجمهور ر.س Public Price (S.R)	Store below 30°C	ظروف التخزين Storage Conditions

Stamp



Certificate No.: 0000011143 رقم الشهادة:  
Issue Date: 11/08/2021 تاريخ الإصدار:  
Expiry Date: 11/08/2026 تاريخ الانتهاء:

شهادة تسجيل مستحضر صيدلاني  
Registration Certificate of a Pharmaceutical Product

الهيئة العامة للغذاء والدواء  
Saudi Food & Drug Authority

Subject To Medical Prescription	طريقة الوصف Legal Status	TERODA	الاسم التجاري Trade Name
By Licensed Doctor In KSA		See Appendix	الاسم العلمي . التركيز . الوحدة Generic Name, Strength, Unit
GP		1108210925	رقم التسجيل Registration Number
SPIMACO ADDWAEIH	الوكيل Marketing Authorization Holder (Agent)	Tablet	الشكل الصيدلاني Dosage Form
Saudi Pharmaceutical Industries and Medical Appliances Corporation SPIMACO ADDWAEIH, Saudi Arabia	الشركة المسوقة و جنسيتها Marketing Company.Nationality	18 mo	مدة الصلاحية Shelf Life
SPIMACO ADDWAEIH,Saudi Arabia	الشركة الصانعة و جنسيتها Manufacturers.Nationality	Blister	نوع العبوة Packaging Type
12.391 / 79.037	سعر التصدير المصنع ر.س CIF/Ex-Factory Price(S.R)	10/1 {tablet}	حجم العبوة Packaging Size/Volume
17.099	سعر الجمهور ر.س Public Price (S.R)	Store below 30°C	ظروف التخزين Storage Conditions

Stamp

